Center: CRE	ZININ	(#28
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	i - 1	Gestational	Total Number	Number of Pts	Fisher's			0	* * * * * * * * * * * * * * * * * * * *	
Body System/Event [2]	. ' '	Age Group [3]	of Pts	w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknown
ENTR & PERIPH NERVOUS SYS	TEM DISORDE	RS (cont.)								
HEADACHE*		≤63 Days (All)	115	44 (38%)	0.9680	64	21 (33%)	35 (55%)	8 (13%)	, O
		≤49 Days (Group 1)	23	8 (35%)		10	5 (50%)	5 (50%)	0	0
		50-56 Days (Group 2)	50	20 (40%)		33	7 (21%)	19 (58%)	7 (21%)	0
		57-63 Days (Group 3)	42	16 (38%)		21	9 (43%)	11 (52%)	1 (5%)	0
MIGRAINE		≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
		≤49 Days (Group 1)	23	0		0	0	0	0	0
		50-56 Days (Group 2)	50	0		0	0	0	0	0
		57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
MARING AND VESTIBULAR DIS	ORDERS									
ANY EVENT	•	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	. 0	0	0
		≤49 Days (Group 1)	23	0		0	0	о '	0	0
		50-56 Days (Group 2)	50	0		0	0	0	0	0
	1	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
TINNITUS		≤63 Days (All)	115	. 1 (<1%)	0.5652	1	1 (100%)	0	0	0
		s49 Days (Group 1)	23	0		0	0	0	0	0
		50-56 Days (Group 2)	50	0		0	0	0	0	Ō
!		57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
SYCHIATRIC DISORDERS			,							
ANY EVENT		'≤63 Days (All)	115	7 (6%)	0.2715	12	4 (33%)	6 (50%)	2 (17%)	0
		≤49 Days (Group 1)	23	0	ļ	0	0	0	0	0
		50-56 Days (Group 2)	50	5 (10%)	1	. 8	2 (25%)	4 (50%)	2 (25%)	Ō
		57-63 Days (Group 3)	42	2 (5%)		4	2 (50%)	2 (50%)	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling. Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

		Gestational	Total Number	Number of Pts	Fisher's exact	Number		Soverth		
Body System/Event [2]	. 1.	Age Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Sever <b>e</b>	Unknown
SYCHIATRIC DISORDERS (con	t.)									
ANOREXIA		≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0 ,	, O
		≤49 Days (Group 1)	23	0		0	0	0	0 '	0
		50-56 Days (Group 2)	50	0		0	0	0	0	0
		57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
ANXIETY		s63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
		≤49 Days (Group 1)	23	0		0	Ö.	0	0	0
	1	50 56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	; 0	0
		57-63 Days (Group 3)	42	0		0	0	0	0	0
DEPRESSION		≤63 Days (All)	115	3 (3%)	1.0000	5	2 (40%)	2 (40%)	1 (20%)	0
	•	≤49 Days (Group 1)	23	0		0	0	` 0 '	0	0
		50-56 Days (Group 2)	50	2 (4%)		2	1 (50%)	0	1 (50%)	0
1		57-63 Days (Group 3)	42	1 (2%)		3	1 (33%)	2 (67%)	0	0
DYSPAREUNIA		≤63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
		≤49 Days (Group 1)	23	0		0	0	0	0	0
		50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
		57-63 Days (Group 3)	42	0		0	0	0	0	0
EMOTIONAL LABILITY		≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
		≤49 Days (Group 1)	23	0		0	0	0	0	o
		50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
		57-63 Days (Group 3)	42	0		0	0	0	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Center: CREININ (#28)

	Gestational	Total	Number	Fisher's		1			
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknown
SYCHIATRIC DISORDERS (cont.)				<del></del>					
INSOMNIA	≤63 Days (All)	115	1 (<1	) 1.0000	1	0	1 (100%)	0 .	, 0
1	≤49 Days (Group 1)	23	0		0	0	0	0	0
•	50-56 Days (Group 2)	50	1 (21	)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	o '	0
PARONIRIA	≤63 Days (All)	115	1 (<1%	) 1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	23	0		0	Ō	0	0	0
• · · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	50	1 (21	)	2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	42	0	•	0	ō	0	0	0
ASTRO-INTESTINAL SYSTEM DISORDERS	•								
ANY EVENT	≤63 Days (All)	115	104 (90%	) 0.0948	305	149 (49%)	106 (35%)	50 (16%)	0
	≤49 Days (Group 1)	23	18 (78)		45	18 (40%)	17 (38%)	10 (22%)	0
	50-56 Days (Group 2)	50	46 (92%		140	61 (44%)	55 (39%)	24 (17%)	0
	57 63 Days (Group 3)	42	40 (95%		120	70 (58%)	34 (28%)	16 (13%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	115	1 (<1%	) 0.5652	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	23	0		0	0	0	0	0
	50 56 Days (Group 2)	50	0		0	0	0	Ô	0
	57 63 Days (Group 3)	42	1 (2)	)	1	0	ō	1 (100%)	Ö
CONSTIPATION	≤63 Days (All)	115	3 (3%	0.5960	3	3 (100%)	<b>o</b> i	0	^
	s49 Days (Group 1)	23	0		)	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%	)	1	1 (100%)	Ö	O	0
	57-63 Days (Group 3)	42	2 (5%		. 2	2 (100%)	0	1 2	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: CREININ (#28)

	1.0	1.	Gestational	Total	Nun	ber	Fisher's					1	; ·	• 11	
	. 1.		Age	Number		Pts	exact	Number				Severit	<b>y</b>	*	
Body System/Event [2]			Group [3]	of Pts	w/E	vent	p value	of Events	Mi	ld	Mode	erate	Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM D	ISORDERS (c	ont.)													
DIARRHEA			≰63 Days (All)	115	45	(39%)	1.0000	63	37	(59%)	18	(29%)	8	(13%)	, 0
			≰49 Days (Group 1)	23	9	(39%)		13	7	(54%)	4	(31%)	2	(15%)	0
			50-56 Days (Group 2)	50	20	(40%)		30	14	(47%)	11	(37%)	5	(17%)	0
			57-63 Days (Group 3)	42	16	(38%)		20	16	(80%)	3	(15%)	1	(5%)	0
DYSPEPSIA			≤63 Days (All)	115	3	(3%)	0.0967	3	2	(67%)	0		1	(331)	0
			≤49 Days (Group 1)	23	0			0	0		0		0		0
	'		50-56 Days (Group 2)	50	0			0	0		0		0		0
			57-63 Days (Group 3)	42	3	(7%)	4	3	2	(67%)	0		1	(33%)	0
FLATULENCE			≤63 Days (All)	115	1	(<1%)	0.5652	1	1	(100%)	0		0		0
			≤49 Days (Group 1)	23	0			,O	0		. 0	1	0		0
			50-56 Days (Group 2)	50	0			O	0		0		0		0
			57-63 Days (Group 3)	42	1	(2%)		1	1	(100%)	0		0		0
NAUSEA			≤63 Days (All)	115	93	(81%)	0.0320	178	85	(481)	61	(34%)	32	(18%)	0
			≰49 Days (Group 1)	23	14	(61%)		26	8	(31%)	12	(46%)	6	(23%)	0
			50-56 Days (Group 2)	50	42	(84%)		84	36	(43%)	31	(37%)	17	(20%)	0
			57-63 Days (Group 3)	42	37	(88%)		68	41	(60%)	18	(26%)	9	(13%)	0
TOOTH ACHE			≤63 Days (All)	115	2	(2%)	1.0000	2	0		2	(100%)	0		o
			.≤49 Days (Group 1)	23	0			0	0		0		0		0
			50-56 Days (Group 2)	50	1	(2%)		1	0		1	(100%)	0		0
			57-63 Days (Group 3)	42	1	(2%)		. 1	0		1	(100%)	0		0

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Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>(2)</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Center.	CREININ	/#2R
center:	CKCIMIM	(#20

	1.4	1	!'Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severit		• • •	
Body System/Event [2]			Group [3]	of Pts		vent	p value	of Events		ld '		rate	•	ere	Unknown
GASTRO-INTESTINAL SYSTEM D	ESORDERS (	cont.)													
VOMITING			≤63 Days (All)	115	36	(31%)	0.0905	54	21	(39%)	25	(46%)	8	(15%)	, 0
			≰49 Days (Group 1)	23	3	(13%)		6	3	(50%)	1	(17%)	2	(334)	. 0
			50·56 Days (Group 2)	50	17	(34%)		24	10	(42%)	12	(50%)	2	(8%)	0
			57-63 Days (Group 3)	42	16	(38%)		24	8	(33%)	12	(50%)	4	(17%)	0
RESPIRATORY SYSTEM DISORDE	RS														
ANY EVENT			≰63 Days (All)	115	3	(3%)	1.0000	3	1	(33%)	2	(67%)	0		0
			≤49 Days (Group 1)	23	0			0	0		0		0		0
			50-56 Days (Group 2)	50	2	(4%)		2	1	(50%)	1	(50%)	0		0
			57-63 Days (Group 3)	42	1	(2%)		1	0		1	(100%)	0		0
PHARYNGITIS	i		≤63 Days (All)	115	1	(<1%)	0.5652	1	0		. 1	(100%)	0		0
			≤49 Days (Group 1)	23	o			0	0		0	•	0		0
			50-56 Days (Group 2)	50	0			0	0		0		0		0
			57-63 Days (Group 3)	42	1	(2%)		1	0		1	(100%)	0		0
RHINITIS			≤63 Days (All)	115	1	(<1%)	1.0000	1	1	(100%)	0		0		0
			≤49 Days (Group 1)	23	0			0	0		0		0		0
			50-56 Days (Group 2)	50	1	(2%)		1	1	(100%)	0		0		0
			57-63 Days (Group 3)	42	0			0	0		0		0		0
SINUSITIS			≤63 Days (All)	115	1	(<1%)	1.0000	1	0		1	(100%)	0		0
			's49 Days (Group 1)	23	0			0	0		0	•	0		0
			50-56 Days (Group 2)	50	1	(21)		1	0		1	(100%)	0		0
			57-63 Days (Group 3)	42	0			. 0	0		0	•	0		0

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Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: CREININ (#28)

$i^{*}i$		Gestational	Total	Numb	er	Fisher's					,	٠.,	
	i ·	Age	Number	of F	Pts	exact	Number	<del></del> .		Severi	t <b>y</b>	<b>*</b>	
Body System/Event [2]		Group [3]	of Pts	w/Ev	vent	p value	of Events	Mild	Mod	erate	Sev	ere	Unknow
URINARY SYSTEM DISORDERS													
ANY EVENT		≰63 Days (All)	115	5	(4%)	0.5170	5	2 (40%)	3	(60%)	0		' O
		≤49 Days (Group 1)	23	1	(4%)		1	0	1	(100%)	0		0
		50-56 Days (Group 2)	50	1	(2%)		1	1 (100%)	0		0		0
		57-63 Days (Group 3)	42	3	(7%)		3	1 (33%)	2	(67%)	0	•	0
DYSURIA		.63 Davis (333)	116		(	0.5550			_			1	
DISURIA		≤63 Days (All)	115		(<1%)	0.5652	1	1 (100%)	0		0		i <b>0</b>
		\$49 Days (Group 1)	23	0				0	0		0		0
·	•	50-56 Days (Group 2)	50	0	(04)		0	0	0		0		0
	i	57-63 Days (Group 3)	42	1	(2%)		1	1 (100%)	0		0		0
MICTURITION FREQUENCY		s63 Days (All)	115	1	(<1%)	1.0000	1	1 (100%)	0		0		0
'		≤49 Days (Group 1)	23	0			0	0	. 0		0		0
		50-56 Days (Group 2)	50	1	(2%)		1	1 (100%)	0		0		0
		57-63 Days (Group 3)	42	0			0	0	0		0		0
URINARY TRACT INFECTION		≰63 Days (All)	115	3	(3%)	0.3075	1	0	,	(100%)	0		•
		≤49 Days (Group 1)	23	1	(4%)	0.3075	1	' 0		(100%)	0		0
		50-56 Days (Group 2)	50	0	,		n	o		(1004)	0		0
		57-63 Days (Group 3)	42	2	(5∜)		2	Ö	•	(100%)	0		0
REPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT		≤63 Days (All)	115	27	(23%)	0.8453	30	9 (30%)		(400)	_		_
ruri Dybiri		s49 Days (Group 1)	23		(22%)	0.0455	6		12			(30%)	0
		50-56 Days (Group 2)	50		(26%)			2 (33%)	2		2	-	0
		57-63 Days (Group 3)	42				13	4 (31%)	6		3	(23%)	0
		21-93 Daka (Group 3)	12	7	(21%)		• 11	3 (27%)	4	(36%)	4	(36%)	0

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Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Mild	Severity Moderate	Severe	Unknown
EPRODUCTIVE DISORDERS, FEMALE (cont.)		· · · · · · · · · · · · · · · · · · ·		<del></del>	· · · · · · · · · · · · · · · · · · ·				
VAGINAL DISCOMFORT	≤63 Days (All)	115	2 (2%)	0.3173	2	1 (50%)	1 (50%)	0	0
	≰49 Days (Group 1)	23	1 (4%)		1	0	1 (100%)	0	0
	50 56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
VAGINITIS	≤63 Days (All)	115	12 (10%)	0.9261	13	4 (31%)	8 (62%)	1 (8%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	1 (50%)	1 (50%)	0	0
1	50-56 Days (Group 2)	50	6 (12%)		6	i (17%)	4 (678)	. 1 (17%)	0
•	57-63 Days (Group 3)	42	4 (10%)		5	2 (40%)	3 (60%)	0	0
VULVA DISORDER	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
•	≤49 Days (Group 1)	23	0		0	0	· 0 i	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
DDY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	115	115 (100%)		493	191 (39%)	154 (31%)	148 (30%)	0
•	≰49 Days (Group 1)	23	23 (100%)		89	37 (42%)	30 (34%)	22 (25%)	0
	50-56 Days (Group 2)	50	50 (100%)		214	78 (36%)	66 (31%)	70 (33%)	0
	57-63 Days (Group 3)	42	42 (100%)		190	76 (40%)	58 (31%)	56 (29%)	0
ABDOMINAL PAIN	≤63 Days (All)	115	114 (>99%)	1.0000	419	144 (34%)	135 (32%)	140 (33%)	0
•	· ≤49 Days (Group 1)	23	23 (100%)		77	30 (39%)	27 (35%)	20 (26%)	0
7.	50-56 Days (Group 2)	50	49 (98%)		183	59 (321)	57 (31%)	67 (37%)	0
•	57-63 Days (Group 3)	42	42 (100%)		159	55 (≱Š <b>₹)</b> ∃	. 51. (321)	53 (33%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Ptr w/Ever	8	Fisher's exact p value	Number of Events	Mi		Moder	-Severity-	Sev		Unknown
ODY AS A MHOLE - GENERAL DISORDERS (cont	.)										_		
ASTHENIA	≤63 Days (All)	115		<11)	0.5652	1		(100%)	0		0		0
	≤49 Days (Group 1)	23	0			0	0		0		0		0
	50 56 Days (Group 2)	50	0			0	0		0		0		0
	57-63 Days (Group 3)	42	1	(2%)		1	1	(100%)	0		U		U
BACK PAIN	s63 Days (All)	115	21 (	18%)	0.5438	25	10	(40%)	9	(36%)	6	(24%)	0
	≤49 Days (Group 1)	23	3 (	13%)		3	2	(67%)	0		1	(33%)	0
,	50 56 Days (Group 2)	50	8 (	16%)		9	2	(22%)	5	(56%)	2	(221)	0
	57-63 Days (Group 3)	42	10 (	24%)		13	6	(46%)	4	(31%)	3	(23%)	0
CHEST PAIN	≤63 Days (All)	115	1 (	<1%)	1.0000	1	1	(100%)	0		0		0
CREST PAIN	≤49 Days (Group 1)	23	0			0	0	·	0	1	0		0
	50-56 Days (Group 2)	50	1	(2%)		1	1	(100%)	0		0		0
	57 63 Days (Group 3)	42	0			0	0		0		0		0
FATIGUE	≤63 Days (All)	115	33 (	29%)	0.4918	35	29	(83%)	5	(14%)	1	(3%)	0
,	\$49 Days (Group 1)	23	6 (	26%)		8	5	(63%)	2	(25%)	1	(13%)	0
	50-56 Days (Group 2)	50	12 (	24%)		12	11	(92%)	1	(8%)	0		0
,	57-63 Days (Group 3)	42	15 (	361)		15	13	(871)	2	(13%)	0		0
FEVER	≤63 Days (All)	115	2	(21)	1.0000	2	2	(100%)	0		0		0
. 57610	≤49 Days (Group 1)	23	0			0	0		0		0		0
	50-56 Days (Group 2)	50	1	(2%)		1	1	(100%)	0		0		0
en e	57-63 Days (Group 3)	42	1	(2%)		. 1	1	(1001)	O <sub>t</sub>		0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

## Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: CREININ (#28)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -	. <b></b>	····Severity	• • • • • • • · · · · · · · · · · · · ·	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
DDY AS A WHOLE - GENERAL DISORDERS (cont	.)								
LEG PAIN	≰63 Days (All)	115	4 (3%)	1.0000	5	1 (20%)	4 (80%)	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	50	2 (4%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
MALAISE	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
· ·	50 56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
· ·	57-63 Days (Group 3)	42	0		0	0	0	O	0
RIGORS	≤63 Days (All)	115	3 (3%)	0.2273	3	2 (67%)	0	1 (33%)	0
·	≤49 Days (Group 1)	23	0		0	0	. 0 ,	0	0
	50-56 Days (Group 2)	50	3 (6%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
SYNCOPE	s63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	23	0		0	0	0	0	0
•	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
BSISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	115	9 (8%)	0.3185	10	3 (30%)	7 (70%)	0	0
•	'≤49 Days (Group 1)	23	0		0	0	0	0	0
÷	50-56 Days (Group 2)	50	5 (10%)		5	1 (20%)	4 (80%)	0	0
	57-63 Days (Group 3)	42	4 (10%)		5	2 (45%)	<b>3</b>	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)

Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Severit	<b>y</b>	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ESISTANCE, MECHANISH DISORDERS (cont.)	,								
INFECTION BACTERIAL	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	23	0		. 0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
INFECTION FUNGAL	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	23	0		0	0	0	0	0
*	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	o	0
	57 63 Days (Group 3)	42	0		0	o	0	0	0
INFECTION PARASITIC	≤63 Days (All)	115	2 (2%)	1.0000	2	0	2 (100%)	o	0
,	≤49 Days (Group 1)	23	0		0	0	· 0 '	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
INFECTION VIRAL	s63 Days (All)	115	6 (5%)	0.6523	6	3 (50%)	3 (50%)	O	0
1	≰49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	3 (6%)		3	1 (33%)	2 (67%)	0	0
•	57-63 Days (Group 3)	42	3 (7%)		3	2 (67%)	1 (33%)	0	0
BCONDARY TERMS									
ANY EVENT	s63 Days (All)	115	1 (<1%)	1.0000	1	0	0	1 (100%)	0
<b>ને</b>	≰49 Days (Group 1)	23	0		0	0	0 .	0	0
	50-56 Days (Group 2)	50	1 (2%)		. 1	0	<b>b</b> . ,	1 (100%)	0
e e e e e e e e e e e e e e e e e e e	57-63 Days (Group 3)	42	0		· • 0	0	9 · ·	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severity	. <b></b>	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
SECONDARY TERMS (cont.)		<del>.</del>							
BITE *	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	23	0		0	0	0	0	ñ
	50-56 Days (Group 2)	50	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	Ô
								1	v

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

> Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Num of w/E	-	Fisher's exact p value	Number of Events	Mi			Severit	Sev	ere	Unk	nown
												(354)		(<1%)
ANY EVENT	≤63 Days (All)	83	79	(95%)	1.0000	379	85	(22%)	160		133		1	
	≤49 Days (Group 1)	28	27	(96%)		124	25	(20%)	68	(55%)	30	(24%)		(<1.0)
	50-56 Days (Group 2)	37	35	(95%)		165	34	(21%)	64	(39%)		(41%)	0	
	57-63 Days (Group 3)	18	17	(94%)		90	26	(29%)	28	(31%)	36	(40%)	0	
SKIN AND APPENDAGES DISORDERS						•	•		,	(100%)	0		0	
ANY EVENT	≤63 Days (All)	83	1	(1%)	0.5542	1	0			(100%)	o		'n	
	<pre>s49 Days (Group 1)</pre>	28	1	(4%)		1	0		_					
	50 56 Days (Group 2)	37	0			0	0		0		0		0	
	57-63 Days (Group 3)	18	0			0	0		0		0		0	
	≤63 Days (All)	83	1	(1%)	0.5542	1	0		1	(100%)	0		0	
URTICARIA	s49 Days (Group 1)	28	1	(4%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	37	0			0	0		0		0		0	
	57-63 Days (Group 3)	18	0			0	0		0		0		0	
CENTR & PERIPH'NERVOUS SYSTEM DISORDERS							_	(000)		(402)	-	(23%)	0	
ANY EVENT	≤63 Days (All)	83	22	(27%)	0.6226	31	9	(29%)	15			(231)	0	
	≤49 Days (Group 1)	28	8	(29%)		11	3	(27%)	7	,				
*	50 56 Days (Group 2)	37	8	(22%)		8	2	(25%)	5		1	(13%)	0	
	57-63 Days (Group 3)	18	6	(33%)		12	. 4	(33%)	3	(25%)	5	(42%)	0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasohography

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational Age	Total Number	Numb	Pte	Fisher's exact	Number				Severity-			
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	ld	Mode	erate	Sev	ere.	Unknow
CENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (cont.)	······································		····						<del></del>			
DIZZINESE	≤63 Days (A11)	83	10	(12%)	0.9102	10	5	(50%)	4	(40%)	1	(10%)	0
	≤49 Days (Group 1)	28	4	(14%)		4	2	(50%)	2		0	(100)	0
	50-56 Days (Group 2)	37	4	(11%)		4	2	(501)	1		1	(25%)	Ö
	57-63 Dayв (Group 3)	18	2	(11%)		2	1		1		0	(230,	0
HEADACHE	≤63 Days (A!1)	83	14	(17%)	0.2640	19	4	(21%)	11	(58%)	4	(211)	0
	≤49 Days (Group 1)	28		(18%)		6	1	(17%)	5		0	(214)	0
1	50-56 Days (Group 2)	37		(111)		4	ō	(-,-,		(10ds)	٥		0
	57-63 Days (Group 3)	18		(28%)		9	3	(33%)		(22%)	4	(44%)	0
MIGRAINE	≤63 Days (All)	83	2	(2%)	0.3041	. ,	0		0		,	(100%)	0
•	≤49 Days (Group 1)	28	1	(4%)		1	0		. 0			(100%)	0
	50-56 Days (Group 2)	37	0	,		0	ň		0	1	ō		0
i e e	57-63 Days (Group 3)	18	1	(61)		1	0		0		-	(100%)	0
SYCHIATRIC DISORDERS													
ANY EVENT	≤63 Days (All)	83	3	(4%)	0.0445	3	0		3	(100%)	0		0
•	≤49 Days (Group 1)	28	3	(11%)		3	0			(100%)	n		ň
	50-56 Days (Group 2)	37	0			0	0		0	(1000)	Ô		n
•	57-63 Days (Group 3)	18	0			0	0		0		0		ō
ANXIETY	≤63 Days (All)	83	2	(21)	0.1560	2	0		2	(100%)	0		0
	'≤49 Days (Group 1)	28	2	(7%)		2	0			(100%)	0		Ô
4,	50-56 Days (Group 2)	37	0			0	0		.0	:	ō		0
	57-63 Days (Group 3)	19	0			. 0	0		, <b>.</b>	.!	0		Ô

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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# Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational Age	Total Number	Numb of 1		Fisher's exact	Number	<b>.</b>			Severi	t <b>v</b>		
Body System/Event [2]	Group [3]	of Pts		vent	p value	of Events		ild		rate	Sev	ere	Unknown
PSYCHIATRIC DISORDERS (cont.)		-141					~~						
DEPRESSION	≤63 Days (All)	83	1	(1%)	0.5542	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	28	1	(4%)		1	0			(100%)	0		o
	50-56 Days (Group 2)	37	0			0	0		0		0		0
	57-63 Days (Group 3)	18	0			0	0		0		0		0
JASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	83	48	(58%)	0.8080	115	10	(16%)	43	(37%)	54	(47%)	0
	≤49 Days (Group 1)	28	15	(54%)		29	3	(10%)	12		14	(48%)	Ö
	50-56 Days (Group 2)	37	23	(62%)		55	6	(114)	23	(42%)	26	(47%)	Õ
	57 63 Days (Group 3)	18	10	(56%)		31	9	(29%)	8		14	(45%)	ō
DIARRHEA	≤63 Days (All)	83	13	(16%)	0.7334	16	3	(19 <b>t</b> )	. 6	(361)	7	(44%)	0
	≤49 Days (Group 1)	28		(11%)		3	0	(120)	1	(33%)	2		0
	50-56 Days (Group 2)	37		(19%)		9	1	(11%)	5	(56%)	3		0
	57-63 Days (Group 3)	18		(17%)		4	2	(50%)	ő	(302)	2	(50%)	0
DYSPEPSIA	s63 Days (All)	83	2	(2%)	0.0450	2	2	(100%)	0		0		0
	≰49 Days (Group 1)	28	0			0	0	, ,	Ö		Ô		n
	50-56 Days (Group 2)	37	0			0	0		0		0		Ô
	57-63 Days (Group 3)	18	2	(11,1)		2	2	(100%)	0		0		Ö
NAUSEA	. s63 Days (All)	83	39	(47%)	0.5120	55	10	(18%)	23	(42%)	22	(40%)	0
<del>,</del>	≤49 Days (Group 1)	28	12	(43%)		16	3	(19%)	.7		6	(38%)	0
, ,	50-56 Days (Group 2)	37	20	(54%)		27	5	(191)		(41%)	11	(41%)	Ö
	57-63 Days (Group 3)	18	7	(391)		12	2	(178)	Ś'		5	(42%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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#### Appendix D, Table 5a (Continued) Adverse Events [1] By Center (Safety Evaluable Patients)

Center: SOGOR (#29)

	Gestational Age	Total Number	Numb of P	_	Fisher's exact	Number -				Severit	y	<b>.</b>	
Body System/Event [2]	Group (3)	of Pts	w/Ev		p value	of Events	Mi	1d '	Mode	rate	Sev	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)						_			•			(100%)	o
TOOTH ACHE	s63 Days (All)	83	1	(1%)	0.5542	1	0		0			(100%)	0
	≰49 Days (Group 1)	28	1	(4%)		1	0		0		Ó	(1001)	0
	50-56 Days (Group 2)	37	0	1 4		0	0		0		0		0
	57-63 Days (Group 3)	18	0			0	0		U		v		Ū
VOMITING	≤63 Days (All)	83	28	(34%)	0.7612	41	3	(7%)	14	(34%)	24	(59%)	0
VOMITING	≰49 Days (Group 1)	28	В	(29%)		9	0		4	(44%)	5	(56%)	0
· ·	50-56 Days (Group 2)	37	14	(38%)		19	0		7	(37%)	12	(63%)	0
	57-63 Days (Group 3)	18	6	(33%)		13	3	(23%)	3	(23%)	7	(54%)	0
METABOLIC AND NUTRITIONAL DISORDERS							•			(100%)	0		0
ANY EVENT	s63 Days (All)	83	1	(1%)	1.0000	1	0			(1004)	0		0
	≰49 Days (Group 1)	28	0			; <b>0</b>	v		•	(100%)	0		0
	50-56 Days (Group 2)	37	1	(3\$)		1	0			(1004)	0		0
	57-63 Days (Group 3)	18	0			O	U		0		v		Ü
DEHYDRATION	≤63 Days (All)	83	1	(1%)	1.0000	1	0		1	(100%)	0		0
DEHIDRATION ,	≰49 Days (Group 1)	28	0			0	0		0		0		0
	50-56 Days (Group 2)	37	1	(3%)		1	0		1	(100%)	0		0
a de la companya de l	57-63 Days (Group 3)	18	0			0	0		0		0		0
HEART RATE AND RHYTHM DISORDERS									_				•
ANY EVENT	'≤63 Days (All)	83	1	(1%)	0.5542	1	0			(100%)	0		0
<del>4</del> .	≤49 Days (Group 1)	28	1	(4%)		. 1	0		4.	(100%)	0		Ü
	50-56 Days (Group 2)	37	0			. 0	0	, j	0	•	0		U
• • • • • • • • • • • • • • • • • • •	57-63 Days (Group 3)	18	0			0	0	r	,0		0		U

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational Age	Total Number	Number of Pts	Fisher's exact:			<b>9</b> -1-1-1		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
EART RATE AND RHYTHM DISORDERS (cont.)									
TACHYCARDIA	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	ō	1 (100%)	Ö	0
	50-56 Days (Group 2)	37	0		. 0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	ő	0
ESPIRATORY SYSTEM DISORDERS		* +							
ANY EVENT	≤63 Days (All)	83	2 (2%)	1.0000	2	n	2 (100%)	0	0
t .	≰49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57 63 Days (Group 3)	18	0		0	o	0	ō	0
ASTHMA	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	28	1 (4%)		1	Ö	1 (100%)	0	0
	50 56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	Ö	ō	0
SINUSITIS	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50 56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	18	0		0	0	0	o	0
LATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	'≤63 Days (All)	83	1 (1%)	1.0000	1	0	0 .	1 (100%)	0
<del>-i</del> .	≤49 Days (Group 1)	28	0		. 0	0	9	0	0
A A A	50-56 Days (Group 2)	37	1 (3%)		1	0 , "	0	1 (100%)	0
•	57-63 Days (Group 3)	18	0	'	0	0	,0	0	0
						r	, <b>,</b>		•

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

FINAL.

<sup>(2)</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling. Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number -			Severit		
Body System/Event [2]	Group [3]	of Pts	w/Ev		p value	of Events	Mild		Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORDER	S (cont.)										
EPISTAXÎS	≰63 Days (All)	83	1	(1%)	1.0000	1	0		0	1 (100%)	0
	≤49 Days (Group 1)	28	0			0	0		0	0	0
	50-56 Days (Group 2)	37	1	(3%)		1	0		0	1 (100%)	0
	57-63 Days (Group 3)	18	0			0	0		0	0	0
RINARY SYSTEM DISORDERS											i
ANY EVENT	≤63 Days (All)	83	1	(1%)	1.0000	1	0		1 (100%)	0	0
i i	≤49 Days (Group 1)	28	0			; 0	0		0 ,	0	0
· · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	37	1	(3%)		1	0		1 (100%)	0	0
	57 63 Days (Group 3)	18	. 0			0	0		0	0	0
URINARY TRACT INFECTION	s63 Days (All)	83	1	(1%)	1.0000	1	0		1 (100%)	0	0
	≰49 Days (Group 1)	28	0			0	0		0	0	0
	50-56 Days (Group 2)	37	1	(3%)		1	0		1 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE	57-63 Days (Group 3)	18	0			0	0	İ	0	0	0
ANY EVENT	≰63 Days (All)	83	4	(5%)	1.0000	4	0		2 (50%)	2 (50%)	0
	≤49 Days (Group 1)	28	1	(4%)		1	0		1 (100%)	0	0
	50-56 Days (Group 2)	37	2	(5%)		2	0		1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	18	1	(61)		1	0		0	1 (100%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS - Not Otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal untraspnography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severity			
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unkn	own
REPRODUCTAVE DISORDERS, FEMALE (cont.)		<u> </u>	*****							
BREAST DISCHARGE	≤63 Days (All)	83	1 (1%	1.0000	1	О .	1 (100%)	0	0	
	≤49 Days (Group 1)	28	0		0	0	0	0	0	
	50 56 Days (Group 2)	37	1 (3%	)	1	0	1 (100%)	0	0	
	57-63 Days (Group 3)	18	0		0	0	0	0	0	
BREAST PAIN FEMALE	≤63 Days (All)	83	1 (1%	0.5542	1	0	1 (100%)	0	0	
_	≤49 Days (Group 1)	28	1 (4%	)	1	0	1 (100%)	0	0	
' .	50-56 Days (Group 2)	37	0		0	0	<b>o</b> ,	0	0	
	57-63 Days (Group 3)	18	0		. 0	0	0	0	0	
UTERINE HAEMORRHAGE	≤63 Days (All)	83	2 (21	0.6956	2	0	0	2 (100%)	0	
'	≤49 Days (Group 1)	28	0		0	0	. 0	0	0	
	50-56 Days (Group 2)	37	1 (3%	)	1	0	0	1 (100%)	0	
	57-63 Days (Group 3)	18	1 (6%	)	1	0	0	1 (100%)	0	
BODY AS A WHOLE - GENERAL DISORDERS										
ANY EVENT	≤63 Days (All)	83	74 (89%	0.5331	214	58 (27%)	86 (40%)	69 (32%)	1	(<1%)
	≰49 Days (Group 1)	28	26 (93%	)	75	19 (25%)	40 (53%)	15 (20%)	1	(1%)
,	50-56 Days (Group 2)	37	33 (89%	)	94	26 (28%)	30 (32%)	38 (40%)	0	
	57-63 Days (Group 3)	18	15 (83%	)	45	13 (29%)	16 (36%)	16 (36%)	0	
ABDOMINAL PAIN	, s63 Days (All)	83	74 (89%	0.5331	198	53 (27%)	77 (39%)	67 (34%)	1	(<1%)
Ť	≰49 Days (Group 1)	28	26 (93%	)	70	17 (24%)	37 (53%)	15 (21%)	1	(11)
	50-56 Days (Group 2)	37	33 (89%	)	. 87	25 (291)	26 (30%)	36 (41%)	0	
	57-63 Days (Group 3)	18	15 (831	)	41	11 (271)	14 (34%)	16 (39%)	0	
						<b>r</b>	•			

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational Age	Total Number	Number of Pts	-	Fisher's exact	No contra an		0-		
Body System/Event [2]	Group [3]	of Pts	w/Ever		p·value	Number of Events	Mild	Moderate	verity Severe	Unknow
ODY AS A WHOLE - GENERAL DISORDERS (cont.	)									
ALLERGY *	≤63 Days (All)	83	1 (	(1%)	1.0000	1	0	1 (100	<b>%</b> ) 0	0
	≤49 Days (Group 1)	28	0			. 0	0	0	0	0
	50-56 Days (Group 2)	37	1 (	(3%)		1	0	1 (100	<b>%</b> ) 0	0
	57 63 Days (Group 3)	18	0			0	0	0	0	0
BACK PAIN	≤63 Days (All)	83	4 (	(5%)	0.8173	5	1 (20%)	3 (60	1 (20%)	0
	≰49 Days (Group 1)	28	2 (	(7%)		2	1 (50%)	1 (50	<b>*</b> ) 0	0
· ·	50-56 Days (Group 2)	37	1 (	(3%)		2	ó	1 (50	1 (50%)	0
	57-63 Days (Group 3)	18	1 (	(6%)		1	0	1 (100	<b>%</b> ) 0	0
CHEST PAIN	s63 Days (All)	83	1 (	(1%)	0.2169	1	o	1 (100	<b>%</b> ) 0	0
·	≰49 Days (Group 1)	28	0			0	0	. 0 .	0	0
	50 56 Days (Group 2)	37	0			0	0	0	0	0
i	57-63 Days (Group 3)	18	1 (	(6%)		1	0	1 (100	<b>*</b> ) 0	0
FEVER	≤63 Days (All)	83	4 (	(5%)	0.8173	4	2 (50%)	2 (50	<b>\$</b> ) 0	0
•	≰49 Days (Group 1)	28	2 (	(7%)		2	1 (50%)	1 (50	•) 0	0
	50-56 Days (Group 2)	37	1 (	(3%)		1	0	1 (100	<b>%</b> ) 0	0
, , , , , ,	57-63 Days (Group 3)	18	1 (	(6%)		1	1 (100%)	0	0	0
MALAISE	≤63 Days (All)	83	2 (	(2%)	1.0000	2	0	2 (100	<b>\$</b> ) 0	0
	≰49 Days (Group 1)	28	1 (	(4%)		1	0	1 (100	<b>\$</b> ) 0	0
	' 50-56 Days (Group 2)	37	1 (	(3%)		1	0	1 (100	<b>4</b> ) 0	0
	57-63 Days (Group 3)	18	0			0	0	þ	o	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = 'Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table Sa (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	· · · · · · · · · · · · · · · · · · ·	Severi	•	
body System/Event (2)	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDE	RS (cont.)								
OEDEMA	≤63 Days (All)	83	1 (19	0.2169	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	Ô	ň
	50 56 Days (Group 2)	37	0		0	0	Ô	n	0
	57-63 Days (Group 3)	18	1 (61	1)	1	1 (100%)	Ö	Ö	Ö
PAIN	s63 Days (All)	83	1 (19	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	28	0		0	0	Ō	0	0
T.	50-56 Days (Group 2)	37	1 (31	t)	2	1 (50%)	o ,	1 (50%)	0
	57-63 Days (Group 3)	18	0		0	0	o	0	o
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	83	4 (51	1.0000	5	0	5 (100%)	0	0
	≤49 Days (Group 1)	28	1 (41		2	0	2 (100%)	n	0
	50-56 Days (Group 2)	37	2 (51	;)	2	0	2 (100%)	Ö	0
	57-63 Days (Group 3)	18	1 (61		1	0	1 (100%)	o	0
INFECTION	≤63 Days (All)	83	1 (19	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0	,	0	0	0	0	•
	50-56 Days (Group 2)	37	1 (31	; )	i	n	1 (100%)	Ô	0
· '	57 63 Days (Group 3)	18	0		0	0	0	0	0
INFECTION PARASITIC	≤63 Days (All)	83	1 (19	, ;) 0.5542	1	0	1 (100%)	0	
· -	s49 Days (Group 1)	28	1 (41		1	0	1 (100%)	. 0	0
<del>4</del> .	50-56 Days (Group 2)	37		•	0			i -	0
A Company of the Comp	57 63 Days (Group 3)	18	ō		• 0	0	0	0	0
	•		0		0	0 .	0	0 0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL.

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Appendix D, Table Sa (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of P w/Eve	ts	Fisher's exact p-value	Number of Events	Mild	Severity Moderate	Severe	Unknown
ESISTANCE MECHANISM DISORDERS (cont.)										
INFECTION VIRAL	≤63 Days (All)	83	3	(4%)	1.0000	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	28	1	(4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1	(3%)		1	0	1 (100%)	0	0
	57 63 Days (Group 3)	18	1	(6%)		1	0	1 (100%)	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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## Appendix D, Table 5b Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number				Severit	: <b>y</b>		
Body System/Event	Group [2]	of Pts	w/E	vent.	p value	of Events	Mi	ld	Mode	rate 	Sev	ere	Unknown
ANY EVENT	≤63 Days (All)	71	48	(68%)	1.0000	103	51	(50%)	44	(43%)	8	(8%)	0
	≰49 Days (Group 1)	28	19	(68%)		38	20	(53%)	18	(47%)	0		0
	50-56 Days (Group 2)	26	18	(69%)		36	18	(50%)	14	(39%)	4	(11%)	0
	57-63 Days (Group 3)	17	11	(65%)		29	13	(45%)	12	(41%)	4	(14%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													į
ANY EVENT	≰63 Days (All)	71	12	(17%)	0.0639	16	7	(44%)	7	(44%)	2	(13%)	O
	≤49 Days (Group 1)	28	7	(25%)		7	4	(57%)	3	(43%)	0		0
•	50-56 Days (Group 2)	26	1	(4 <b>%</b> )		3	1	(33%)	1	(33%)	`1	(33%)	0
	57-63 Days (Group 3)	17	4	(24%)		6	2	(33%)	3	(50%)	1	(17%)	0
DIZZINESS	s63 Days (All)	71	3	(4%)	0.0119	4	1	(25%)	. 2	(50%)	1	(25%)	0
	≰49 Days (Group 1)	28	0			0	0		0		0		0
	50-56 Days (Group 2)	26	0			0	0		0		0		0
	57-63 Days (Group 3)	17	3	(18%)		4	1	(25%)	2	(50%)	1	(25%)	0
HEADACHE	≤63 Days (All)	71	10	(14%)	0.0666	12	. 6	(50%)	5	(42%)	1	(8%)	0
•	\$49 Days (Group 1)	28	7	(25%)		7	4	(57%)	3	(43%)	0		0
	50-56 Dayв (Group 2)	26	1	(4%)		3	1	(33%)	1	(33%)	1	(33%)	0
	57-63 Days (Group 3)	17	2	(12%)		2	1	(50%)	1	(50%)	0		0
PSYCHIATRIC DISORDERS													
ANY EVENT	. ≤63 Days (All)	71	2	(3%)	0.7070	3	0		2	. (67%)	1	(33%)	0
<b>4</b> . ,	s49 Days (Group 1)	28	1	(4%)		1	0	"* L	1	(100%)	0		0
	50-56 Days (Group 2)	26	0			0	0	<b>i</b>	0	•	0		0
•	57 63 Days (Group 3)	17	1	(61)		2	0	,	,1	(50%)	1	(50%)	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristome.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number				Severi			
Body System/Event	Group [2]	of Pts	w/Ev		p value	of Events		ild		erate	Sev		Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)							-					
VOMITING	≤63 Days (All)	71	14	(20%)	0.9300	15	7	(47%)	6	(40%)	2	(13%)	0
	≤49 Days (Group 1)	28		(18%)		5	2	(40%)	3		0	(134)	-
	50-56 Days (Group 2)	26		(19%)		6	1	(50%)	2	-	-	(17%)	0
	57 63 Days (Group 3)	17		(24%)		4	<b>,</b> 2	(50%)	1			(25%)	0
VASCULAR (EXTRACARDIAC) DISORDERS													
ANY EVENT	≤63 Days (All)	71	1	(1%)	0.6056	1	0		1	(100%)	0		•
	≤49 Days (Group 1)	28	0			0	0		Ô	(1000)	0		0
	50 56 Days (Group 2)	26	1	(4%)		1	ō		•	(100%)	0		0
	57-63 Days (Group 3)	17	0			0	0		0	(1004)	0		0
FLUSHING	≤63 Days (All)	71	1	(1%)	0.6056	1	0		,	(100%)	•		
	≤49 Days (Group 1)	28	0	(/	0.0050	0	0		0	(1004)	0		0
	50-56 Days (Group 2)	26	1	(4%)		1	0		_	(1004)	0		0
	57-63 Days (Group 3)	17	ō	( ,		0	0		0	(100%)	0		0
RESPIRATORY SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	71	1	(1%)	1.0000	1	0		,	(100%)	0		0
	≤49 Days (Group 1)	28	1	(4%)		_ 1	0			(100%)	0		0
	50-56 Days (Group 2)	26	0			0	0		0	(1001)	0		
	57-63 Days (Group 3)	17	0			0	ŏ		0		0		0
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Source Data: Appendix A.1, Table 25

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<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Numb of P w/Ev	et <b>s</b>	Fisher's exact	Number of Events	 Mild			Severit	•			
	G10up (2)	OL PES	W/EV	ent	p value	or Evenus	MIIG		mode	rate	Sev	ere 		Unknown
RESPIRATORY SYSTEM DISORDERS	(cont.)						,							
PULMONARY CONGESTION	≤63 Days (All)	71	1	(1%)	1.0000	1	ó		1	(100%)	0			0
	≰49 Days (Group 1)	28	1	(4%)		1	0			(100%)	0			0
	50-56 Days (Group 2)	26	0			0	0		0		0			0
	57 63 Days (Group 3)	17	0			0	0		0		0			0
EPRODUCTIVE DISORDERS, FEMALE														
ANY EVENT	≤63 Days (All)	71	1	(1%)	0.6056	1	1 (1	00%)	0		0			0
	s49 Days (Group 1)	28	0			0	0		0		0			0
	50-56 Days (Group 2)	26	1	(4%)		. 1	1 (1	00%)	0		0			0
	57-63 Days (Group 3)	17	0			0	0		0		0			0
LEUKORRHOEA	≤63 Days (All)	71	1	(1%)	0.6056	1	1 (1	00%)	0		0			0
1	≤49 Days (Group 1)	28	0	-		0	0		0		0			0
1	50-56 Days (Group 2)	26	1	(4%)		1	1 (1	00%)	0		ō			0
	57-63 Days (Group 3)	17	0			0	0	·	0		0			0
ODY AS A WHOLE - GENERAL DISORDERS	•													
ANY EVENT	≤63 Days (All)	71	33	(46%)	0.2664	37	21 (	57%)	14	(38%)	2	(5%)		0
•	≤49 Days (Group 1)	28		(54%)		15		50%)	6	(40%)	0	,347	,	0
	50 56 Days (Group 2)	26		(50%)		15		40%)	7	(47%)	2	(13%)		0
	57-63 Days (Group 3)	17		(29%)		7		86%)	1	(14%)	0	,,,		0
ā.							- •	•	_		•			-

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	γ	
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
ABDOMINAL PAIN	≤63 Days (All)	71	28 (39%)	0.2916	30	17 (57%)	11 (37%)	2 (7%)	0
	≤49 Days (Group 1)	28	13 (46%)		13	8 (62%)	5 (38%)	0	0
	50-56 Days (Group 2)	26	11 (42%)		13	6 (46%)	5 (38%)	2 (15%)	0
	57-63 Days (Group 3)	17	4 (24%)		4	3 (75%)	1 (25%)	0	0
ASTHENIA	≤63 Days (All)	71	1 (1%)	0.2394	1	1 (100%)	0	0	0
T .	≤49 Days (Group 1)	28	0	0.2371	0	0	<b>o</b> .	0	n
	50-56 Days (Group 2)	26	0		0	o	0	Ô	0
	57 63 Days (Group 3)	17	1 (6%)		• 1	1 (100%)	0	o	0
BACK PAIN	≤63 Days (All)	71	2 (3%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	26	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	71	I (1%)	0.2394	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	28	O <sub>.</sub>		0	0	0	0	0
	50-56 Days (Group 2)	26	o o		0	0	. 0	0	0
•	57-63 Days (Group 3)	17	1 (6%)		2	2 (100%)	0	0	• 0
FEVER	≤63 Days (All)	71	1 (1%)	0.6056	1	0	1 (100%)	0	0
,	≰49 Days (Group 1)	28	0		0	0	0	0	0
7.	50-56 Days (Group 2)	26	1 (4%)		1	٠ -	1 (100%)	0	0
1 ) <b>6</b>	57-63 Days (Group 3)	17	0		• 0	0	0	0	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number		Severit	· v · · · · · · · · · · ·	
Body System/Event	Group (2)	of Pts	w/Ev		p value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)	***************************************					•			
RIGORS	≤63 Days (All)	71	1	(1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1	(4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	0			0	0	0	0	0
	57-63 Days (Group 3)	17	0			0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number				Severit	.v		
Body System/Event	Group [2]	of Pts	w/Even		p value	of Events	Mi	.1d	Mod	lerate	•	ere	Unknow
ANY EVENT	≤63 Days (All)	151	122 (8	11%)	0.9300	278	108	(391)	139	(50%)	31	(11%)	0
	≤49 Days (Group 1)	70		111)		132	52	(391)	69		11	(8%)	0
	50-56 Days (Group 2)	43		111)	1	93	31	(37%)	41	(49%)	11	(13%)	0
	57-63 Days (Group 3)	38	30 (7	91)		63	25	(40%)	29	(46%)	9	(14%)	0
rusculo-skeletal system disorders													
ANY EVENT	≤63 Days (All)	151	1 (<	11)	0.5364	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	0			0	0		C	,	0		0
	50-56 Days (Group 2)	. 43	1 (	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	0			0	0		: C	•	0		0
ARTHRALGIA	≤63 Days (All)	151	1 (<	:1\$)	0.5364	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	0			0	0		0	)	0		0
	50-56 Days (Group 2)	43	1 (	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	0			0	0		0	ı	0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	151	43 (2	(48)	0.8219	50	24	(48%)	21	(42%)	5	(10%)	0
	s49 Days (Group 1)	70		178)		22	13	(59%)	6		1	(5%)	* 0
	50-56 Days (Group 2)	43	14 (3	3%)		16	7	(44%)	8	(50%)	1	(6%)	0
	57-63 Days (Group 3)	38	10 (2	(6%)		12	4	(33%)	5	(42%)	3	(25%)	0
<b>4</b> .	•												

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational	Total		ber	Fisher's								
Dadu Contac (South	Age	Number		Pts vent	exact p value	Number of Events		ild		Severit Prate	•	еге	Unknown
Body System/Event	Group [2]	of Pts	W/E	vent	p varue	OI Events	M.	110	Mode	race			Olikilowii
CENTR & PERIPH NERVOUS SYSTEM DISORDE	RS(cont.)												
DIZZINESS	≤63 Days (All)	151	14	(9%)	0.9368	14	6	(43%)	7	(50%)	1	(7%)	0
	≤49 Days (Group 1)	70	6	(9%)		6	4	(67%)	2	(33%)	0		0
	50 56 Days (Group 2)	43	4	(9%)		4	1	(25%)	3	(75%)	0		0
	57-63 Days (Group 3)	38 -	4	(11%)		4	1	(25%)	2	(50%)	1	(25%)	0
HEADACHE	≤63 Days (All)	151	34	(23%)	0.6316	35	17	(49%)	14	(40%)	4	(11%)	0
	≰49 Days (Group 1)	70	14	(20%)		15	8	(53%)	6	(40%)	1	(7%)	0
,	50-56 Days (Group 2)	43	12	(28%)		12	6	(50%)	5	(42%)	1	(8%)	0
	57-63 Days (Group 3)	38	8	(21%)		. 8	3	(38%)	3	(38%)	2	(25%)	0
HYPOAESTHESIA	≤63 Days (All)	151	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≰49 Days (Group 1)	70	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	43	0			0	0		0		0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
BEARING AND VESTIBULAR DISORDERS							i						
ANY EVENT	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	70	0			0	0		0		0		0
· '	50-56 Days (Group 2)	43	0			0	0		. 0		0		0
	57-63 Days (Group 3)	38	1	(3%)		1	0		1	(100%)	0		0
TINNITUS	≤63 Days (All)	151	1	(<1%)	0.2517	ı	0		1	(100%)	0		0
• · · · · · · · · · · · · · · · · · · ·	≤49 Days (Group 1)	70	0			0	0		, 0		0		0
, , , , , , , , , , , , , , , , , , ,	50-56 Days (Group 2)	43	0			; 0	0	•	i 0	4. !	0		0
•	57-63 Days (Group 3)	38	1	(3%)		• 1	0	i i		(100%)	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational	Total	Num		Fisher's					<b>.</b>			
Body System/Event	Age Group [2]	Number of Pts	of w/E	rts vent	exact p-value	Number of Events		1d		Severit erate	Sever		Unknown
PSYCHIATRIC DISORDERS													*****
ANY EVENT	≤63 Days (All)	151	8	(5%)	0.8096	8	1	(13%)	5	(63%)	2 (	25%)	0
	≤49 Days (Group 1)	70	4	(6%)		4	1	(25%)	3	(75%)	0		0
	50-56 Days (Group 2)	43	3	(7%)		3	0		2	(67%)	1 (	33%)	0
	57-63 Days (Group 3)	38	1	(3%)		1	0		0		1 (1	00%)	0
ANOREXIA	≤63 Days (All)	151	2	(1%)	0.2861	2	0		1	(50%)	1 (	50%)	0
1	≤49 Days (Group 1)	70	0			0	0		0		0		0
	50 56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	1	(3%)		· 1	0		0		1 (1	00%)	0
EMOTIONAL LABILITY	s63 Days (All)	151	2	(1%)	1.0000	2	1	(50%)	0		1 (	50%)	0
	≤49 Days (Group 1)	70	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	43	1	(2%)		1	0		0		1 (1	00%)	0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
INSOMNIA	≤63 Days (All)	151	4	(3%)	0.6950	4	0		4	(100%)	0		0
	s49 Days (Group 1)	70	3	(4%)		3	0		3	(100%)	0		0
	50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	O		0
•	57-63 Days (Group 3)	38	0			0	0		0		0		0
SASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	151	75	(50%)	0.8332	95	30	(32%)	52	(55%)	13 (	14%)	0
*	≤49 Days (Group 1)	70	34	(49%)		40	12	(30%)**	• 24	(60%)	4 (	10%)	0
- In • 2 · 2	50-56 Days (Group 2)	43	23	(53%)		31	8	(26 <b>%</b> )	17	(55%)	6 (	19%)	0
•	57-63 Days (Group 3)	38	18	(47%)		24	10	(42%)	11	1(46%)	3 (	13%)	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational	Total	Numb		Fisher's					C	<b>.</b>		
Body System/Event	Age Group [2]	Number of Pts	of I		exact p-value	Number of Events	Mi			Severi erate	•	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												
DIARRHEA	≤63 Days (All)	151	3	(2%)	0.4489	3	1	(33%)	2	(67%)	0		0
	s49 Days (Group 1)	70	1	(1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	43	2	(5%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	38 .	0			0	0		0		0		0
DYSPEPSIA	≤63 Days (All)	151	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	1	(1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	43	0			0	0		0		0		0
	57-63 Days (Group 3)	38	0			. 0	0		0		0		0
NAUSEA	≤63 Days (All)	151	65	(43%)	0.7560	65	25	(38%)	30	(46%)	10	(15%)	0
	≰49 Days (Group 1)	70	28	(40%)		28	11	(39%)	13	(46%)	4	(14%)	0
	50-56 Days (Group 2)	43	20	(47%)		20	5	(25%)	11	(55%)	4	(20%)	0
	57-63 Days (Group 3)	38	17	(45%)		17	9	(53%)	6	(35%)	2	(12%)	0
VOMITING	≤63 Days (All)	151	26	(17%)	0.6197	26	4	(15%)	19	(73%)	3	(12%)	0
,	≤49 Days (Group 1)	70	10	(14%)		10	1	(10%)	9	(90%)	0		0
	50 56 Days (Group 2)	43	9	(21%)		9	2	(22%)	5	(56%)	2	(22%)	0
1 · · · · · · · · · · · · · · · · · · ·	57 63 Days (Group 3)	38	7	(18%)		7	1	(14%)	5	(71%)	1	(14%)	0
METABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	s63 Days (All)	151	1	(<1%)	0.5364	1	0		1	(100%)	0		0
<del>4</del> .	≤49 Days (Group 1)	70	0			0	0	_	. 0	4	0		0
	50-56 Days (Group 2)	43	1	(2%)		. 1	0		՝ լ 1	(1001)	0		0
, -	57-63 Days (Group 3)	38	0			0	0	ŗ	0	•	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center {Safety Evaluable Patients}

Center: VARGAS (#22)

	Gestational	Total	Number	Fisher's					
	Age	Number	of Pts	exact	Number		Severi	t <b>y</b>	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS	(cont.)								
THIRST	≤63 Days (All)	151	1 (<1%)	0.5364	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	70	0		0	0	0	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	38 ·	0		0	0	0	0	0
PLATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	. ≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	<b>o</b> ,	0	0
	≰49 Days (Group 1)	70	0		0	0	o .	0	0
	50-56 Days (Group 2)	43	1 (2%)		. 1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
EPISTAXIS	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	70	0		0	0	0	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	151	1 (<1%)	1.0000	1	0	1 (100%)	0	0
•	≤49 Days (Group 1)	70	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
•	57-63 Days (Group 3)	38	0		0	0	0	0	0
<del>.</del>	*								

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational	Total	Numl		Fisher's	Nb.a				Severi	+ <b></b>		
Body System/Event	Age Group [2]	Number of Pts	of : w/E	vent	exact p-value	Number of Events	Mi			rate	Sev		Unknown
REPRODUCTIVE DISORDERS, FEMALE	(cont.)												
LEUKORRHOEA	≤63 Days (All)	151	1	(<1%)	1.0000	1	0		1	(100%)	0		0
220	≤49 Days (Group 1)	70	1	(1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	43	0			0	0		0		0		0
	57-63 Days (Group 3)	38 .	0			0	. 0		0		0		0
BODY AS A WHOLE - GENERAL DISORDERS													_
ANY EVENT	≤63 Days (All)	151	98	(65%)	0.5519	120	52		57		11	(9%)	0
,	≰49 Days (Group 1)	70	48	(69%)		65	26	(40%)	33	(51%)	6	(9%)	0
	50-56 Days (Group 2)	43	28	(65%)		30	15	(50%)	12	(40%)	3	(10%)	0
	57-63 Days (Group 3)	38	22	(58%)		25	11	(44%)	12	(48%)	2	(B\$)	0
ABDOMINAL PAIN	≤63 Days (All)	151	94	(62%)	0.4483	98	39	(40%)	48	(49%)	11	(11%)	0
nooning the	s49 Days (Group 1)	70	47	(67%)		51	17	(33%)	28	(55%)	6	(12%)	0
	50-56 Days (Group 2)	43	26	(60%)		26	13	(50%)	10	(38%)	3	(12%)	0
	57-63 Days (Group 3)	38	21	(55%)		21	9	(43%)	10	(48%)	2	(10%)	0
BACK PAIN	≤63 Days (All)	151	8	(5%)	1.0000	8	6	(75%)	2	(25%)	0		0
then then	≤49 Days (Group 1)	70	4	(6%)		4	3	(75%)	1	(25%)	0		0
· · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	43	2	(5%)		2	2	(100%)	0		0		0
	57-63 Days (Group 3)	38	2	(5%)		2	1	(50%)	1	(50%)	0		0
FATIGUE	≤63 Days (All)	151	7	(5%)	0.8873	7	2	(29%)		(71%)	0		0
#. , ,	≤49 Days (Group 1)	70	4	(6%)		4	2	(50%)		. į (Ś0 <b>%</b> )	0		0
· p · s · s	50-56 Days (Group 2)	43	2	(5%)		. 2	0	4	į 2	(100%)	0		0
, <del>.</del> .	57-63 Days (Group 3)	38	1	(3∜)		• 1	0	i Ve L	1	(100%)	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severit	<b>:у</b>	
Body System/Event	Group (2)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
FEVER	≰63 Days (All)	151	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38 .	0		0	0	0	0	0
HOT FLUSHES	≤63 Days (All)	151	3 (2%)	0.6120	3	2 (67%)	1 (33%)	0	0
ı	s49 Days (Group 1)	70	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38	1 (3%)		1	1 (100%)	0	o	0
RIGORS	≤63 Days (All)	151	3 (2%)	0.3365	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	70	3 (4%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

	Gestational	Total	Num		Fisher's								
Body System/Event	Age Group [2]	Number of Pts	of w/F	Pts vent	exact p-value	Number of Events		1d	Mode	Severit	y Sev		Unknown
body System, Event	Group (2)			ve.iic	p varue	Of Brenes			1.000				
ANY EVENT	≤63 Days (All)	89	75	(84%)	0.7079	210	114	(54%)	82	(39%)	14	(7%)	0
	≤49 Days (Group 1)	35	28	(80%)		80	45	(56%)	29	(36%)	6	(8%)	0
	50 56 Days (Group 2)	34	30	(88%)		83	38	(46%)	37	(45%)	8	(10%)	0
	57-63 Days (Group 3)	20	17	(85%)		47	31	(66%)	16	(34%)	0		0
USCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	≰63 Days (All)	89	1	(1%)	0.2247	3	3	(100%)	0		0		0
•	s49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	1	(5%)		3	3	(100%)	0		0		0
ARTHRALGIA	s63 Days (All)	89	1	(1%)	0.2247	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	0			0	0		0		0		0
	57 63 Days (Group 3)	20	1	(5%)		1	1	(100%)	0		0		0
SKELETAL PAIN	≤63 Days (All)	89	1	(1%)	0.2247	2	' 2	(100%)	0		0		0
	≰49 Days (Group 1)	35	0			0	0		0		0		0
•	50-56 Days (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	1	(5%)		2	2	(100%)	0		0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS	•												
ANY EVENT	≤63 Days (All)	89	25	(28%)	0.8682	31	14	(45%)	16	. <sub>(</sub> (52 <b>%</b> )	1	(3%)	0
	≤49 Days (Group 1)	35	11	(31%)		12	8	(67%)	` <sub>1</sub> 4	<b>(333)</b>	0		0
, -	50-56 Days (Group 2)	34	9	(26%)		14	3	(21%)	10	(71%)	1	(7%)	0
	57-63 Days (Group 3)	20	5	(25%)		5	3	(60%)	ا ء	(40%)	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristome.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center:

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Mild	Severit	y Severe	Unknowr
	71-71-71-1								
CENTR & PERIPH NERVOUS SYSTEM DI DIZZINESS	sorders(cont.) ≤63 Days (All)	89	10 (119	) 0.0281	12	8 (67%)	4 (33%)	0	0
DIDBINGS	s49 Days (Group 1)	35	8 (231		9	7 (78%)	2 (22%)	0	0
	50-56 Days (Group 2)	34	1 (31	•	2	0	2 (100%)	0	0
	57-63 Days (Group 3)	20	1 (59		1	1 (100%)	0	0	0
HEADACHE	≤63 Days (All)	89	15 (179	) 0.2145	19	6 (32%)	12 (63%)	1 (5%)	0
	≤49 Days (Group 1)	35	3 (91		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	34	8 (24)		12	3 (25%)	8 (671)	1 (8%)	n
	57-63 Days (Group 3)	20	4 (201		4	2 (50%)	2 (50%)	0	0
SYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	89	3 (31	0.1772	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	35	3 (98	)	3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
ANOREXIA	≤63 Days (All)	89	2 (21	) 0.3437	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	35	2 (61	)	2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
INSOMNIA	≰63 Days (All)	89	1 (19	) 1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	1 (38	)	1	0 - •	0	1 (100%)	0
	50-56 Days (Group 2)	34	0		• 0	o .i	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0,	0	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center:

	Gestational Age	Total Number	Numb of F		Fisher's exact	Number				Severit	- 1/	<b></b>	
Body System/Event	Group [2]	of Pts	w/Ev		p value	of Events		ld		rate	Seve		Unknown
SASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	<b>s63 Days (All)</b>	89	42	(47%)	0.4325	77	39	(51%)	36	(47%)	2	(3%)	0
	≰49 Days (Group 1)	35	14	(40%)		23	12	(52%)	11	(48%)	0		0
	50-56 Days (Group 2)	34	19	(56%)		37	16	(43%)	19	(51%)	2	(5%)	0
	57-63 Days (Group 3)	20 .	9	(45%)		17	11	(65%)	6	(35%)	0		0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	89	1	(1%)	0.6067	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
•	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0	1	0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
DIARRHEA	≤63 Days (All)	89	3	(3%)	1.0000	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	35	1	(3%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	20	1	(5%)		1	0		1	(100%)	0		0
DYSPEPSIA .	≰63 Days (All)	89	1	(1%)	0.6067	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	89	35	(39%)	0.1987	47	23	(49%)	24	(51%)	0		0
	≤49 Days (Group 1)	35	10	(29%)		13	6	(46%)		(54%)	0		0
ने.	50-56 Days (Group 2)	34	17	(50%)		23	10	(431).	, 13	(57%)	0		0
or pro set of the set	57-63 Days (Group 3)	20	8	(40%)		; 11	7	(6 <b>4</b> })	1	.(;36¥) •	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center:

	Gestational	Total	Number	Fisher's							
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	Number of Events		11 <b>d</b>		erate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)			***************************************			·				
VOMITING	≤63 Days (All)	89	18 (20%)	0.4694	25	12	(48%)	11	(44%)	2 (8%)	0
	≰49 Days (Group 1)	35	5 (14%)		9	5	(56%)	4	(44%)	0	0
	50-56 Days (Group 2)	34	9 (26%)		11	3	(27%)	6	(55%)	2 (18%)	0
	57-63 Days (Group 3)	20 .	4 (20%		5	4	(80%)	1	(20%)	0	0
REPRODUCTIVE DISORDERS, FEMALE											
ANY EVENT	≤63 Days (All)	89	1 (1%)	1.0000	1	0		0		1 (100%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	0		0	*	1 (100%)	0
	50-56 Days (Group 2)	34	0		. 0	0		0		0	0
	57-63 Days (Group 3)	20	0		0	0		0		0	0
BREAST PAIN FEMALE	≤63 Days (All)	89	1 (1%)	1.0000	1	0		0		1 (100%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	0		0		1 (100%)	0
	50 56 Days (Group 2)	34	0		0	0		0		0	0
	57-63 Days (Group 3)	20	0		0	0		0		0	0
BODY AS A WHOLE - GENERAL DISORDERS											
ANY EVENT	≤63 Days (All)	89	61 (69%)	0.9566	94	57	(61%)	29	(31%)	8 (9%)	0
r '	≤49 Days (Group 1)	35	23 (66%)		40	24	(60%)	13		3 (8%)	0
	50-56 Days (Group 2)	34	24 (71%)		32	19	(591)	8	(25%)	5 (16%)	0
	57-63 Days (Group 3)	20	14 (70%)		22	14	(64%)	8		0	0
<del>4</del>	1										

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center:

	Gestational Age	Total Number	Numb of F		Fisher's exact	Number				Conomi			
Body System/Event	Group [2]	of Pts	w/Ev		p-value	of Events		1d		erate	•	ere	Unknow
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)												
ABDOMINAL PAIN	≤63 Days (All)	89	55	(62%)	0.8865	70	47	(67%)	18	(26%)	5	(7%)	0
	≰49 Days (Group 1)	35	22	(63%)		27	18	(67%)	7	(26%)	2	(7%)	0
	50-56 Days (Group 2)	34	20	(59%)		25	16	(64%)	6	(24%)	3	(12%)	0
	57-63 Days (Group 3)	20 .	13	(65%)		18	13	(72%)	5	(28%)	0		0
BACK PAIN	≤63 Days (All)	89	2	(2%)	1.0000	2	2	(100%)	0		0		0
· ·	≤49 Days (Group 1)	35	1	(3%)		1	1	(100%)	0		0		0
	50 56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0	•	0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
FATIGUE	≤63 Days (All)	89	14	(16%)	0.7079	18	6	(33%)	9	(50%)	3	(17%)	0
	≤49 Days (Group 1)	35	7	(20%)		9	3	(33%)	5	(56%)	1	(11%)	0
	50-56 Days (Group 2)	34	4	(12%)		5	2	(40%)	1	(20%)	2	(40%)	0
	57 63 Days (Group 3)	20	3	(15%)		4	1	(25%)	3	(75%)	0		0
FEVER .	≤63 Days (All)	89	2	(2%)	1.0000	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	35	1	(3%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	0		1	(100%)	0		0
•	57-63 Days (Group 3)	20	0			0	0		0		0		0
LEG PAIN	≤63 Days (All)	89	1	(1%)	1.0000	1	0		1	(100%)	0		0
	<b>s49</b> Days (Group 1)	35	1	(3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	34	0			0	0		0		0		0
r province de la companya de la com	57-63 Days (Group 3)	20	0			• 0	0		0 	1. !	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

	Gestational Age	Total Number	Numb of F		Fisher's exact	Number		Severi	tv	
Body System/Event	Group [2]	of Pts	w/Ev		p-value	of Events	Mild	Moderate	Severe	Unknowr
BODY AS A WHOLE - GENERAL DISORI	ERS (cont.)	······								
RIGORS	≤63 Days (All)	89	1	(1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57 63 Days (Group 3)	20 .	0			0	0	0	0	0
RESISTANCE MECHANISM DISORDERS										
ANY EVENT	. ≤63 Days (All)	89	1	(1%)	1.0000	1	0	0	1 (100%)	0
	s49 Days (Group 1)	35	1	(3%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	34	0			. 0	0	0	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
HERPES SIMPLEX	≤63 Days (All)	89	1	(1%)	1.0000	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	35	1	(3%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57 63 Days (Group 3)	20	0			0	0	0	0	` 0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center {Safety Evaluable Patients}

Center: WESTHOFF (#24)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number				Severi	ty		
Body System/Event	Group [2]	of Pts	w/E	Event	p-value	of Events	Mi	1 <b>d</b>	Mod	erate	Sev	ere	Unknow
ANY EVENT	≤63 Days (All)	175	112	(64%)	0.2663	182	91	(50%)	69	(38%)	22	(12%)	0
	≤49 Days (Group 1)	71	46	(65%)		72	33	(46%)	28	(39%)	11	(15%)	0
	50-56 Days (Group 2)	72	42	(58%)		73	43	(59%)	22	(30%)	8	(11%)	0
	57-63 Days (Group 3)	32 .	24	(75%)		37	15	(41%)	19	(51%)	3	(8%)	0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	175	5	(3%)	0.6146	ڌ	2	(40%)	3	(60%)	0		0
·	<pre>s49 Days (Group 1)</pre>	71	1	(1%)		1	0		1	(10 <b>0%</b> )	0		0
	50-56 Days (Group 2)	72	3	(4%)		3	2	(67%)	1	(33%)	0		0
	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		0
DIZZINESS	≤63 Days (All)	175	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≰49 Days (Group 1)	71	0			0	0		0		0		0
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
HEADACHE	≤63 Days (All)	175	4	(2%)	0.8318	4	1	(25%)	3	(75%)	0		0
	≰49 Days (Group 1)	71	1	(1%)		1	0		1	(100%)	0		0
1	50-56 Days (Group 2)	72	2	(3%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		0
ASTRO-INTESTINAL SYSTEM DISORDERS	,												
ANY EVENT	≤63 Days (All)	175	41	(23%)	0.7746	65	24	(37%),	, 27	(421)	14	(22%)	0
the 🖈 🖰	s49 Days (Group 1)	71	16	(23%)		26	10	(381)	9	(35%)	7	(27%)	0
	50-56 Days (Group 2)	72	16	(22%)		28	12	(43%)	11	(39%)	5	(18%)	0
	57-63 Days (Group 3)	32	9	(28%)		11	2	(18¶)	7	(64%)	2	(18%)	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	y	
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS (CO	nt.)			· · · · · · · · · · · · · · · · · · ·					
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	175	1 (<1	0.1829	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32 ·	1 (3	)	1	0	1 (100%)	0	0
DIARRHEA	≤63 Days (All)	175	4 (2	0.6779	4	1 (25%)	3 (75%)	0	0
ì	≤49 Days (Group 1)	71	2 (3	)	2	0	2 (100%)	0	0
·	50-56 Days (Group 2)	72	1 (1	:)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	32	1 (3	)	. 1	0	1 (100%)	0	0
DYSPEPSIA	≤63 Days (All)	175	3 (21	0.4032	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	2 (3	)	2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	32	1 (3	)	1	0	1 (100%)	0	0
NAUSEA	≤63 Days (All)	175	32 (18	) 0.9035	36	15 (42%)	13 (36%)	8 (22%)	0
	≰49 Days (Group 1)	71	14 (201	)	17	9 (53%)	5 (29%)	3 (18%)	0
•	50-56 Days (Group 2)	72	13 (189	)	14	6 (43%)	5 (36%)	3 (21%)	o
	57-63 Days (Group 3)	32	5 (16)	)	5	0	3 (60%)	2 (40%)	0
VOMITING	≤63 Days (All)	175	20 (11	) 0.7771	21	7 (33%)	8 (38%)	6 (29%)	0
Ť	≰49 Days (Group 1)	71	7 (109	)	7	1 (14%)	2 (29%)	4 (57%)	0
	50-56 Days (Group 2)	72	10 (14	)	11	4 (36%)	5 (45%)	2 (18%)	0
11 • • · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	32	3 (91	)	3	2 (671)	1 (331)	0	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number				Sever	itv		
Body System/Event	Group [2]	of Pts		vent	p-value	of Events		1 <b>d</b>		derate	•	ere	Unknown
REPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	175	1	(<1%)	0.5886	1	0			0	1	(100%)	0
	≤49 Days (Group 1)	71	1	(1%)		1	0			0	1	(100%)	0
	50-56 Days (Group 2)	72	0			0	0			0	0		0
	57-63 Days (Group 3)	32 ·	0			0	. 0			0	0		0
UTERINE HAEMORRHAGE	s63 Days (All)	175	1	(<1%)	0.5886	1	0			0	1	(100%)	0
	≤49 Days (Group 1)	71	1	(1%)		1	0			0	· 1	(100%)	0
	50-56 Days (Group 2)	72	0			0	0			ο ΄	0		0
	57-63 Days (Group 3)	32	0			. 0	0			0	0		0
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	175	96	(55%)	0.0655	111	65	(59%)	3	9 (35%)	7	(6%)	0
	≰49 Days (Group 1)	71	39	(55%)		44	23	(52%)	1	8 (41%)	3	(7%)	0
	50-56 Days (Group 2)	72	34	(47%)		42	29	(69%)	1	0 (24%)	3	(7%)	0
	57-63 Days (Group 3)	32	23	(72%)		25	13	(52%)	1	1 (44%)	1	(4%)	0
•	• • •												
ABDOMINAL PAIN	≤63 Days (All)	175	93	(53%)	0.0947	102	61	(60%)	3	5 (34%)	6	(6%)	o
	≤49 Days (Group 1)	71	38	(54%)		41	22	(54%)	1	6 (39%)	3	(7%)	0
t '	50-56 Days (Group 2)	72	33	(46%)		38	27	(71%)		9 (24%)	2	(5%)	0
	57-63 Days (Group 3)	32	22	(69%)		23	12	(52%)	1	0 (43%)	1	(4%)	0
BACK PAIN	≤63 Days (All)	175	5	(3%)	0.7278	5	2	(40%)		2 (4.0%)	1	(20%)	0
ने <u>.</u>	≰49 Days (Group 1)	71	3	(4%)		3	1	(33%).	•	2 (67%)	0		0
+ p - ♣** - 3	50-56 Days (Group 2)	72	2	(3%)		. 2	1	(50%)		0	1	(50%)	0
•	57-63 Days (Group 3)	32	0			0	0	,		о,	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center {Safety Evaluable Patients}

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severit	·v	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)								,
FEVER	≰63 Days (All)	175	1 (<1%)	0.1829	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32 .	1 (3%)		1	1 (100%)	0	0	0
MALAISE	≤63 Days (All)	175	2 (1%)	0.3331	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
•	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0 '	0	0
	57-63 Days (Group 3)	32	1 (3%)		. 1	0	1 (100%)	0	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	175	1 (<1%)	1.0000	1	0	1 (100%)	0	0 -
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50 56 Days (Group 2)	72	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone {1} By Center {Safety Evaluable Patients}

Center: NICHOLS (#25)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severi			
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events		.1d		rate	•	ere	Unknown
ANY EVENT	≤63 Days (All)	178	52 (29%)	0.0176	72	40	(56%)	21	(29%)	11	(15%)	0
	≤49 Days (Group 1)	72	13 (18%)	0.0170	19	9	(47%)	5		5	(26%)	0
	50 56 Days (Group 2)	54	18 (33%)		23	15	(65%)	5	(22%)	3		0
	57-63 Days (Group 3)	52	21 (40%)		30	16	(53%)	11		3		ō
PECIAL SENSES OTHER, DISORDERS												
ANY EVENT	≤63 Days (All)	178	1 (<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	72	1 (1%)		1	0		0	•		(100%)	0
	50 56 Days (Group 2)	54	0		. 0	0		0		0		0
	57-63 Days (Group 3)	52	0		0	0		0		0		0
TASTE PERVERSION	≤63 Days (All)	178	1 (<1%)	1.0000	1	0		0		1	(100%)	0
	s49 Days (Group 1)	72	1 (1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	54	0		0	0		0		0		0
	57-63 Days (Group 3)	52	0		0	0		0		0		0
JASTRO-INTESTINAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	178	27 (15%)	0.4218	36	16	(44%)	13	(36%)	7	(19%)	0
· ´	≰49 Days (Group 1)	72	8 (11%)		12	6	(50%)	3	(25%)	3	(25%)	0
	50-56 Days (Group 2)	54	9 (17%)		10	6	(60%)	2	(20%)	2		0
	57-63 Days (Group 3)	52	10 (19%)		14	4	(29%)	8		2		0
<b>.</b>	•											

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational	Total	Numb		Fisher's					_			
Body System/Event	Age Group (2)	Number of Pts	of E	ent Vent	exact p value	Number of Events		1 <b>d</b>	Mode	Severit rate	-	ere	Unknowr
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)		-			•							
NAUSEA	≤63 Days (All)	178	25	(14%)	0.1595	30	14	(47%)	11	(37%)	5	(17%)	0
	≤49 Days (Group 1)	72	6	(8%)		8	4	(50%)	2	(25%)	2	(25%)	0
	50-56 Days (Group 2)	54	9	(17%)		10	6	(60%)	2	(20%)	2	(20%)	0
	57-63 Days (Group 3)	<b>52</b> .	10	(19%)		12	4	(33%)	7	(58%)	1	(8%)	0
VOMITING	≤63 Days (All)	178	5	(3%)	0.3309	6	2	(33%)	2	(33%)	2	(33%)	0
į.	≰49 Days (Group 1)	72	3	(4%)		4	2	(50%)	1	(25%)	1	(25%)	0
	50-56 Days (Group 2)	54	0			0	0		0	1	0		0
	57 63 Days (Group 3)	52	2	(4%)		2	0		1	(50∜)	1	(50∜)	0
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	178	32	(18%)	0.0007	35	24	(69%)	8	(23%)	3	(9%)	0
	≤49 Days (Group 1)	72	4	(6%)		6	3	(50%)	2	(33%)	1	(17%)	0
	50-56 Days (Group 2)	54	13	(24%)		13	9	(69%)	3	(23%)	1	(8♦)	0
	57-63 Days (Group 3)	52	15	(29%)		16	12	(75%)	3	(19%)	1	(6%)	0
ABDOMINAL PAIN	≤63 Days (All)	178	32	(18%)	0.0007	35	24	(691)	8	(23%)	3	(9%)	0
	≤49 Days (Group 1)	72	4	(6%)		6	3	(50%)	2	(33%)	1	(17%)	0
t .	50-56 Days (Group 2)	54	13	(24%)		13	9	(69%)	3	(23%)	1	(8%)	0
	57 63 Days (Group 3)	52	15	(29%)		16	12	(75%)	3	(19%)	1	(6%)	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severit	.y			
Body System/Event	Group [2]	of Pts	w/E	Event	p-value	of Events	Mi	ld	Mode	erate	Sev	ere	Unk	nown
ANY EVENT	≤63 Days (All)	179	164	(92%)	0.1663	359	161	(45%)	140	(42%)	47	(13%)	2	(<1%)
	≤49 Days (Group 1)	63	55	(87%)	0.1003	120	59		45		15	(13%)		(<1%
	50 56 Days (Group 2)	59	57			126	51	(40%)	57		17	(13%)		(<1%
	57-63 Days (Group 3)	57	52			113	51	(45%)	47		15	(13%)	0	(<18)
SKIN AND APPENDAGES DISORDERS														
ANY EVENT	≤63 Days (All)	179	1	(<1%)	1.0000	1	0		1	(100%)	0		0	
	≰49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	59	0			. 0	0		0		0		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
SWEATING INCREASED	≤63 Days (All)	179	1	(<1%)	1.0000	1	0		1	(100%)	0		0	
	≰49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
CENTR & PERIPH NERVOUS SYSTEM DISORDERS							,							
ANY EVENT	≰63 Days (All)	179	26	(15%)	0.1804	29	9	(31%)	17	(59%)	3	(10%)	0	
,	≰49 Days (Group 1)	63	13	(21%)		16	6	(38%)	7		3	(19%)	0	
	50-56 Days (Group 2)	59	5	(8%)		5	1	(20%)	4	(80%)	0	•	0	
	57-63 Days (Group 3)	57	8	(14%)		8	2	(25%)	6	(75%)	0		0	
<b>4</b> ,														

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational	Total	Numb		Fisher's	Number				Savorit			
Body System/Event	Age Group [2]	Number of Pts	of F w/Ev		exact p-value	of Events		ld		erate	Severe  3 (27%) 3 (30%) 0 0 0 0 0 1 (100%) 1 (100%) 0 0 1 (100%) 0 0 1 (100%) 1 (100%) 0 0 1 (100%)	Unknown	
ENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (cont.)												
DIZZINESS	≤63 Days (All)	179	10	(6%)	0.0008	11	5	(45%)	3	(27%)	3	(27%)	0
	≰49 Days (Group 1)	63	9	(14%)		10	4	(40%)	3	(30%)	3	(30%)	0
	50-56 Days (Group 2)	59	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	57	0			0	. 0		0		0		0
HEADACHE	≤63 Days (All)	179	17	(9%)	0.4097	18	4	(22%)	14	(78%)	0		0
	≤49 Days (Group 1)	63	5	(8%)		6	2	(33%)	4	(67%)	0		0
	50-56 Days (Group 2)	59	4	(7%)		4	0		4	(100%)	0		0
	57-63 Days (Group 3)	57	8	(14%)		. 8	2	(25%)	6	(75%)	0		0
ISION DISORDERS													
ANY EVENT	≤63 Days (All)	179	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	63	1	(2%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	59	0			0	0		0		0		0
	57-63 Days (Group 3)	57	0			0	0		0		0		0
VISION ABNORMAL	≤63 Days (All)	179	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	63	1	(2%)		1	0		0		1	(100%)	0
ř ,	50-56 Days (Group 2)	59	0			0	0		0		0		0
	57-63 Days (Group 3)	57	0			0	0		0		0		0
SYCHIATRIC DISORDERS		1											
ANY EVENT	≤63 Days (All)	179	3	(2%)	0.7746	3	2	(67%).	0	1	1	(33%)	0
1	≤49 Days (Group 1)	63	2	(3%)		, 2	1	(50%)	. 0	4. !	1	(50%)	0
•	50-56 Days (Group 2)	59	1	(2%)		` 1	1	(100%)	0		0		0
	57-63 Days (Group 3)	57	0			0	0		0	•	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center {Safety Evaluable Patients}

Center: SHEEHAN (#26)

	Gestational	Total	Numb		Fisher's							
Body System/Event	Age Group [2]	Number of Pts	of F w/Ev		exact p-value	Number of Events	Mild	Moder		Seve	ere	Unknow
PSYCHIATRIC DISORDERS (c	ont.)									·		
ANOREXIA	≤63 Days (All)	179	1	(<1%)	1.0000	1	1 (100%)	0		0		0
	≤49 Days (Group 1)	63	1	(2%)		1	1 (100%)	0		0		0
	50-56 Days (Group 2)	59	0			0	0	0		0		0
	57-63 Days (Group 3)	57	0			0	0	0		0		0
DEPRESSION	≤63 Days (All)	179	1	(<1%)	0.6480	1	1 (100%)	0		0		0
	≤49 Days (Group 1)	63	0			0	0	0		0		0
•	50 56 Days (Group 2)	59	1	(2%)		1	1 (100%)	0	•	0		0
	57-63 Days (Group 3)	57	0			, 0	0	0		0		0
EMOTIONAL LABILITY	≤63 Days (All)	179	1	(<1%)	1.0000	1	0	0		1	(100%)	0
	≤49 Days (Group 1)	63	1	(2%)		1	0	0		1	(100%)	0
	50-56 Days (Group 2)	59	0			0	0	0		0		0
	57 63 Days (Group 3)	57	0			0	0	0		0		0
ASTRO-INTESTINAL, SYSTEM DISORDERS												
ANY EVENT	s63 Days (All)	179	123	(69%)	0.0422	192	86 (45%)	78	(41%)	27	(14%)	1 (<
	≤49 Days (Group 1)	63	36	(57%)		54	28 (52%)	22	(41%)	4	(7%)	0
1	50-56 Days (Group 2)	59	46	(78%)		75	30 (40%)	31	(41%)	13	(17%)	1 (
	57-63 Days (Group 3)	57	41	(72%)		63	28 (44%)	25	(40%)	10	(16%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	179	2	(1%)	0.7667	2	1 (50%)	0		1	(50%)	0
÷.	≤49 Days (Group 1)	63	1	(2%)		1	1 (100%),.	. 0 '	! *. !	0		0
· · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	59	0			0	0 ,i	0		0		0
	57-63 Days (Group 3)	57		(2%)		1	0	0 ,		1	(100%)	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Num of		Fisher's exact	Number			<b></b>	Severi	tv			
Body System/Event	Group [2]	of Pts		vent	p value	of Events		ild		erate	Sev			nown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)									·····				
DIARRHEA	≤63 Days (All)	179	4	(2%)	1.0000	5	1	(20%)	4	(80%)	0		0	
	≤49 Days (Group 1)	63	2.	(3%)		2	1	(50%)	1	(50%)	0		0	
	50-56 Days (Group 2)	59	1	(2%)		2	0		2	(100%)	0		0	
	57-63 Days (Group 3)	57 .	1	(2%)		1	0		1	(100%)	0		0	
DYSPEPSIA	≤63 Days (All)	179	3	(2%)	0.5336	3	1	(33%)	1	(33%)	1	(33%)	0	
i i	≤49 Days (Group 1)	63	1	(2%)		1	1	(100%)	0		0		0	
	50-56 Days (Group 2)	59	2	(3₺)		2	0		1	(50 <b>%</b> )	1	(50%)	0	
	57-63 Days (Group 3)	57	0			. 0	0		0		0		0	
NAUSEA	≤63 Days (All)	179	114	(64%)	0.0393	141	68	(48%)	55	(39%)	17	(12%)	1	(<1%
	≰49 Days (Group 1)	63	33	(52%)		42	24	(57%)	16	(38%)	2	(5%)	0	•
	50.56 Days (Group 2)	59	44	(75%)		56	24	(43%)	23	(41%)	8	(14%)	1	(2%
	57-63 Days (Group 3)	57	37	(65%)		43	20	(47%)	16	(37%)	7	(16%)	0	
VOMITING	≤63 Days (All)	179	36	(20%)	0.1848	41	15	(37%)	18	(44%)	8	(20%)	0	
	≰49 Days (Group 1)	63	8	(13%)		8	1	(13%)	5	(63%)	2	(25%)	0	
	50-56 Days (Group 2)	59	14	(24%)		15	6	(40%)	5	(33%)	4	(27%)	0	
· '	57-63 Days (Group 3)	57	14	(25%)		18	8	(44%)	8	(44%)	2	(11%)	0	
METABOLIC AND NUTRITIONAL DISORDERS														
ANY EVENT	≤63 Days (All)	179	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
<b>4</b> .	s49 Days (Group 1)	63	1	(2%)		1	1	(100%),-	, 0	1	0		0	
· p · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	59	0			. 0	0	i	0	4 . !	0		0	
•	57-63 Days (Group 3)	57	0			0	0	*. *	0	1	0		0	

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	.y	
Group [2]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
(cont.)								
≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
50-56 Days (Group 2)	59	0		0	0	0	0	0
57 63 Days (Group 3)	57 .	0		0	0	0	0	0
≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
≤49 Days (Group 1)	63	0		0	0	ο '	0	0
	59	1 (2%)		1	1 (100%)	0	0	0
57-63 Days (Group 3)	57	0		0	0	0	0	0
≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	63	0		0	0	0	0	0
	59	1 (2%)		1	1 (100%)	0	0	0
57-63 Days (Group 3)	57	0		0	0	0	0	0
≤63 Days (All)	179	1 (<1%)	0.3184	1	1 (100%)	0	0	0
≤49 Days (Group 1)	63	0		0	0	0	0	0
	59	0		0	0	0	0	0
57-63 Days (Group 3)	57	1 (2%)		1	1 (100%)	0	0	0
	Age Group [2]  (comt.) <pre> <a href="#">663 Days</a> (All) <a href="#">649 Days</a> (Group 1) <a href="#">50-56 Days</a> (Group 2) <a href="#">57-63 Days</a> (Group 3)  <a href="#">663 Days</a> (Group 1) <a href="#">50-56 Days</a> (Group 2) <a href="#">57-63 Days</a> (Group 3)  <a href="#">663 Days</a> (Group 1) <a href="#">50-56 Days</a> (Group 2) <a href="#">57-63 Days</a> (Group 3)  <a href="#">663 Days</a> (Group 1) <a href="#">50-56 Days</a> (Group 1) <a href="#">50-56 Days</a> (Group 1) <a href="#">50-56 Days</a> (Group 2) <a href="#">50-56 Days</a> (Group 2) <a href="#">67-040</a> /pre>	Age Group [2] Of Pts  (cont.) <pre></pre>	Age Group [2]  (cont.)  (cont.	Age Group [2]    Number of Pts   exact	Age Group [2] of Pts w/Event p-value of Events  (cont.) <pre></pre>	Age Group [2]       Number of Pts w/Event       exact p-value       Number of Events       Mild         (cont.)       *63 Days (All)       179       1 (<1%)       1.0000       1       1 (100%)         *49 Days (Group 1)       63       1 (2%)       1       1 (100%)         50-56 Days (Group 2)       59       0       0       0         57 63 Days (Group 3)       179       1 (<1%)       0.6480       1       1 (100%)         *49 Days (Group 1)       63       0       0       0       0         50-56 Days (Group 2)       59       1 (2%)       1       1 (100%)         57-63 Days (Group 3)       57       0       0       0       0         *63 Days (All)       179       1 (<1%)       0.6480       1       1 (100%)         *49 Days (Group 1)       63       0       0       0       0         *50-56 Days (Group 2)       59       1 (2%)       1       1 (100%)         57-63 Days (Group 3)       57       0       0       0         *49 Days (Group 1)       63       0       0       0         *49 Days (Group 2)       59       1 (<1%)       0.3184       1       1 (100%)         *49 D	Age Group [2] of Pts of Pts exact Number of Events Mild Moderate  (cont.)  =63 Days (All)	Age Group [2]         Number of Pts of Pts w/Event         exact p value         Number of Events         Mild         Moderate         Severe           (cont.)         \$63 Days (All)         179         1 (<1%)         1.0000         1         1 (100%)         0         0         0           \$49 Days (Group 1)         63         1 (2%)         1         1 (100%)         0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational	Total	Numb	er	Fisher's									
	Age	Number	of P	ts	exact	Number				Severi	ty			
Body System/Event	Group [2]	of Pts	w/Ev	ent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unk	nown
RED BLOOD CELL DISORDERS	(cont.)													-
ANAEMIA	≰63 Days (All)	179	1	(<1%)	0.3184	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	63	0			0	0		0		0		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57 -	1	(2%)		1	1	(100%)	0		0		0	
REPRODUCTIVE DISORDERS, FEMALE														
ANY EVENT	≰63 Days (All)	179	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	63	1	(2%)		1	1	(100%)	0	•	0		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
LEUKORRHOEA	≤63 Days (All)	179	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	63	1	(2%)		1	1	(100%)	0		0		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
BODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	179	117	(65%)	0.9040	128	60	(47%)	52	(41%)	15	(12%)	1	(<1%)
· '	≤49 Days (Group 1)	63	40	(63%)		44	22		15	(34%)		(14%)	1	(2%)
	50-56 Days (Group 2)	59		(68%)		43	18		21	(49%)	4	(9%)	0	
	57 63 Days (Group 3)	57		(65%)		41	20		16	(39%)	5		0	
2														

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational	Total		mber	Fisher's									
Body System/Event	Age Group [2]	Number of Pts		Pts Event	exact p-value	Number of Events		ild		Severi erate		vere		nown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)													
ABDOMINAL PAIN	≤63 Days (All)	179	116	(65%)	0.9800	122	58	(48%)	51	(42%)	12	(10%)	1	(<1%
	≤49 Days (Group 1)	63	40	(63%)		43	22	(51%)	15	(35%)	5	(12%)	1	(2%
	50-56 Days (Group 2)	59	39	(66%)		39	17	(44%)	20	(51%)	2	(5%)	0	
	57-63 Days (Group 3)	<b>57</b> .	37	(65%)		40	19	(48%)	16	(40%)	5	(13%)	0	
ASTHENIA	≤63 Days (All)	179	2	(1%)	1.0000	2	0		0		2	(100%)	0	
i	≰49 Days (Group 1)	63	1	(2%)		1	0		0		1	(100%)	0	
	50-56 Days (Group 2)	59	1	(2%)		1	0		0	•	1	(100%)	0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
BACK PAIN	≤63 Days (All)	179	2	(1%)	0.5413	2	1	(50%)	1	(50%)	0		0	
	≰49 Days (Group 1)	63	0			0	0		0		0		0	
	50-56 Days (Group 2)	59	1	(2%)		1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	57	1	(2%)		1	1	(100%)	0		0		0	
FATIGUE .	≤63 Days (All)	179	2	(1%)	0.2076	2	,1	(50%)	0		1	(50%)	0	
	≰49 Days (Group 1)	63	0			0	0		0		0		0	
	50-56 Days (Group 2)	59	2	(3%)		2	1	(50%)	0		1	(50%)	0	
· '	57-63 Days (Group 3)	57	0			0	0		. 0		0		0	
RESISTANCE MECHANISM DISORDERS														
ANY EVENT	≰63 Days (All)	179	1	(<1%)	0.6480	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	63	0			0	0	,,*	. 0	4	0		0	
e pro 🔥 🔭 Arman e e e e e e e e e e e e e e e e e e e	50-56 Days (Group 2)	59	1	(2%)		, 1	0	i	1 1	(li,00%)	0		0	
•	57-63 Days (Group 3)	57	0			. 0	0	, ,	0	•	0		0	

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	<b></b>	Severit	:y	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS	(cont.)								
INFECTION VIRAL	≤63 Days (All)	179	1 (<1%)	0.6480	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	57	0		0	0	o	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event	Gestational Age	Total Number	of	ber Pts	Fisher's exact	Number				Severity				
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events	M1	.1u	Mode	rate	sev	ere	Unki	nown
ANY EVENT	≤63 Days (All)	191	138	(72%)	0.2852	385	136	(35%)	170	(44%)	71	(18%)	В	(2%)
THE DESIGN	≤49 Days (Group 1)	29	24		0.2032	68	24	(35%)	37	(541)	7	(10%)	0	(20)
	50-56 Days (Group 2)	73	49	(67%)		142	47	(33%)	68	(48%)	25	(18%)	2	(1%)
	57 63 Days (Group 3)	89	65	(73%)		175	65	(37%)	65	(37%)	39	(22%)	6	(3%)
SKIN AND APPENDAGES DISORDERS														
ANY EVENT	≤63 Days (All)	191	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	29	0			0	0		0	•	0		0	
	50-56 Days (Group 2)	73	0			0	0		0		0		0	
	57-63 Days (Group 3)	89	1	(1%)		1	1	(100%)	0		0		0	
PRURITUS	≤63 Days (All)	191	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	29	0			0	0		0		0		0	
•	50-56 Days (Group 2)	73	0			0	0		0		0		0	
:	57-63 Days (Group 3)	89	1	(1%)		1	1	(100%)	0		0		0	
MUSCULO-SKELETAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	191	1	(<1%)	0.5340	2	0		2	(100%)	0		0	
, ,	≤49 Days (Group 1)	29	0			0	0		0		0		0	
	50-56 Days (Group 2)	73	- 1	(1%)		2	0		2	(100%)	0		0	
	57-63 Days (Group 3)	89	0			0	0		0		0		0	

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center {Safety Evaluable Patients}

Center: DEAN (#27)

	Gestational Age	Total Number	Num of		Fisher's exact	Number				Severit	y			
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unkı	nown
MUSCULO-SKELETAL SYSTEM DISORDERS	(cont.)													
MYALGIA	≤63 Days (All)	191	1	(<1%)	0.5340	2	0		2	(100%)	0		0	
	≰49 Days (Group 1)	29	0			0	0		0		0		0	
	50-56 Days (Group 2)	73	1	(1%)		2	0		2	(100%)	0		0	
	57-63 Days (Group 3)	89	0			0	0		0		0		0	
CENTR & PERIPH NERVOUS SYSTEM DISORDER	S													
ANY EVENT	. s63 Days (All)	191	33	(17%)	0.9010	49	14	(29%)	29	(59%)	5	(10%)	1	(2%)
	≤49 Days (Group 1)	29	5	(17%)		7	1	(14%)	6	(86%)	0		0	
	50 56 Days (Group 2)	73	14	(19%)		18	7	(39%)	9	(50%)	1	(6%)	1	(6%)
	57-63 Days (Group 3)	89	14	(16%)		24	6	(25%)	14	(58%)	4	(17%)	0	
DIZZINESS	≤63 Days (All)	191	10	(5%)	0.7536	11	2	(18%)	8	(73%)	1	(9%)	0	
	≰49 Days (Group 1)	29	1	(3%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	73	3	(4%)		3	1	(33%)	2	(67%)	0		0	
	57-63 Days (Group 3)	89	6	(7%)		7	1	(14%)	5	(71%)	1	(14%)	0	
HEADACHE	≤63 Days (All)	191	29	(15%)	0.8248	37	11	(30%)	21	(57%)	4	(11%)	1	(3%)
	≤49 Days (Group 1)	29	5	(17%)		6	1	(17%)	5	(83%)	0		0	
'	50-56 Days (Group 2)	73	12	(16%)		14	5	(36%)	7	(50%)	1	(7%)	1	(7%)
	57-63 Days (Group 3)	89	12	(13%)		17	5	(29%)	9	(53%)	3	(18%)	0	
MUSCLE CONTRACTIONS INVOLUNTARY	≤63 Days (All)	191	1	(<1%)	0.5340	1	1	(100%)	0		0		0	
** ** ** ** ** ** ** ** ** ** ** ** **	≤49 Days (Group 1)	29	0			0	0		` <sub>i</sub> 0		0		0	
* P • • "	50-56 Days (Group 2)	73	1	(1%)		• 1	1	(100≰)	i o	• •	0		0	
	57-63 Days (Group 3)	89	0			0	0	(	0	•	0		0	

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: DEAN (#27)

	Gestational	Total	Number	Fisher's					
	Age	Number	of Pts	exact	Number		Severit	y	
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
VISION DISORDERS		•							
ANY EVENT	≤63 Days (All)	191	1 (<1%)	0.1518	1	0	1 (100%)	0	0
	∡49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
MYDRIASIS	≤63 Days (All)	191	1 (<1%)	0.1518	1	0	1 (100%)	0	0
ı	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50 56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	0		. 0	0	0	0	0
SPECIAL SENSES OTHER, DISORDERS		,							
ANY EVENT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
TASTE PERVERSION	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
r '	50 56 Days (Group 2)	73	0		0	0	. 0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	. 0	1 (100%)	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	191	2 (1%)	0.6419	2	0	2 (1001)	0	0
and the second s	≰49 Days (Group 1)	29	0		. 0	0 j	0 .	0	0
•	50-56 Days (Group 2)	73	0		0	0	10.	0	0
	57-63 Days (Group 3)	89	2 (2%)		2	0 ′	2 (100%)	0	0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: DEAN (#27)

	Gestational Age	Total Number	Numb		Fisher's exact	Number				Severit	·v			
Body System/Event	Group [2]	of Pts		vent	p-value	of Events		.ld		rate	Sev			nown
PSYCHIATRIC DISORDERS	(cont.)													
ANOREXIA	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	29	0			0	0		0		0		0	
	50-56 Days (Group 2)	73	0			0	0		0		0		0	
	57-63 Days (Group 3)	89	1	(1%)		1	- 0		1	(100%)	0		0	
INSOMNIA	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		1	(100%)	0		0	
1	≤49 Days (Group 1)	29	0			0	0		0	,	0		0	
	50 56 Days (Group 2)	73	0			0	0		0		0		0	
	57-63 Days (Group 3)	89	1	(1%)		• 1	0		1	(100%)	0		0	
GASTRO-INTESTINAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	191	80	(42%)	0.9796	161	42	(26%)	74	(46%)	44	(27%)	1	(<1%)
	≤49 Days (Group 1)	29	12	(41%)		30	11	(37%)	15	(50%)	4	(13%)	0	
	50-56 Days (Group 2)	73	30	(41%)		57	12	(21%)	31	(54%)	14	(25%)	0	
	57-63 Days (Group 3)	89	38	(43%)		74	19	(26%)	28	(38%)	26	(35%)	1	(1%)
DIARRHEA	≤63 Days (All)	191	3	(2%)	0.1818	3	1	(33%)	1	(33%)	1	(33%)	0	
	≤49 Days (Group 1)	29	1	(3%)		1	1	(100%)	, 0		0		0	
,	50-56 Days (Group 2)	73	2	(3%)		2	0		1	(50%)	1	(50%)	0	
	57.63 Days (Group 3)	89	0			0	0		0		0		0	
DYSPEPSIA	≤63 Days (All)	191	1	(<1%)	0.5340	1	0		0		1	(100%)	0	
* * *	≤49 Days (Group 1)	29	0			0	0	**	• . 0	4.	0		0	
11 • • · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	. 73	1	(1%)		• 1	0	, <b>i</b>	, 0	• •	1	(100%)	0	
	57-63 Days (Group 3)	89	0			O	0	Ţ	0	•	0		0	

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: DEAN (#27)

	Gestational	Total	Number		Fisher's									
Parks Overhau /P	Age	Number	of Pts		exact					Severi	•			
Body System/Event	Group [2]	of Pts	w/Even	t	p value	of Events	Mi	ld	Mode	rate	Sev	ere 	Unk	nown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)													
FLATULENCE	≤63 Days (All)	191	2 (	1%)	0.6419	?	0		1	(50%)	0		1	(50%)
	≤49 Days (Group 1)	29	0			0	0		0		0		0	
	50-56 Days (Group 2)	73	0			0	0		0		0		0	
	57-63 Days (Group 3)	89 .	2 (	2%)		2	0		1	(50%)	0		1	(50%)
NAUSEA	≤63 Days (All)	191	66 (3	5%)	0.9566	99	33	(33%)	46	(46%)	20	(20%)	0	
1	≤49 Days (Group 1)	29	10 (3	41)		22	8	(36%)	12	(55%)	2	(9%)	0	
	50 56 Days (Group 2)	73	24 (3	3%)		33	9	(27%)	18	(55%)	6	(18%)	0	
	57-63 Days (Group 3)	89	32 (3	<b>6\$</b> )		44	16	(36%)	16	(36%)	12	(27%)	0	
VOMITING	≤63 Days (All)	191	38 (2	0%)	0.9103	56	8	(14%)	26	(46%)	22	(39%)	0	
	s49 Days (Group 1)	29	5 (1	7%)		7	2	(29%)	3	(43%)	2	(29%)	0	
	50-56 Days (Group 2)	73	14 (1	9%)		21	3	(14%)	12	(57%)	6	(29%)	0	
	57-63 Days (Group 3)	89	19 (2	1%)		28	3	(11%)	11	(39%)	14	(50%)	0	
RESPIRATORY SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	191	1 (<	1%)	0.1518	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	29	1 (	3%)		1	1	(100%)	0		0		0	
, ,	50-56 Days (Group 2)	73	0			0	0		0		0		0	
	57-63 Days (Group 3)	89	0			0	0		0		0		0	
DYSPNOEA	⊴63 Days (All)	191	1 (<	1%)	0.1518	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	29	1 (	3₹)		1	1	(100%)	0 -		0		0	
r in • ° · · <sup>a</sup>	50-56 Days (Group 2)	73	0			. 0	0		i. <b>0</b>	9. 1	0		0	
	57-63 Days (Group 3)	89	0			0	0	r	0	•	0		0	

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

 $<sup>\</sup>label{local_J:USA\166B\SASPGMS\apdxd\final\ade2.SAS 30NOV98:10:58} J:\USA\166B\SASPGMS\apdxd\final\ade2.SAS 30NOV98:10:58$ 

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#### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: DEAN (#27)

	Gestational	Total	Numbe		Fisher's								
Body System/Event	Age Group (2)	Number of Pts	of P		exact p-value	Number of Events		ld		Severit rate	Severe	Unkno	own
REPRODUCTIVE DISORDERS, FEMALE			*********		·····					<del></del> ~			
ANY EVENT	≤63 Days (All)	191	3	(2%)	0.0607	3	1	(33%)	1	(33%)	1 (33%)	0	
	≤49 Days (Group 1)	29	2	(7%)		2	1	(50%)	1	(50%)	0	0	
	50 56 Days (Group 2)	73	0			0	0		0		0	0	
	57-63 Days (Group 3)	89	1	(1%)		1	0		0		1 (100%)	0	
LEUKORRHOEA	≤63 Days (All)	191	1	(<1%)	0.1518	1	1	(100%)	0		0	0	
1	. ≤49 Days (Group 1)	29	1	(3%)		i.	1	(100%)	0		0	0	
	50-56 Days (Group 2)	73	0			0	0		0		0	0	
	57-63 Days (Group 3)	89	0			. 0	0		0		0	0	
UTERINE HAEMORRHAGE	s63 Days (All)	191	1	(<1%)	0.1518	1	0		1	(100%)	0	0	
	≤49 Days (Group 1)	29	1	(3%)		1	0		1	(100%)	0	0	
	50-56 Days (Group 2)	73	0			0	0		0		0	0	
	57-63 Days (Group 3)	89	0			0	0		0		0	0	
VAGINAL DISCOMFORT	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		0		1 (100%)	0	
	≤49 Days (Group 1)	29	0			0	0		0		0	0	
	50 56 Days (Group 2)	73	0			0	0		0		0	0	
· · · · · · · · · · · · · · · · · · ·	57 63 Days (Group 3)	89	1	(1%)		1	0		0		1 (100%)	0	
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	191	105	(55%)	0.7532	164	77	(47%)	60	(37%)	21 (13%)	6	(4%
$oldsymbol{\dot{oldsymbol{\psi}}}_{i,j}$	≰49 Days (Group 1)	29	18	(62%)		27	10	(37%)*	1 14		3 (11%)	0	
s produce a series of the seri	50-56 Days (Group 2)	73	39	(53%)		• 65	28	(43¥ <sup>ì</sup> )	26	(40%)	10 (15%)	1	(2%
·	57-63 Days (Group 3)	89	48	(54%)		72	39	(54%)	20	(28%)	8 (11%)	5	(7%

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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FINAL

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: DEAN (#27)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number				Severi	<b>-</b>			
Body System/Event	Group [2]	of Pts		Event	p value	of Events	Mi	.1d	Mod	erate	•	ere	Unkr	nown
BODY AS A WHOLE - GENERAL DISORDE	ERS (cont.)													· · · · · · · · · · · · · · · · · · ·
ABDOMINAL PAIN	≰63 Days (All)	191	103	(54%)	0.6419	147	71	(48%)	50	(34%)	20	(14%)	6	(4%)
	≤49 Days (Group 1)	29	18	(62%)		23	8	(35%)	12	(52%)	3	(13%)	0	
	50-56 Days (Group 2)	73	38	(52%)		58	27	(47%)	21	(36%)	9	(16%)	1	(2%)
	57-63 Days (Group 3)	89 .	47	(53%)		66	36	(55%)	17		8		5	(8%)
ASTHENIA	≤63 Days (All)	191	4	(2%)	0.8085	4	1	(25%)	3	(75%)	0		0	
1	≤49 Days (Group 1)	29	0			0	0		0		0		0	
	50-56 Days (Group 2)	73	1	(1%)		1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	89	3	(3%)		3	1	(33%)		(67%)	0		0	
BACK PAIN	s63 Days (All)	191	8	(4%)	0.0551	9	4	(44%)	4	(44%)	1	(11%)	0	
	≤49 Days (Group 1)	29	3	(10%)		3	2	(67%)	1	(33%)	0		0	
	50-56 Days (Group 2)	73	4	(5%)		5	1	(20%)	3	(60%)	1	(20%)	0	
	57 63 Days (Group 3)	89	1	(1%)		1	1	(100%)	0		0		0	
FATIGUE .	≤63 Days (All)	191	3	(2%)	0.5453	3	0		3	(100%)	0		0	
	≤49 Days (Group 1)	29	1	(3%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	73	1	(1%)		1	0		1	(100%)	0		0	
•	57 63 Days (Group 3)	89	1	(1%)		1	0		1	(100%)	0		0	
FEVER	≤63 Days (All)	191	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	29	0			0	0		0		0		0	
<b>4</b> .	50-56 Days (Group 2)	73	0			0	0	٠ - ٠	, 0	• !	0		0	
ene • • • • • • • • • • • • • • • • • •	57-63 Days (Group 3)	89	1	(1%)		; 1	1	(100%)	. 0	• !	0		0	

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: CREININ (#28)

	Gestational	Total		ber	Fisher's								
Body System/Event	Age Group [2]	Number of Pts		Pts vent	exact p-value	Number of Events		1 <b>d</b>		Severit rate	•	(13%) (22%) (15%)	Unknown
ANY EVENT	≤63 Days (All)	115	94		0.4921	216	110	(51%)	68		38		0
	≰49 Days (Group 1)	23	19	(83%)		46	24	(52%)	16	(35%)	6		0
	50-56 Days (Group 2)	50	43	(86%)		97	42	(43%)	34	(35%)	21		0
	57-63 Days (Group 3)	42 .	32	(76%)		73	44	(60%)	18	(25%)	11	(15%)	0
SKIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	115	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	s49 Days (Group 1)	23	0			0	0		0		0		0
	50-56 Days (Group 2)	50	1	(2%)		1	0		1	(100%)	0		0
	57 63 Days (Group 3)	42	0			0	0		0		0		0
SWEATING INCREASED	≤63 Days (All)	115	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	23	0			0	0		0		0		0
	50-56 Days (Group 2)	50	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	42	0			0	0		0		0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	115	21	(18%)	0.7389	25	15	(60%)	7	(28%)	3	(12%)	0
· · · · · · · · · · · · · · · · · · ·	≤49 Days (Group 1)	23	3	(13%)		3	3	(100%)	0		0		0
	50-56 Days (Group 2)	50	9			12	. 5	(42%)	5	(42%)	2	(17%)	0
	57-63 Days (Group 3)	42	9	(21%)		10	7	(70%)	2	(20%)	1		0
•	,												

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: CREININ (#28)

	Gestational Age	Total Number	Num of	ber Pts	Fisher's exact	Number		·	~ ~	Severi	ty	••••	
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events		114		erate		ere	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISORDER	S(cont.)				·			<del></del>	<del></del> -				
DIZZINESS	s63 Days (All)	115	7	(6%)	1.0000	7	6	(86%)	1	(14%)	0		0
	≤49 Days (Group 1)	23	1	(4%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	50	3	(6%)		3	3	(100%)	0		0		0
	57-63 Days (Group 3)	42	3	(7%)		3	2	(67%)	1	(33%)	0		0
HEADACHE	≤63 Days (All)	115	15	(13%)	0.8756	18	. 9	(50%)	6	(33%)	3	(17%)	0
	≤49 Days (Group 1)	23	2	(9%)		2	2	(100%)	0		0	(2:-/	0
•	50-56 Days (Group 2)	50	7			9	2	(22%)	5		2	(22%)	0
	57 63 Days (Group 3)	42	6	(14%)		7	5	(71%)		(14%)	_	(14%)	0
ASTRO-INTESTINAL SYSTEM DISORDERS						,							
ANY EVENT	≤63 Days (All)	115	49	(43%)	0.6670	72	31	(43%)	25	(35%)	16	(22%)	0
	s49 Days (Group 1)	23	11	(48%)		19	7	(37%)	8	-	4	(21%)	0
	50 56 Days (Group 2)	50	19	(38%)		28	11	(39%)	8		9	(32%)	0
	57-63 Days (Group 3)	42	19	(45%)		25	13	(52%)	9		3		0
CONSTIPATION	≤63 Days (All)	115	2	(2%)	1.0000	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	23	0	(20)	1.0000	0	0	(1000)	0		0		0
1	50-56 Days (Group 2)	50	1	(2%)		1	-	(100%)	. 0		0		0
	57-63 Days (Group 3)	42	1	(2%)		1		(100%)	0		0		0
DIARRHEA	≤63 Days (All)	115	7	(6%)	0.3142	10	6	(60%)	1	(30%)	1	(10%)	a
<del>4</del> ,	≤49 Days (Group 1)	23	3	(13%)	0.31 <b>.2</b>	4	3	(75%)		(25%)	0	(104)	0
	50-56 Days (Group 2)	50	2	(4%)		. 1	2	(50%)		(25%)	1	(25%)	0
	57-63 Days (Group 3)	42	2	(5%)		2	1	(50%)	i.	(50%)	0	(4.20)	0
	02 2212 (212mb 2)	••	~	(30)			_	(300)	1	1	J		v

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: CREININ (#28)

	Gestational	Total	Numl		Fisher's	••							
Body System/Event	Age Group [2]	Number of Pts	of w/E	vent	exact p-value	Number of Events		ld		Severit rate	Sev	ere	Unknown
JASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)		•					•					
DYSPEPSIA	≤63 Days (All)	115	2	(2%)	0.1699	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	23	0			0	0		0		0		0
	50-56 Days (Group 2)	50	0			0	0		0		0		0
	57-63 Days (Group 3)	42	2	(5%)		2	2	(100%)	0		0		0
NAUSEA	≤63 Days (All)	115	30	(26%)	0.7897	39	13	(33%)	15	(38%)	11	(28%)	0
•	≤49 Days (Group 1)	23	7	(30%)		12	3	(25%)	6	(50%)	3	(25%)	0
	50-56 Days (Group 2)	50	12	(24%)		14	4	(29%)	4	(29%)	6	(43%)	0
	57-63 Days (Group 3)	42	11	(26%)		13	6	(46%)	5	(38%)	2	(15%)	0
VOMITING	≤63 Days (All)	115	17	(15%)	0.7018	19	8	(42%)	7	(37%)	4	(21%)	0
	≤49 Days (Group 1)	23	2	(9%)		3	1	(33%)	1	(33%)	1	(33%)	0
	50-56 Days (Group 2)	50	8	(16%)		9	4	(44%)	3	(33%)	2	(22%)	0
	57-63 Days (Group 3)	42	7	(17%)		7	3	(43%)	3	(43%)	1	(14%)	0
EPRODUCTIVE DISÓRDERS, FEMALE													
ANY EVENT	≤63 Days (All)	115	1	(<1%)	1.0000	1	0		0		1	(100%)	0
, , , , , , , , , , , , , , , , , , , ,	≤49 Days (Group 1)	23	0			0	0		0		0		0
	50-56 Days (Group 2)	50	1	(2%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	42	0			0	0		0		0		0
UTERINE HAEMORRHAGE	≤63 Days (All)	115	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	23	0			0	0	. P*	• 0	4. !	0		0
* 1° •	50-56 Days (Group 2)	50	1	(2%)		1	0	j	; o		1	(100%)	0
	57-63 Days (Group 3)	42	0			0	0	ŗ	0	•	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: CREININ (#28)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severit	· v		
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	M:	ild	Mode	rate	•	ere	Unknown
BODY AS A WHOLE - GENERAL DISORDERS			~									
ANY EVENT	≤63 Days (All)	115	85 (74%)	0.4191	117	64	(55%)	35	(30%)	18	(15%)	0
	≰49 Days (Group 1)	23	16 (70%)		24	14	(58%)	8	(33%)	2	(8%)	0
	50-56 Days (Group 2)	50	40 (80%)		55	26	(47%)	20	(36%)	9	(16%)	0
	57-63 Days (Group 3)	42	29 (69%)		38	24	(63%)	7	(18%)	7	(18%)	0
ABDOMINAL PAIN	≤63 Days (All)	115	83 (72%)	0.4705	102	57	(56%)	29	(28%)	16	(16%)	0
1	≤49 Days (Group 1)	23	16 (70%)		19	10	(53%)	7	(37%)	2	(11%)	0
•	50-56 Days (Group 2)	50	39 (78%)		47	24	(51%)	15	(321)	8	(17%)	0
	57-63 Days (Group 3)	42	28 (67%)		.36	23	(64%)	7		6		0
BACK PAIN	≤63 Days (All)	115	9 (8%)	0.6621	9	4	(44%)	3	(33%)	2	(22%)	0
	≰49 Days (Group 1)	23	2 (9%)		2	2	(100%)	0		0		0
	50-56 Days (Group 2)	50	5 (10%)		5	1	(20%)	3	(60%)	1	(20%)	0
	57-63 Days (Group 3)	42	2 (5%)		2	1	(50%)	0		1	(50%)	0
FATIGUE .	≤63 Days (All)	115	3 (3%)	0.1479	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	23	2 (9%)		2	2	(100%)	0		0		0
	50 56 Days (Group 2)	50	1 (2%)		1	0		1	(100%)	0		0
,	57-63 Days (Group 3)	42	0		0	0		0		0		0
LEG PAIN	≤63 Days (All)	115	2 (2%)	0.4928	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	23	1 (4%)		1	0		1	(100%)	0		0
<del>,</del> , , , , , , , , , , , , , , , , , ,	50-56 Days (Group 2)	50	1 (2%)		1	0	. جر	. 1	(1001)	0		0
er en	57 63 Days (Group 3)	42	0		. 0	0				0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Mild	Severi	ty Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)	·	·						
SYNCOPE	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50 56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	n	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SOGOR (#29)

Group [2] 663 Days (All) 649 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)	of Pts		vent	p value	of Events	Mi		Mode	Severity				
49 Days (Group 1) 50-56 Days (Group 2)		56								Sev	ere	Unkı	nown
49 Days (Group 1) 50-56 Days (Group 2)			(66%)	0.9552	107	28	(26%)	50	(47%)	28	(251)		
50-56 Days (Group 2)	28		(64%)	0.3332	35	10	(29%)	18	(4/4) (51 <b>%</b> )		(26%) (17%)		(<1%
	37		(68%)		42	10	(24%)	16	(38%)	6		1	(3%
si sa saja (droup 3)	18		(67%)		30	8	(27%)	16	(53%)	16 6	(38%) (20%)	0	
63 Days (All)	83	9	(11%)	1.0000	9	3	(33%)		(44%)	2	(22%)	•	
49 Days (Group 1)	28		(11%)		3	1	(33%)	2		0	(221)	0	
0-56 Days (Group 2)	37		(11%)		4	2	(50%)	1	(25%)	1	(25%)	0	
57-63 Days (Group 3)	18		(11%)		2	0	(300)	1	(50%)	1		0	
63 Days (All)	83	5	(6%)	0.7091	5	2	(40%)	2	(40 <b>)</b> )	1	(201)	•	
49 Days (Group 1)	28	2	(7%)	*****			(100)			_	(20%)		
0-56 Days (Group 2)	37	3	(8%)		3		(67%)		(1004)	-	(225)	•	
7-63 Days (Group 3)	18	0			0	ō	(0,0)	ō		ō	(334)	0	
63 Days (All)	83	3	(4%)	1.0000	3	1	(33%)	2	(67%)	n		0	
:49 Days (Group 1)	28	1			1	-			(0,0)	-		Ū	
0-56 Days (Group 2)	37	1	(3%)		1		(1000)	-	(100%)	•		~	
7 63 Days (Group 3)	18	1	(6%)		1	o				0		0	
:63 Days (All)	83	1	(1%)	0.2169	1	n		0		,	(100%)	0	
49 Days (Group 1)	28	0	1								(1004)		
0-56 Days (Group 2)	37	0			=		• •		4. 1	-		0	
7-63 Days (Group 3)	18	1	(6%)		1	0		0.	• •	-	(100%)	0	
6 4 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	19 Days (Group 1) 19-56 Days (Group 2) 19-63 Days (Group 3) 19-56 Days (Group 1) 19-56 Days (Group 2) 19-56 Days (Group 3) 19-56 Days (Group 3) 19-56 Days (Group 1) 19-56 Days (Group 1) 19-56 Days (Group 2)	19 Days (Group 1) 28 2-56 Days (Group 2) 37 2-63 Days (Group 3) 18 3 Days (All) 83 3 Days (Group 1) 28 3 Days (Group 2) 37 2-63 Days (Group 2) 37 2-63 Days (Group 3) 18 3 Days (All) 83 3 Days (Group 1) 28 3 Days (Group 1) 28 3 Days (Group 1) 28 3 Days (Group 1) 37	19 Days (Group 1) 28 2 2-56 Days (Group 2) 37 3 3-63 Days (Group 3) 18 0 3 Days (All) 83 3 19 Days (Group 1) 28 1 2-56 Days (Group 2) 37 1 3 Days (Group 3) 18 1 3 Days (All) 83 1 3 Days (All) 83 1 3 Days (Group 1) 28 0 3 Days (Group 1) 28 0 3 Days (Group 2) 37 0	19 Days (Group 1) 28 2 (7%) 2-56 Days (Group 2) 37 3 (8%) 2-63 Days (Group 3) 18 0  33 Days (All) 83 3 (4%) 2-56 Days (Group 1) 28 1 (4%) 2-56 Days (Group 2) 37 1 (3%) 2-63 Days (Group 3) 18 1 (6%) 33 Days (All) 83 1 (1%) 39 Days (Group 1) 28 0 39-56 Days (Group 2) 37 0	19 Days (Group 1) 28 2 (7%) 2-56 Days (Group 2) 37 3 (8%) 2-63 Days (Group 3) 18 0  33 Days (All) 83 3 (4%) 1.0000 19 Days (Group 1) 28 1 (4%) 2-56 Days (Group 2) 37 1 (3%) 2-63 Days (Group 3) 18 1 (6%)  33 Days (All) 83 1 (1%) 0.2169 19 Days (Group 1) 28 0 1-56 Days (Group 2) 37 0	19 Days (Group 1) 28 2 (7%) 2 2-56 Days (Group 2) 37 3 (8%) 3 3 (5-63 Days (Group 3) 18 0 0  3 Days (All) 83 3 (4%) 1.0000 3 19 Days (Group 1) 28 1 (4%) 1 2-56 Days (Group 2) 37 1 (3%) 1 2-63 Days (Group 3) 18 1 (6%) 1  3 Days (All) 83 1 (1%) 0.2169 1 29 Days (Group 1) 28 0 0 2-56 Days (Group 2) 37 0	19 Days (Group 1) 28 2 (7%) 2 0 0-56 Days (Group 2) 37 3 (8%) 3 2 0-63 Days (Group 3) 18 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	19 Days (Group 1) 28 2 (7%) 2 0 2-56 Days (Group 2) 37 3 (8%) 3 2 (67%) 2-63 Days (Group 3) 18 0 0 0 33 Days (All) 83 3 (4%) 1.0000 3 1 (33%) 39 Days (Group 1) 28 1 (4%) 1 1 (100%) 30 Days (Group 2) 37 1 (3%) 1 0 31 Days (Group 3) 18 1 (6%) 1 0 31 Days (Group 3) 18 1 (1%) 0.2169 1 0 31 Days (Group 1) 28 0 0 0 0 32 Days (Group 1) 28 0 0 0 0 33 Days (Group 2) 37 0 0 0 0	19 Days (Group 1) 28 2 (7%) 2 0 2 2-56 Days (Group 2) 37 3 (8%) 3 2 (67%) 0 7-63 Days (Group 3) 18 0 0 0 0  33 Days (All) 83 3 (4%) 1.0000 3 1 (33%) 2 19 Days (Group 1) 28 1 (4%) 1 1 (100%) 0 1-56 Days (Group 2) 37 1 (3%) 1 0 1 1-63 Days (Group 3) 18 1 (6%) 1 0 1 1-63 Days (Group 1) 28 0 0 0 0 1-56 Days (Group 1) 28 0 0 0 0 1-56 Days (Group 2) 37 0 0 0 0 0 1-56 Days (Group 2) 37 0 0 0 0 0 1-56 Days (Group 2) 37 0 0 0 0 0 1-56 Days (Group 2) 37 0 0 0 0 0 0 1-56 Days (Group 2) 37 0 0 0 0 0 0	19 Days (Group 1) 28 2 (7%) 2 0 2 (100%) 19 Days (Group 2) 37 3 (8%) 3 2 (67%) 0 19 Days (Group 3) 18 0 0 0 0 19 Days (Group 3) 18 0 0 0 0 19 Days (Group 1) 28 1 (4%) 1 1 (100%) 0 19 Days (Group 2) 37 1 (3%) 1 0 1 (100%) 19 Days (Group 3) 18 1 (6%) 1 0 1 (100%) 19 Days (Group 3) 18 1 (1%) 0.2169 1 0 0 19 Days (Group 1) 28 0 0 0 0 0 19 Days (Group 2) 37 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	19 Days (Group 1) 28 2 (7%) 2 0 2 (100%) 0 1-56 Days (Group 2) 37 3 (8%) 3 2 (67%) 0 1 1 (63 Days (Group 3) 18 0 0 0 0 0 0 19 Days (Group 1) 28 1 (4%) 1 1 (100%) 0 0 19 Days (Group 2) 37 1 (3%) 1 0 1 (100%) 0 19 Days (Group 3) 18 1 (6%) 1 0 1 (100%) 0 19 Days (Group 3) 18 1 (6%) 1 0 1 (100%) 0 10 Days (Group 3) 18 1 (1%) 0.2169 1 0 0 1 (100%) 0 10 Days (Group 1) 28 0 0 0 0 0 0 0 0 0 10 Days (Group 2) 37 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	19 Days (Group 1) 28 2 (7%) 2 0 2 (100%) 0 10-56 Days (Group 2) 37 3 (8%) 3 2 (67%) 0 1 (33%) 163 Days (Group 3) 18 0 0 0 0 0 163 Days (Group 3) 18 0 0 0 0 0 17 G3 Days (Group 3) 18 0 0 0 0 0 0 18 Days (Group 1) 28 1 (4%) 1 1 (100%) 0 0 0 19 Days (Group 2) 37 1 (3%) 1 0 1 (100%) 0 0 19 Days (Group 3) 18 1 (6%) 1 0 1 (100%) 0 19 Days (Group 3) 18 1 (6%) 1 0 1 (100%) 0 19 Days (Group 3) 18 1 (1%) 0.2169 1 0 0 1 (100%) 19 Days (Group 1) 28 0 0 0 0 0 0 0 10 Days (Group 2) 37 0 0 0 0 0 0 0 0 0 0 10 Days (Group 2) 37 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	19 Days (Group 1)

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational	Total	Numb		Fisher's								
Body System/Event	Age Group [2]	Number of Pts	of F w/Ev		exact p-value	Number of Events		ild		Severi erate	•	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	83	30	(36%)	0.8737	48	11	(23%)	22	(46%)	15	(31%)	0
	≤49 Days (Group 1)	28		(32%)		13	3	(23%)	7	(54%)	3	(23%)	0
	50-56 Days (Group 2)	37		(38%)		20	3	(15%)	8		9	(45%)	0
	57-63 Days (Group 3)	18		(39%)		15	5	(33%)	7	(47%)	3		0
DIARRHEA	≤63 Days (All)	83	3	(4%)	1.0000	3	1	(33*)	2	(67%)	0		0
	≤49 Days (Group 1)	28	1	(4%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	37	1	(3%)		1	0		1	(100%)	0		0
	57 63 Days (Group 3)	18	1	(6%)		. 1	1	(100%)	0		0		0
NAUSEA	≤63 Days (All)	83	24	(29%)	0.9503	28	8	(29%)	13	(46%)	7	(25%)	0
	≤49 Days (Group 1)	28	9	(32%)		10	3	(30%)	5	(50%)	2	(20%)	0
	50-56 Days (Group 2)	37	10	(27%)		11	3	(27%)	4	(36%)	4	(36%)	0
	57 63 Days (Group 3)	18	5	(28%)		7	2	(29%)	4	(57%)	1	(14%)	0
VOMITING	≤63 Days (All)	83	14	(17%)	0.2069	17	2	(12%)	7	(41%)	8	(47%)	o
	≰49 Days (Group 1)	28	2	(7%)		2	0		1	(50%)	1	(50%)	0
	50 56 Days (Group 2)	37	8	(22%)		8	0		3	(38%)	5	(63%)	0
, ,	57-63 Days (Group 3)	18	4	(22%)		7	2	(29%)	3	(43%)	2	(29%)	0
HEART RATE AND RHYTHM DISORDERS													
ANY EVENT	≤63 Days (All)	83	1	(1%)	0.5542	1	0		1	(100%)	0		0
* , , , , , , , , , , , , , , , , , , ,	≤49 Days (Group 1)	28	1	(4%)		1	0		• 1	(100%)	0		0
Apr. ★**	50-56 Days (Group 2)	37	0			. 0	0	ji			0		0
·	57-63 Days (Group 3)	18	0			0	0	ċ	0	•	0		0

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristome.

Source Data: Appendix A.1, Table 25

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<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational	Total	Number	Fisher's									
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Even	exact p value	Number of Events		ild		Severi erate	•	лете		nown
HEART RATE AND RHYTHM DISORDERS	(cont.)												
TACHYCARDIA	≤63 Days (All)	83	1 (	.%) 0.5542	1	0		1	(100%)	0		0	
	s49 Days (Group 1)	28	1 (	. % )	1	0			(100%)	0		0	
	50-56 Days (Group 2)	37	0		0	0		0		0		0	
	57-63 Days (Group 3)	18 .	0		0	0		0		0		0	
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	83	42 (5	<b>%</b> ) 0.7469	49	14	(29%)	23	(47%)	11	(22%)	1	(2%)
	≤49 Days (Group 1)	28	15 (5	*)	18	6	(33%)	8	(448)	3	(17%)	1	(6%)
	50-56 Days (Group 2)	37	17 (4)	<b>(%)</b>	18	5	(28%)	7	(39%)	6	(33%)	0	
	57-63 Days (Group 3)	18	10 (5	*)	13	3	(23%)	8	(62%)	2	(15%)	0	
ABDOMINAL PAIN	≤63 Days (All)	83	42 (5)	<b>%</b> ) 0.7469	46	14	(30%)	20	(43%)	11	(24%)	1	(2%)
	≤49 Days (Group 1)	28	15 (54	<b>%</b> )	17	6	(35%)	7	(41%)	3	(18%)	1	(6%)
	50-56 Days (Group 2)	37	17 (46	<b>%</b> )	18	5	(28%)	7	(39%)	6	(33%)	0	
	57-63 Days (Group 3)	18	10 (5	<b>(%)</b>	11	3	(27%)	6	(55%)	2	(18%)	0	
BACK PAIN	≤63 Days (All)	83	1 (	<b>%</b> ) 0.2169	1	o		1	(100%)	0		0	
	≤49 Days (Group 1)	28	0		0	0		0		0		0	
r · · ·	50-56 Days (Group 2)	37	0		0	0		0		0		0	
	57-63 Days (Group 3)	18	1 (6	*)	1	0		1	(100%)	0		0	
CHEST PAIN	<b>±63 Days (All)</b>	83	1 (:	<b>%</b> ) 0.2169	1	0		1	(100%)	0		0	
<b>4</b> . ,	≤49 Days (Group 1)	28	0		0	0	,,•	, 0	1	0		0	
	50-56 Days (Group 2)	37	0		0	0	j	i. o	4. !	0		0	
•	57-63 Days (Group 3)	18	1 (6	<b>*</b> )	1	0	,	1	(100%)	0		0	

<sup>[1]</sup> Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Source Data: Appendix A.1, Table 25

<sup>[2]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severit	:y	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
FEVER	≤63 Days (All)	83	1 (14	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (41	)	1	0	1 (100%)	0	0
	50 56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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## Appendix D, Table 5c Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number	<b>-</b>	<b></b>		Severit	: <b>v</b>		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events		ld		erate	•	ere	Unknow
ANY EVENT	≤63 Days (All)	71	61	(86%)	0.5665	213	76	(36%)	109	(51%)	28	(13%)	0
	s49 Days (Group 1)	28	24	(86%)	0.3003	64	24	(38%)	38		28	(3%)	0
	50 56 Days (Group 2)	26	21			73	22	(30%)	34		17	(23%)	0
	57-63 Days (Group 3)	17	16	(94%)		76	30	(39%)	37		9		0
KIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	71	1	(1%)	0.2394	1	0		1	(100%)	n		0
	s49 Days (Group 1)	28	0			0	ō		0	(1000)	n		0
	50-56 Days (Group 2)	26	0			0	0		0		0		0
	57-63 Days (Group 3)	17	1	(6%)		1	0		1	(100%)	0		0
SWEATING INCREASED	≤63 Days (All)	71	1	(1%)	0.2394	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	28	0	,		0	ō		0	(1001)	0		0
	50-56 Days (Group 2)	26	0			0	o		n		ň		0
	57-63 Days (Group 3)	17	1	(6%)		1	0		1	(100%)	0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	71	14	(20%)	0.3532	21	7	(33%)	11	(52%)	3	(14%)	0
(	≤49 Days (Group 1)	28	6		<b></b>	6	2	(33%)	4	(67%)	0	(111)	0
	50-56 Days (Group 2)	26	3			4	0	, , , , ,	2	(50%)	2	(50%)	0
	57-63 Days (Group 3)	17	5			11	5	(45%)	5		1	(9%)	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational	Total	Numb		Fisher's	••				<b>~</b>			
Body System/Event [2]	Age Group [3]	Number of Pts	of P w/Ev		exact p-value	Number of Events		ild		Severit erate	•	ere	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISORDERS (co.	nt.)												
HEADACHE	≤63 Days (All)	71	14	(20%)	0.3532	20	7	(35%)	10	(50%)	3	(15%)	0
	≤49 Days (Group 1)	28	6	(21%)		6	2	(33%)	4	(67%)	0		0
	50-56 Days (Group 2)	26	3	(12%)		4	0		2	(50%)	2	(50%)	0
	57-63 Days (Group 3)	17	5	(29%)		10	. 5	(50%)	4	(40%)	1	(10%)	0
MIGRAINE	≤63 Days (All)	71	1	(1%)	0.2394	1	0		1	(100%)	0		0
The state of the s	≤49 Days (Group 1)	28	0			0	0		0		0		0
	50-56 Days (Group 2)	26	0			0	0		0	·	0		0
	57-63 Days (Group 3)	17	1	(6%)		. 1	0		1	(100%)	0		0
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	71	35	(49%)	0.7211	66	23	(35%)	31	(47%)	12	(18%)	0
	s49 Days (Group 1)	28	12	(43%)		14	6	(43%)	7	(50%)	1	(7%)	0
	50-56 Days (Group 2)	26	14	(54%)		28	7	(25%)	13	(46%)	8	(29%)	0
	57-63 Days (Group 3)	17	9	(53%)		24	10	(42%)	11	(46%)	3	(13%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≰63 Days (All)	71	1	(1%)	1.0000	1	1	(100%)	0		0		0
	≰49 Days (Group 1)	28	1	(4%)		1	1	(100%)	0		0		0
r '	50-56 Days (Group 2)	26	0			0	0		0		0		0
	57-63 Days (Group 3)	17	0			O	0		0		0		0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p∙value	Number of Events	Mild	Moderate	Severe	Unknow
GASTRO-INTESTINAL SYSTEM DISORDERS (	cont.)								
DIARRHEA	≤63 Days (All)	71	6 (8	b) 0.5594	6	3 (50%)	3 (50%)	0	0
	≤49 Days (Group 1)	28	1 (4	<b>b</b> )	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	26	3 (12	<b>b</b> )	3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	17	2 (12	<b>b</b> )	2	1 (50%)	1 (50%)	0	0
DYSPEPSIA	≤63 Days (All)	71	2 (3	<b>b</b> ) 0.5155	2	1 (50%)	0	1 (50%)	0
i .	≤49 Days (Group 1)	28	0		0	0	<b>o</b> .	0	0
	50-56 Days (Group 2)	26	1 (4	<b>b</b> )	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	17	1 (6	<b>k</b> )	1	1 (100%)	0	0	0
NAUSEA	≤63 Days (All)	71	27 (38	0.7787	34	11 (32%)	15 (44%)	8 (24%)	0
	s49 Days (Group 1)	28	9 (32	<b>t</b> )	9	3 (33%)	5 (56%)	1 (11%)	0
	50-56 Days (Group 2)	26	11 (42	<b>k</b> )	14	4 (29%)	5 (36%)	5 (36%)	0
	57-63 Days (Group 3)	17	7 (41	<b>b</b> )	11	4 (36%)	5 (45%)	2 (18%)	0
VOMITING	s63 Days (All)	71	16 (23	0.1143	23	7 (30%)	13 (57%)	3 (13%)	0
	≤49 Days (Group 1)	28	3 (11	<b>b</b> )	3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	26	7 (27	<b>t</b> )	10	2 (20%)	6 (60%)	2 (20%)	0
•	57-63 Days (Group 3)	17	6 (35	<b>b</b> )	10	4 (40%)	5 (50%)	1 (10%)	0
PLATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	71	1 (1	1.0000	1	0	1 (100%)	0	0
<i>•</i>	≤49 Days (Group 1)	28	1 (4	<b>t</b> )	. 1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	0		• 0	o .i	0	0	0
· ·	57-63 Days (Group 3)	17 -	0		0	0	0 1	0	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography. Source Data: Appendix A.1, Tables 16 and 25

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Severit Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISC	Phene (cont.)					<del></del>		<del></del>	
EPISTAXIS	≤63 Days (All)	71	1 (1	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4		1	0	1 (100%)		0
	50-56 Days (Group 2)	26	0	,	0	0	0	0	0
	57-63 Days (Group 3)	17 .	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	71	2 (3	) 1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	28	1 (4	:)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	1. (4	)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	71	1 (1	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	28	1 (4	)	1	0	1 (100%)	0	0
	50 56 Days (Group 2)	26	0		0	0	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	71	1 (1	) 0.6056	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	28	0		0	0	0	0	0
· · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	26	1 (4	)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	17	0		0	0	0	0 0 0 0 0 1 (50%) 0 1 (100%) 0 0	0

<sup>[1]</sup> Includes nausea, womiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] Py Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pt		Fisher's exact	Number				Severit	.y		
Body System/Event [2]	Group [3]	of Pts	w/Eve	ent	p-value	of Events	Mi	ild	Mode	rate	Sev	ere	Unknow
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	71	59	(83%)	0.6130	122	46	(38%)	64	(52%)	12	(10%)	0
	≰49 Days (Group 1)	28	24	(86%)		42	16	(38%)	25	(60%)	1	(2%)	0
	50-56 Days (Group 2)	26	20	(77%)		40	15	(38%)	19	(48%)	6	(15%)	0
	57-63 Days (Group 3)	17	15	(88%)		40	15	(38%)	20	(50%)	5	(13%)	0
ABDOMINAL PAIN	≤63 Days (All)	71	59	(83%)	0.6130	115	42	(37%)	63	(55%)	10	(9%)	0
1	≤49 Days (Group 1)	28	24	(86%)		39	14	(36%)	24	(62%)	1	(3%)	0
	50-56 Days (Group 2)	26	20	(77%)		38	14	(37%)	19	(50%)	5	(13%)	0
	57-63 Days (Group 3)	17	15	(88%)		38	14	(37%)	20	(53%)	4	(11%)	0
ASTHENIA	≤63 Days (All)	71	1	(1%)	0.2394	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	28	0			0	0		0		0		0
	50-56 Days (Group 2)	26	0			0	0		0		0		0
	57-63 Days (Group 3)	17	1	(6%)		1	1	(100%)	0		0		0
BACK PAIN	s63 Days (All)	71	5	(7%)	0.8396	5	3	(60%)	1	(20%)	1	(20%)	0
	≰49 Days (Group 1)	28	3	(11%)		3	2	(67%)	1	(33%)	0		0
	50-56 Days (Group 2)	26	1	(4%)		1	1	(100%)	. 0		0		0
	57-63 Days (Group 3)	17	1	(6%)		1	0		0		1	(100%)	0
RIGORS	≤63 Days (All)	71	1	(1%)	0.6056	1	0		0		1	(100%)	0
<del>1</del> .	\$49 Days (Group 1)	28	0			0	0		0 -		0		0
	50-56 Days (Group 2)	26	1	(4%)		1	0		լ 0	4. !	1	(100%)	0
•	57-63 Days (Group 3)	17	0			• 0	0	•	0	•	0		0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number				Severi	tv		
Body System/Event [2]	~		Event	p value	of Events		ld		rate	-	ere	Unknown	
ANY EVENT	≤63 Days (All)	151	137	(91%)	0.1814	513	162	(32%)	201	(39%)	150	(29%)	0
	≤49 Days (Group 1)	70	60	(86%)	0.1014	187	59	(32*)	82	(44%)	46	(25%)	0
	50-56 Days (Group 2)	43	41	(95%)		174	58	(33%)	64	(37%)	52	(30%)	0
	57-63 Days (Group 3)	38	36	(95%)		152	45	(30%)	55	(36%)	52	(34%)	ő
SKIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	151	1	(<1%)	0.5364	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	70	0			0	0		0	1	0		0
	50-56 Days (Group 2)	43	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
RASH	≤63 Days (All)	151	1	(<1%)	0.5364	1	1	(100%)	0		0		o
	≤49 Days (Group 1)	70	0			0	0		0		0		0
	50 56 Days (Group 2)	43	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
MUSCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0		0
1	≤49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	43	0			Э	. 0		0		0		0
•	57-63 Days (Group 3)	38	1	(3%)		1	0		1	(100%)	0		0
Ť	•												

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table Sc (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number -				Severit	·V		
Body System/Event [2]	Group [3]	of Pts	w/Ever		p-value	of Events		1 <b>d</b>		erate	-	еге	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS	(cont.)												
MYALGIA	≤63 Days (All)	151	1 (	<1%)	0.2517	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	43	0			0	0		0		0		0
	57-63 Days (Group 3)	38	1	(3%)		1	. 0		1	(100%)	0		0
ENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS												
ANY EVENT	≤63 Days (All)	151	29 (1	19%)	0.0650	37	9	(24%)	25	(68%)	3	(88)	0
	s49 Days (Group 1)	70	8 (1	11%)		11	2	(18%)	8	(73%)	1	(9%)	0
	50-56 Days (Group 2)	43	11 (2	26%)		- 13	6	(46%)	7	(54%)	0		0
	57-63 Days (Group 3)	38	10 (	26%)		13	1	(8%)	10	(77%)	2	(15%)	0
DIZZINESS	s63 Days (All)	151	11	(7%)	0.8507	13	4	(31%)	9	(69%)	0		0
	≰49 Days (Group 1)	70	5	(7%)		7	2	(29%)	5	(71%)	0		0
	50-56 Days (Group 2)	43	4	(9%)		4	2	(50%)	2	(50%)	0		0
	57-63 Days (Group 3)	38	2	(5%)		2	0		2	(100%)	0		0
HEADACHE	≤63 Days (All)	151	20 (1	13%)	0.0182	24	5	(21%)	16	(67%)	3	(13%)	0
	≤49 Days (Group 1)	70	4	(6%)		4	0		3	(75%)	1	(25%)	0
· '	50-56 Days (Group 2)	43	7 (1	16%)		9	4	(44%)	5	(56%)	0		0
	57-63 Days (Group 3)	38	9 (2	24%)		11	1	(9%)	8	(73%)	2	(18%)	0
		1											

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severit	: <b>v</b>	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
VISION DISORDERS					***************************************				
ANY EVENT	≰63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	70	0		0	0	0	n	n
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	o	0	0
	57-63 Days (Group 3)	38	0		0	0	0	ō	0
VISION ABNORMAL	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	70	0		0	0	o ·	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
ASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	151	99 (66%)	0.0669	211	93 (44%)	76 (36%)	42 (20%)	0
	s49 Days (Group 1)	70	39 (56%)		76	31 (41%)	33 (43%)	12 (16%)	0
1	50-56 Days (Group 2)	43	32 (74%)		72	33 (46%)	23 (32%)	16 (22%)	0
	57-63 Days (Group 3)	38	28 (74%)		63	29 (46%)	20 (32%)	14 (22%)	0
CONSTIPATION	≤63 Days (All)	151	1 (<1%)	0.5364	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	70	0		ō	ō	. 0	0	0
	50 56 Days (Group 2)	43	1 (2%)		1	ñ	1 (100%)	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
•	•								

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational	Total	Number	Fisher's					_			
Body System/Event [2]		Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mi		Mode	Severi rate	•	ere	Unknown
	· · · · · · · · · · · · · · · · · · ·				<del></del>		·					<del></del>
JASTRO-INTESTINAL SYSTEM DISORDERS DIARRHEA	(cont.)	151	47 (31%)	0.2075	65	33	/6161	2.2	(35%)	0	(14%)	0
DIARRHEA	s63 Days (All)	151		0.2075			(51%)	23 9				
	≤49 Days (Group 1)	70	17 (24%)		23	11	(48%)		,	3		0
	50-56 Days (Group 2)	43	17 (40%)		22	10	(45%)		(41%)		(14%)	0
	57-63 Days (Group 3)	38	13 (34%)		20	12	(60≹)	5	(25%)	3	(15%)	0
NAUSEA	≤63 Days (All)	151	80 (53%)	0.2462	95	44	(46%)	33	(35%)	18	(19%)	0
ı	<pre>\$49 Days (Group 1)</pre>	70	32 (46%)		36	16	(44%)	15	(42%)	5	(14%)	0
	50-56 Days (Group 2)	43	26 (60%)		32	16	(50%)	10	(31%)	6	(19%)	0
	57-63 Days (Group 3)	38	22 (58%)		27	12	(44%)	8	(30%)	7	(26%)	0
VOMITING	≤63 Days (All)	151	43 (28%)	0.1960	50	16	(32%)	19	(38%)	15	(30%)	0
	≤49 Days (Group 1)	70	15 (21%)		17	4	(24%)	9	(53%)	4	(24%)	0
	50-56 Days (Group 2)	43	15 (35%)		17	7	(41%)	3	(18%)	7	(41%)	0
	57-63 Days (Group 3)	38	13 (34%)		16	5	(31%)	7	(44%)	4	(25%)	0
METABOLIC AND NUTRITIONAL DISORDERS												
ANY EVENT	≤63 Days (All)	151	1 (<1%)	0.2517	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	70	0		0	0		0		0		0
•	50-56 Days (Group 2)	43	0		0	0		0		0		0
	57-63 Days (Group 3)	38	1 (3%)		1	1	(100%)	0		0		0
•												

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational Age	Total Number	Number	Fisher's					
Body System/Event [2]	_	of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS	(cont.)								
DEHYDRATION	≤63 Days (All)	151	1 (<1%)	0.2517	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	70	0		0	0	0	0	0
	50 56 Days (Group 2)	43	0		Ô	0	0	0	0
	57-63 Days (Group 3)	38 ·	1 (3%)		1	1 (100%)	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	s63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0 (	0	0
	≤49 Days (Group 1)	70	0		0	0	0	0	ō
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	Ö	o o	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
MICTURITION DISORDER	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0		
	≤49 Days (Group 1)	70	0	0.3304	0	0	0	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
•	•		-		ŭ	Ü	U	U	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	151	7 (5%)	1.0000	7	1 (14%)	2 (29%)	4 (57%)	0
t .	≤49 Days (Group 1)	70	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	43	2 (5%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	38	2 (5%)		2	o	0	2 (100%)	0
4,	•								

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational	Total	Number	Fisher's				<b>.</b>	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknowr
REPRODUCTIVE DISORDERS, FEMALE	(cont.)				VA				
LEUKORRHOEA	≤63 Days (All)	151	1 (<19	) 1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	70	1 (19	)	1	1 (100%)	0	0	0
	50 56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38 ·	0		0	0	0	0	0
UTERINE HAEMORRHAGE	s63 Days (All)	151	5 (31	) 0.7184	5	0	1 (20%)	4 (80%)	0
1	. ≤49 Days (Group 1)	70	2 (31	)	2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	43	1 (21	}	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	. 38	2 (51	)	2	0	0	2 (100%)	0
VAGINITIS	≤63 Days (All)	151	1 (<18	0.5364	1	0	1 (100%)	o	0
	≰49 Days (Group 1)	70	0		0	0	0	0	0
	50-56 Days (Group 2)	43	1 (21	)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	151	137 (91	0.1814	253	55 (22%)	97 (38%)	101 (40%)	0
,	≤49 Days (Group 1)	70	60 (861	)	97	25 (26%)	40 (41%)	32 (33%)	0
•	50-56 Days (Group 2)	43	41 (951	)	84	16 (19%)	33 (39%)	35 (42%)	0
	57 63 Days (Group 3)	38	36 (951	)	72	14 (19%)	24 (33%)	34 (47%)	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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# Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational	Total	Numbe		Fisher's	N				Council				
Body System/Event [2]	3.	3		Number of Pts of Pts w/Event		exact p-value	Number of Events		ld		erate	Sev		Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)													
ABDOMINAL PAIN	≤63 Days (All)	151	137	(91%)	0.1814	236	47	(20%)	88	(37%)	101	(43%)	0	
	≰49 Days (Group 1)	70	60	(86%)		94	24	(26%)	38	(40%)	32	(34%)	0	
	50-56 Days (Group 2)	43	41	(95%)		74	11	(15%)	28	(38%)	35	(47%)	0	
	57 63 Days (Group 3)	38	36	(95%)		68	12	(18%)	22	(32%)	34	(50%)	0	
BACK PAIN	≤63 Days (All)	151	6	(4%)	0.5591	7	3	(43%)	4	(57%)	0		0	
1	s49 Days (Group 1)	70	2	(3%)		2	1	(50%)	1	(50%)	0		0	
	50-56 Days (Group 2)	43	3	(7%)		4	2	(50%)	2	(5 <b>0</b> %)	0		0	
	57-63 Days (Group 3)	38	1	(3%)		_ 1	0		1	(100%)	0		0	
FATIGUE	≤63 Days (All)	151	2	(1%)	0.1418	2	0		2	(100%)	0		0	
	≤49 Days (Group 1)	70	0			0	0		0		0		0	
	50-56 Days (Group 2)	43	2	(5%)		2	0		2	(100%)	0		0	
	57-63 Days (Group 3)	38	0			0	0		0		0		0	
FEVER	≤63 Days (All)	151	2	(1%)	0.2861	2	2	(100%)	0		0		0	
	≤49 Days (Group 1)	70	0			0	0		0		0		0	
,	50-56 Days (Group 2)	43	1	(2%)		1	1	(100%)	0		0		0	
'	57-63 Days (Group 3)	38	1	(3%)		1	1	(100%)	0		0		0	
LEG PAIN	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0		0	
•	≰49 Days (Group 1)	70	0			0	0		0		0		0	
7.	50-56 Days (Group 2)	43	0			0	0	٠.	, 0	9. 1	0		0	
• • • •	57-63 Days (Group 3)	38	1	(3%)		, 1	0	į	1	(ipo*)	0		0	

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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### Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	•		Severit	_y	
Body System/Event [2]	Group [3]	of Pts	w/Eve	ent	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)									
RIGORS	≤63 Days (All)	151	3	(2%)	0.1517	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	70	0			0	0	0	0	0
	50-56 Days (Group 2)	43	2	(5%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	38	1	(3%)		1	1 (100%)	0	0	0
SYNCOPE	s63 Days (All)	151	2	(1%)	1.0000	2	1 (50%)	1 (50%)	0	0
T.	≤49 Days (Group 1)	70	1	(1%)		1	0	1 (10.0%)	0	0
	50-56 Days (Group 2)	43	1	(2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0			0	0	0	0	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational 'age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center:

	Gestational	Total	Number	Fisher's								
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mi			Severi erate	•	ere	Unknown
					··							
ANY EVENT	≤63 Days (All)	89	88 (99%)	1.0000	505	165	(33%)	204	(40%)	135	(27%)	1 (<13
	≤49 Days (Group 1)	35	34 (97%)		175	59	(34%)	66	(38%)	49	(28%)	1 (<19
	50-56 Days (Group 2)	34	34 (100%)		210	67	(32%)	91	(43%)	52	(25%)	0
	57-63 Days (Group 3)	20 .	20 (100%)		120	39	(33%)	47	(39%)	34	(28%)	0
SKIN AND APPENDAGES DISORDERS												
ANY EVENT	≤63 Days (All)	89	1 (1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	0		0	1	1	(100%)	0
	50-56 Days (Group 2)	34	0		0	0		0		0		0
	57-63 Days (Group 3)	20	0		0	0		0		0		0
SWEATING INCREASED	≤63 Days (All)	89	1 (1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	34	0		0	0		0		0		0
!	57-63 Days (Group 3)	20	Ó		0	0		0		0		0
MUSCULO-SKELETAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	89	1 (1%)	0.6067	1	0		0		1	(100%)	0
1	≤49 Days (Group 1)	35	0		0	0		0		0		0
	50-56 Days (Group 2)	34	1 (3%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	20	0		0	0		0		0		0
,												

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center:

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severit	v		
Body System/Event [2]	Group [3]	of Pts		vent	p value	of Events	Mild		Moderate		•	ere	Unknown
USCULO-SKELETAL SYSTEM DISORDERS	(cont.)									<del></del>			
MYALGIA	≤63 Days (All)	89	1	(1%)	0.6067	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
ENTR & PERIPH NERVOUS SYSTEM DISOR	DERS												
ANY EVENT	≤63 Days (All)	89	33	(37%)	0.3615	61	15	(25%)	30	(49%)	16	(26%)	0
	≤49 Days (Group 1)	35	11	(31%)		17	3	(18%)	10	(59%)	4	(24%)	0
	50-56 Days (Group 2)	34	12	(35%)		19	7	(37%)	7	(37%)	5	(26%)	0
	57-63 Days (Group 3)	20	10	(50%)		25	5	(20%)	13	(52%)	7	(28%)	0
DIZZINESS	≤63 Days (All)	89	13	(15%)	0.5865	17	5	(29%)	4	(24%)	8	(47%)	0
	≤49 Days (Group 1)	35	7	(20%)		8	2	(25%)	2	(25%)	4	(50%)	0
	50-56 Days (Group 2)	34	4	(12%)		5	2	(40%)	2	(40%)	1	(20%)	0
	57-63 Days (Group 3)	20	2	(10%)		4	1	(25%)	0		3	(75%)	0
HEADACHE	≤63 Days (All)	89	24	(27%)	0.0079	44	10	(23%)	26	(59%)	8	(18%)	0
· · · · · · · · · · · · · · · · · · ·	≤49 Days (Group 1)	35	4	(11%)		9	1	(11%)	8	(89%)	0		0
	50-56 Days (Group 2)	34	10	(29%)		14	5	(36%)	5	(36%)	4	(29%)	0
	57-63 Days (Group 3)	20	10	(50%)		21	4	(19%)	13	(62%)	4	(19%)	0

<sup>[1]</sup> Includes naugea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Center:

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#### Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

	Gestational Age	Total Number	Number of Pt		Fisher's exact	Number		Severit	; <b>y</b>	
Body System/Event [2]	Group [3]	of Pts	w/Eve	ent	p-value	of Events	Mild	Moderate	Severe	Unknown
VISION DISORDERS										
ANY EVENT	≤63 Days (All)	89	1 .	(1%)	0.6067	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	0			0	0	0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
BLEPHARITIS	≤63 Days (All)	89	1	(1%)	0.6067	1	0	1 (100%)	0	0
•	. ≤49 Days (Group 1)	35	0			0	0	ο .	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	20	0			- 0	0	0	0	0
SYCHIATRIC DISORDERS										
ANY EVENT	≤63 Days (All)	89	5	(6%)	1.0000	6	3 (50%)	1 (17%)	2 (33%)	0
	≤49 Days (Group 1)	35	2	(6%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	34	2	(6%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	20	1	(5%)		1	1 (100%)	0	0	0
ANOREXIA	≤63 Days (All)	89	2	(2%)	0.6961	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	35	1	(3%)		1	1 (100%)	0	0	0

(5%)

1 (100%)

34

20

50-56 Days (Group 2)

57-63 Days (Group 3)

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all'events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

~			
Cen	٠	PT	

Age Group [3]	Number of Pts		Pts	exact	Number				Severit	v		
		w/E	vent	p-value	of Events			Moderate		Severe		Unknown
ont.)					,							
≤63 Days (All)	89	3	(3%)	0.6123	4	1	(25%)	1	(25%)	2	(50%)	0
≤49 Days (Group 1)	35	1	(3%)		1	0		0		1	(100%)	0
	34	2	(6%)		3	1	(33%)	1	(33%)	1	(33%)	0
57-63 Days (Group 3)	20	0			0	0		0		0		0
s63 Days (All)	89	57	(64%)	0.5184	126	42	(33%)	62	(49%)	22	(17%)	0
s49 Days (Group 1)	35	22	(63%)		40	11	(28%)	17	(43%)	12	(30%)	0
50-56 Days (Group 2)	34	24	(71%)		56	18	(32%)	32	(57%)	6	(11%)	0
57-63 Days (Group 3)	20	11	(55%)		30	13	(43%)	13	(43%)	4	(13%)	0
s63 Days (All)	89	1	(1%)	0.2247	1	0		0		1	(100%)	0
≰49 Days (Group 1)	35	0			0	0		0		0		0
50-56 Days (Group 2)	34	0			0	0		0		0		0
57-63 Days (Group 3)	20	1	(5%)		1	0		0		1	(100%)	0
≤63 Days (All)	89	24	(27%)	0.7512	30	13	(43%)	13	(43%)	4	(13%)	0
≤49 Days (Group 1)	35	10	(29%)		12	7	(58%)	4	(33*)	1	(8%)	0
50-56 Days (Group 2)	34	10	(29%)		13	5	(38%)	7	(54%)	1	(8%)	0
57-63 Days (Group 3)	20	4	(20%)		5	1	(20%)	2	(40%)	2	(40%)	0
	<pre>*49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  *63 Days (All) *49 Days (Group 1) 50-56 Days (Group 3)  *63 Days (All) *49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  *63 Days (Group 3)  *64 Days (Group 3)</pre> *65 Days (Group 3)	\$49 Days (Group 1) 35 50-56 Days (Group 2) 34 57-63 Days (Group 3) 20  \$63 Days (All) 89 \$49 Days (Group 1) 35 50-56 Days (Group 2) 34 57-63 Days (Group 3) 20  \$63 Days (All) 89 \$49 Days (Group 1) 35 50-56 Days (Group 2) 34 57-63 Days (Group 3) 20  \$63 Days (Group 1) 35 50-56 Days (Group 3) 20  \$63 Days (All) 89 \$49 Days (Group 1) 35 50-56 Days (Group 2) 34 57-63 Days (Group 1) 35 50-56 Days (Group 1) 35 50-56 Days (Group 2) 34 57-63 Days (Group 3) 20	\$49 Days (Group 1) 35 1 50-56 Days (Group 2) 34 2 57-63 Days (Group 3) 20 0  \$63 Days (All) 89 57 \$49 Days (Group 1) 35 22 50-56 Days (Group 2) 34 24 57-63 Days (Group 3) 20 11  \$63 Days (All) 89 1 \$49 Days (Group 1) 35 0 50-56 Days (Group 1) 35 0 57-63 Days (Group 2) 34 0 57-63 Days (Group 3) 20 1  \$63 Days (Group 1) 35 10 50-56 Days (Group 1) 35 10 50-56 Days (Group 1) 35 10 50-56 Days (Group 2) 34 10 57-63 Days (Group 2) 34 10 57-63 Days (Group 3) 20 4	\$49 Days (Group 1)       35       1 (3%)         50-56 Days (Group 2)       34       2 (6%)         57-63 Days (Group 3)       20       0         \$63 Days (All)       89       57 (64%)         \$49 Days (Group 1)       35       22 (63%)         50-56 Days (Group 2)       34       24 (71%)         57-63 Days (Group 3)       20       11 (55%)         \$63 Days (All)       89       1 (1%)         \$49 Days (Group 1)       35       0         50-56 Days (Group 2)       34       0         57-63 Days (Group 3)       20       1 (5%)         \$63 Days (All)       89       24 (27%)         \$49 Days (Group 1)       35       10 (29%)         50-56 Days (Group 2)       34       10 (29%)         50-56 Days (Group 3)       20       4 (20%)	\$49 Days (Group 1)       35       1 (3%)         50-56 Days (Group 2)       34       2 (6%)         57-63 Days (Group 3)       20       0         \$63 Days (All)       89       57 (64%)       0.5184         \$49 Days (Group 1)       35       22 (63%)         50-56 Days (Group 2)       34       24 (71%)         57-63 Days (Group 3)       20       11 (55%)         \$63 Days (All)       89       1 (1%)       0.2247         \$49 Days (Group 1)       35       0         57-63 Days (Group 3)       20       1 (5%)         \$63 Days (All)       89       24 (27%)       0.7512         \$49 Days (Group 1)       35       10 (29%)         50-56 Days (Group 2)       34       10 (29%)         50-56 Days (Group 3)       20       4 (20%)	\$49 Days (Group 1)       35       1 (3%)       1         50-56 Days (Group 2)       34       2 (6%)       3         57-63 Days (Group 3)       20       0       0         \$63 Days (All)       89       57 (64%)       0.5184       126         \$49 Days (Group 1)       35       22 (63%)       40         50-56 Days (Group 2)       34       24 (71%)       56         57-63 Days (Group 3)       20       11 (55%)       30         \$63 Days (All)       89       1 (1%)       0.2247       1         \$49 Days (Group 1)       35       0       0       0         57-63 Days (Group 2)       34       0       0       0         57-63 Days (Group 3)       20       1 (5%)       1       1         \$63 Days (All)       89       24 (27%)       0.7512       30         \$49 Days (Group 1)       35       10 (29%)       12         50-56 Days (Group 2)       34       10 (29%)       13         57-63 Days (Group 3)       20       4 (20%)       5	\$49 Days (Group 1)       35       1 (3%)       1 0         50-56 Days (Group 2)       34       2 (6%)       3 1         57-63 Days (Group 3)       20       0       0       0         \$63 Days (All)       89       57 (64%)       0.5184       126       42         \$49 Days (Group 1)       35       22 (63%)       40       11         50-56 Days (Group 2)       34       24 (71%)       56       18         57-63 Days (Group 3)       20       11 (55%)       30       13         \$63 Days (All)       89       1 (1%)       0.2247       1       0         \$49 Days (Group 1)       35       0       0       0       0         50-56 Days (Group 2)       34       0       0       0       0         57-63 Days (Group 3)       20       1 (5%)       1       0         \$49 Days (Group 1)       35       10 (29%)       12       7         50-56 Days (Group 2)       34       10 (29%)       12       7         50-56 Days (Group 3)       20       4 (20%)       5       1	\$49 Days (Group 1)       35       1 (3%)       1 0         50-56 Days (Group 2)       34       2 (6%)       3 1 (33%)         57-63 Days (Group 3)       20       0       0         \$63 Days (All)       89       57 (64%)       0.5184       126       42 (33%)         \$49 Days (Group 1)       35       22 (63%)       40 11 (28%)         50-56 Days (Group 2)       34 24 (71%)       56 18 (32%)         57-63 Days (Group 3)       20 11 (55%)       30 13 (43%)         \$63 Days (All)       89       1 (1%) 0.2247       1 0         \$49 Days (Group 1)       35 0 0 0       0         50-56 Days (Group 2)       34 0 0 0       0         57-63 Days (Group 3)       20 1 (5%)       1 0         \$49 Days (Group 3)       20 1 (5%)       1 0         \$63 Days (All)       89       24 (27%) 0.7512       30 13 (43%)         \$49 Days (Group 1)       35 10 (29%)       12 7 (58%)         \$50-56 Days (Group 2)       34 10 (29%)       13 5 (38%)         \$57-63 Days (Group 3)       20 4 (20%)       5 1 (20%)	\$49 Days (Group 1)       35       1 (3%)       1 0 0       0         50-56 Days (Group 2)       34       2 (6%)       3 1 (33%)       1         57-63 Days (Group 3)       20 0       0 0       0       0         \$63 Days (All)       89       57 (64%)       0.5184       126       42 (33%)       62         \$49 Days (Group 1)       35       22 (63%)       40 11 (28%)       17         50-56 Days (Group 2)       34 24 (71%)       56 18 (32%)       32         57-63 Days (Group 3)       20 11 (55%)       30 13 (43%)       13         \$63 Days (All)       89       1 (1%) 0.2247       1 0 0 0       0         \$49 Days (Group 1)       35 0 0 0 0 0 0       0       0       0         \$50-56 Days (Group 2)       34 0 0 0 0 0 0       0       0       0         \$57-63 Days (Group 3)       20 1 (5%)       1 0 0       0         \$63 Days (All)       89 24 (27%) 0.7512       30 13 (43%)       13         \$49 Days (Group 1)       35 10 (29%)       12 7 (58%)       4         \$50-56 Days (Group 2)       34 10 (29%)       12 7 (58%)       4         \$50-56 Days (Group 3)       20 4 (20%)       5 1 (20%)       5	\$49 Days (Group 1)       35       1 (3%)       1 0 0 0         50-56 Days (Group 2)       34       2 (6%)       3 1 (33%)       1 (33%)         57-63 Days (Group 3)       20 0 0 0 0 0       0 0 0         \$63 Days (All)       89       57 (64%)       0.5184       126       42 (33%)       62 (49%)         \$49 Days (Group 1)       35       22 (63%)       40 11 (28%)       17 (43%)         50-56 Days (Group 2)       34 24 (71%)       56 18 (32%)       32 (57%)         57-63 Days (Group 3)       20 11 (55%)       30 13 (43%)       13 (43%)         \$63 Days (All)       89       1 (1%) 0.2247       1 0 0       0         \$49 Days (Group 1)       35 0 0 0 0 0       0       0       0         50-56 Days (Group 2)       34 0 0 0 0 0       0       0       0         57-63 Days (Group 3)       20 1 (5%)       1 0 0 0       0         \$63 Days (All)       89 24 (27%) 0.7512       30 13 (43%)       13 (43%)         \$49 Days (Group 1)       35 10 (29%)       12 7 (58%)       4 (33%)         \$49 Days (Group 2)       34 10 (29%)       12 7 (58%)       4 (33%)         50-56 Days (Group 3)       20 4 (20%)       5 1 (20%)       2 (40%)	\$49 Days (Group 1)       35       1 (3%)       1 0 0 0 1         50-56 Days (Group 2)       34 2 (6%)       3 1 (33%)       1 (33%)       1 (33%)       1         57-63 Days (Group 3)       20 0 0 0 0 0 0 0       0 0 0 0       0 0       0       0         \$63 Days (All)       89 57 (64%)       0.5184       126 42 (33%)       62 (49%)       22         \$49 Days (Group 1)       35 22 (63%)       40 11 (28%)       17 (43%)       12         50-56 Days (Group 2)       34 24 (71%)       56 18 (32%)       32 (57%)       6         57-63 Days (Group 3)       20 11 (55%)       30 13 (43%)       13 (43%)       4         \$63 Days (All)       89 1 (1%) 0.2247       1 0 0 0       0       0         \$50-56 Days (Group 1)       35 0 0 0 0 0 0 0       0       0       0         \$57-63 Days (Group 2)       34 0 0 0 0 0 0 0 0       0       0       0         \$57-63 Days (Group 3)       20 1 (5%)       1 0 0 0 1       1         \$63 Days (Group 3)       20 1 (5%)       1 0 0 0 0 0 0 0       0         \$57-63 Days (Group 1)       35 10 (29%)       12 7 (58%)       4 (33%)       1         \$63 Days (Group 2)       34 10 (29%)       12 7 (58%)       4 (33%)       1 <t< td=""><td>\$49 Days (Group 1)       35       1 (3%)       1       0       0       1 (100%)         50-56 Days (Group 2)       34       2 (6%)       3       1 (33%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%</td></t<>	\$49 Days (Group 1)       35       1 (3%)       1       0       0       1 (100%)         50-56 Days (Group 2)       34       2 (6%)       3       1 (33%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%)       1 (30%

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center:

	Gestational	Total	Numbe		Fisher's	N				G			
Body System/Event [2]	Age Group [3]	Number of Pts	of Pt w/Eve		exact p value	Number of Events	Mi			Severit erate	Sev		Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)					· · · · · · · · · · · · · · · · · · ·							
DYSPEPSIA	≤63 Days (All)	89	2	(2%)	0.6961	4	1	(25%)	3	(75%)	0		0
	≤49 Days (Group 1)	35	1	(3%)		1	0		1	(100%)	0		0
	50 56 Days (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	1	(5%)		3	1	(33%)	2	(67%)	0		0
FLATULENCE	≤63 Days (All)	89	1	(1%)	1.0000	1	0		0		1	(100%)	0
1	s49 Days (Group 1)	35	1	(3%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	89	50	(56%)	0.4256	66	25	(38%)	27	(41%)	14	(21%)	0
	≤49 Days (Group 1)	35	17	(49%)		21	4	(19%)	9	(43%)	8	(38%)	0
	50-56 Days (Group 2)	34	22	(65%)		30	12	(40%)	13	(43%)	5	(17%)	0
	57-63 Days (Group 3)	20	11	(55%)		15	9	(60%)	5	(33%)	1	(7%)	0
SALIVA INCREASED	≤63 Days (All)	89	1	(1%)	0.2247	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	35	0			0	0		0		0		0
· · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	1	(5%)		1	0		1	(100%)	0		0
VOMITING	≰63 Days (All)	89	22	(25%)	0.1241	23	3	(13%)	18	(78%)	2	(9%)	0
<b>4</b>	≤49 Days (Group 1)	35	5	(14%)		5	0	,.•	, 3	(60%)	2	(40%)	0
	50-56 Days (Group 2)	34	12	(35%)		13	1	(8,8)		ື (92∜)	0		0
	57-63 Days (Group 3)	20		(25%)		• 5	2	(40 <b>%</b> )	3	(60%)	0		0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center:	
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	Gestational Age	Total Number	Numb of P		Fisher's exact	Number -		Severit	•••	
Body System/Event [2]	Group [3]	of Pts	w/Ev		p-value	of Events	Mild	Moderate	Severe	Unknown
ARDIOVASCULAR DISORDERS, GENERAL						•				
ANY EVENT	≤63 Days (All)	89	2	(2%)	0.5174	2	0	1 (50%)	1 (50%)	0
	≰49 Days (Group 1)	35	0			0	0	0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20 .	1	(5%)		1	0	1 (100%)	0	0
HYPOTENSION	≤63 Days (All)	89	2	(2%)	0.5174	2	0	1 (50%)	1 (50%)	0
ı	• ≤49 Days (Group 1)	35	0			0	0	0 .	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	1	(5%)		· 1	0	1 (100%)	0	0
BART RATE AND RHYTHM DISORDERS										
ANY EVENT	≤63 Days (All)	89	1	(1%)	0.2247	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	0			0	0	0	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	0	1 (100%)	0
PALPITATION	≤63 Days (All)	89	1	(1%)	0.2247	1	0	0	1 (100%)	0
,	≤49 Days (Group 1)	35	0			0	0	. 0	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	0	1 (100%)	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table Sc (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center ·

	Gestational Age	Total Number	Number of Pt		Fisher's exact	Number -		Severit	:y	
Body System/Event [2]	Group [3]	of Pts	w/Eve	€nt	p-value	of Events	Mild	Moderate	Severe	Unknow
ESPIRATORY SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	89	1	(1%)	0.2247	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	0			0	0	0	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	1 (100%)	0	0
PULMONARY CONGESTION	≤63 Days (All)	89	1	(1%)	0.2247	1	0	1 (100%)	0	0
ı	• ≤49 Days (Group 1)	35	0			0	0	O ·	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	1 (100%)	0	0
RINARY SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	89	1	(1%)	0.6067	2	1 (50%)	0	1 (50%)	0
	<pre>s49 Days (Group 1)</pre>	35	O			0	0	0	0	0
•	50-56 Days (Group 2)	34	1	(3%)		2	1 (50%)	0	1 (50%)	0
•	57-63 Days (Group 3)	20	0			0	0	0	0	0
MICTURITION URGENCY	≤63 Days (All)	89	1	(1%)	0.6067	1	1 (100%)	0	0	0
, ,	≤49 Days (Group 1)	35	0			0	0	• 0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0

<sup>[1]</sup> Includes nausea, womiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

	Gestational Age	Total Number	Numb of F		Fisher's exact			Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Ev	rent	p-value	of Events	Mild	Moderate	Severe	Unknown
RINARY SYSTEM DISORDERS	(cont.)							-		
URINARY TRACT INFECTION	≤63 Days (All)	89	1	(1%)	0.6067	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	0			0	0	0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
EPRODUCTIVE DISORDERS, FEMALE										
ANY EVENT	s63 Days (All)	89	11	(12%)	0.0587	14	4 (29%)	0 '	10 (71%)	0
	≤49 Days (Group 1)	35	2	(6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	34	8	(24%)		11	2 (18%)	0	9 (82%)	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	0	1 (100%)	0
BREAST DISCHARGE	≤63 Days (All)	89	1	(1%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	35	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
BREAST PAIN FEMALE	≰63 Days (All)	89	1	(1%)	0.6067	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	35	0			0	0	. 0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1 .	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Cen	٠	P	r	٠

<i>:</i>	Gestational Age	Total Number	Number of Pts	Fisher's exact		Severity					
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown		
REPRODUCTIVE DISORDERS, FEMALE	(cont.)										
LEUKORRHOEA	≤63 Days (All)	89	1 (1%)	0.6067	1	1 (100%)	0	0	0		
	≤49 Days (Group 1)	35	0		0	0	0	0	0		
	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0		
	57-63 Days (Group 3)	20	0		0	0	0	0	0		
OVARIAN DISORDER	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0		
1	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0 '	0	0		
	50-56 Days (Group 2)	34	0		0	0	0	0	0		
	57-63 Days (Group 3)	20	0		. 0	0	0	0	0		
UTERINE HAEMORRHAGE	≤63 Days (All)	89	7 (8%)	0.0113	10	1 (10%)	o	9 (90%)	0		
	≤49 Days (Group 1)	35	0		0	0	0	0	0		
	50 56 Days (Group 2)	34	6 (18%)		9	1 (11%)	0	8 (89%)	0		
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0		
NEOPLASM .											
ANY EVENT	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0		
	s49 Days (Group 1)	35	1 (3%)		1	1 (100%)	. 0	0	0		
1	50-56 Days (Group 2)	34	0		0	0	0	0	0		
	57-63 Days (Group 3)	20	0		0	0	0	0	0		

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all'events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center:	•	-
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	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severi	٠			
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mi			rate	•	/ere	Unk	nown
NEOPLASM	(cont.)												
OVARIAN CYST	s63 Days (All)	89	1 (1%)	1.0000	1	1	(100%)	0		0		0	
	≰49 Days (Group 1)	35	1 (3%)		1	1	(100%)	0		0		0	
	50-56 Days (Group 2)	34	0		0	0		0		0		0	
	57-63 Days (Group 3)	20	0		0	0		0		0		0	
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	89	87 (98%)	1.0000	288	99	(34%)	108	(38%)	80	(28%)	1	(<1%)
	≰49 Days (Group 1)	35	34 (97%)		112	41	(37%)	39	(35%)	31	(28%)	1	(<1%)
	50-56 Days (Group 2)	34	33 (97%)		116	38	(33%)	50	(43%)	28	(24%)	0	
	57-63 Days (Group 3)	20	20 (100%)		60	20	(33%)	19	(32%)	21	(35%)	0	
ABDOMINAL PAIN	≤63 Days (All)	89	87 (98%)	1.0000	260	89	(34%)	99	(38%)	71	(27%)	1	(<1%)
	≰49 Days (Group 1)	35	34 (97%)		101	38	(38%)	33	(33%)	29	(29%)	1	(<1%)
	50-56 Days (Group 2)	34	33 (97%)		103	32	(31%)	48	(47%)	23	(22%)	0	
•	57-63 Days (Group 3)	20	20 (100%)		56	19	(34%)	18	(32%)	19	(34%)	0	
ASTHENIA	≤63 Days (All)	89	3 (3%)	0.6123	5	1	(20%)	2	(40%)	2	(40%)	0	
	s49 Days (Group 1)	35	1 (3%)		2	1	(50%)	. 1	(50%)	0		0	
,	50-56 Days (Group 2)	34	2 (6%)		3	0		1	(33%)	2	(67%)	0	
	57-63 Days (Group 3)	20	0		0	0		0		0		0	

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristome and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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## Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Body System/Event [2]		Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		S <b>eve</b> rit	. <b>y</b>	
BACK PAIN  #63 Days (All) #69 Days (Group 1) #65 Days (Group 2) #65 Days (Group 2) #65 Days (Group 3) #65 Da	Body System/Event [2]	<del>-</del>	of Pts	w/Event					•	Unknown
#49 Days (Group 1)	ODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
So-56 Days (Group 2)	BACK PAIN	≤63 Days (All)	89	7 (8%)	0.6016	7	2 (29%)	1 (14%)	4 (57%)	0
CHEST PAIN  *63 Days (All) *49 Days (Group 2) *57 -63 Days (Group 2) *57 -63 Days (Group 3) *60 Days (Group 3) *60 Days (Group 2) *61 Days (Group 3) *62 Days (Group 3) *63 Days (Group 3) *60 Days (Group		≤49 Days (Group 1)	35	2 (6%)		2	0	1 (50%)	1 (50%)	0
CHEST PAIN  \$63 Days (All)  \$89		50-56 Days (Group 2)	34 ·	4 (12%)		4	2 (50%)	0	2 (50%)	0
FATIGUE  \$63 Days (Group 1)		57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0
FATIGUE  \$63 Days (All) \$9 6 (7t) 0.2181 6 2 (33t) 2 (33t) 2 (33t) \$49 Days (Group 3) 20 3 (15t) 1 (100t) 0 0  FEVER  \$63 Days (All) \$9 2 (2t) 1.0000 2 2 (100t) 0 0  FEVER  \$63 Days (Group 3) 20 3 (15t) 1 (100t) 0 0  \$649 Days (Group 3) 20 3 (15t) 1 (100t) 0 0  \$65 Days (Group 3) 20 3 (15t) 1 (100t) 0 0  \$65 Days (Group 3) 20 3 (15t) 1 (100t) 0 0  \$65 Days (Group 3) 20 3 (15t) 1 (100t) 0 0  \$65 Days (Group 3) 20 3 (15t) 1 (100t) 0 0  \$65 Days (Group 3) 20 0 0 0 0 0 0 0  \$65 Days (Group 3) 20 0 0 0 0 0 0 0  \$65 Days (Group 3) 20 0 0 0 0 0 0 0 0  \$65 Days (Group 3) 20 0 0 0 0 0 0 0 0 0  \$65 Days (Group 3) 20 0 0 0 0 0 0 0 0 0 0  \$65 Days (Group 3) 20 0 0 0 0 0 0 0 0 0 0 0  \$65 Days (Group 3) 20 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	CHEST PAIN	≤63 Days (All)	89	1 (1%)	0.6067	2	1 (50%)	1 (50%)	0	0
FATIGUE  FATIGUE  \$63 Days (All) \$89 6 (71) 0.2181 6 2 (331) 2 (331) 2 (331) \$49 Days (Group 1) 35 2 (61) 50.56 Days (Group 2) 34 1 (31) 1 1 (1001) 0 0 57-63 Days (Group 3) 20 3 (151) 3 1 (331) 1 (331) 1 (331) 1 (331)  FEVER  \$63 Days (All) \$89 2 (21) 1.0000 2 2 (1001) 0 0 50.56 Days (Group 1) 35 1 (31) 1 1 (1001) 0 0 50.56 Days (Group 2) 34 1 (31) 1 1 (1001) 0 0 50.56 Days (Group 2) 34 1 (31) 1 1 (1001) 0 0 50.56 Days (Group 3) 20 0 0 0 0 0 0 0 0  LEG PAIN  \$63 Days (All) \$89 1 (11) 1.0000 2 0 0 2 (1001) 0 50.56 Days (Group 1) 35 1 (31) 1 0000 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	·	≤49 Days (Group 1)	35	0		0	0	0	0	0
FATIGUE  \$63 Days (All)		50-56 Days (Group 2)	34	1 (3%)		. 2	1 (50%)	1 (50%)	0	0
FEVER  \$63 Days (Group 1) 35 2 (6%) 2 0 1 (50%) 1 (50%) 50-56 Days (Group 2) 34 1 (3%) 1 1 (100%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		57-63 Days (Group 3)	20	0		0	0	0	0	0
FEVER  50-56 Days (Group 3) 34 1 (3%) 1 (100%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	FATIGUE	s63 Days (All)	89	6 (7%)	0.2181	6	2 (33%)	2 (33%)	2 (33%)	0
FEVER  57-63 Days (All) 89 2 (24) 1.0000 2 2 (1004) 0 0 50-56 Days (Group 1) 57-63 Days (Group 2) 57-63 Days (Group 3) 20 0 0 0 0 0 0  LEG PAIN  57-63 Days (Group 1) 50-56 Days (Group 1) 50-56 Days (Group 2) 50-56 Days (Group 3) 50-56 Days (Group 2) 50-56 Days		≰49 Days (Group 1)	35	2 (6%)		2	0	1 (50%)	1 (50%)	0
FEVER  \$63 Days (All) \$89 2 (21) 1.0000 2 2 (1001) 0 0 \$49 Days (Group 1) 35 1 (31) 1 1 (1001) 0 0 50-56 Days (Group 2) 34 1 (31) 1 1 (1001) 0 0 0  LEG PAIN  \$63 Days (All) \$89 1 (11) 1.0000 2 0 2 (1001) 0 0  \$49 Days (Group 1) 35 1 (31) 2 0 2 (1001) 0 0  \$60 Days (Group 2) 34 0 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0 0  \$60 Days (Group 2) 0 0 0 0 0 0 0 0  \$60 Days (Group 2)		50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0
±49 Days (Group 1)       35       1       (3%)       1       1 (100%)       0       0         50-56 Days (Group 2)       34       1       (3%)       1       1 (100%)       0       0       0         57 63 Days (Group 3)       20       0       0       0       0       0       0       0         LEG PAIN       *63 Days (All)       89       1       (1%)       1.0000       2       0       2 (100%)       0         *49 Days (Group 1)       35       1       (3%)       2       0       2 (100%)       0         *50-56 Days (Group 2)       34       0       0       0       0       0       0		57-63 Days (Group 3)	20	3 (15%)		3	1 (33%)	1 (33%)	1 (33%)	0
LEG PAIN  *63 Days (Group 2) 34 1 (3%) 1 1 (100%) 0 0  *65 Days (Group 3) 20 0 0 0 0 0  *65 Days (All) 89 1 (1%) 1.0000 2 0 2 (100%) 0  *49 Days (Group 1) 35 1 (3%) 2 0 2 (100%) 0  *50-56 Days (Group 2) 34 0 0 0 0 0 0 0 0	FEVER	≤63 Days (All)	89	2 (2%)	1.0000	2	2 (100%)	0	0	0
50-56 Days (Group 2) 34 1 (3%) 1 1 (100%) 0 0 0 57 63 Days (Group 3) 20 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		≰49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
LEG PAIN  \$63 Days (All)  89 1 (1%) 1.0000 2 0 2 (100%) 0  \$49 Days (Group 1) 35 1 (3%) 2 0 2 (100%) 0  50-56 Days (Group 2) 34 0 0 0 0 0 0	•	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0
≤49 Days (Group 1) 35 1 (3%) 2 0 . 2 (100%) 0 50-56 Days (Group 2) 34 0 0 0 ; 0 0		57 63 Days (Group 3)	20	0		0	0	0	0	0
50-56 Days (Group 2) 34 0 0 0 0 0		≤63 Days (All)	89	1 (1%)	1.0000	2	0	2 (100%)	0	0
		<pre>s49 Days (Group 1)</pre>	35	1 (3%)		2	0 . ,	2 (100%)	0	0
57 (3 Davis (Green 3) 20 0		50-56 Days (Group 2)	34	0		, 0	0 ,i	0	0	0
57-63 Days (Group 3) 20 0 0 0 0 0	•	57-63 Days (Group 3)	20	0		0	0 '	0,	0	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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#### Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center:

	Gestational Age	Total Number	Number of P		Fisher's exact			Severit	·v	
Body System/Event (2)	Group [3]	of Pts	w/Eve		p-value	of Events	Mild	Moderate	Severe	Unknown
DDY AS A WHOLE - GENERAL DISORDERS	(cont.)	·.		,						
PAIN	≤63 Days (All)	89	1	(1%)	0.6067	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	35	0			0	0	0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
RIGORS	≤63 Days (All)	89	2	(2%)	1.0000	2	1 (50%)	0	1 (50%)	0
1	≤49 Days (Group 1)	35	1	(3%)		1	1 (100%)	<b>o</b> '	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
SYNCOPE	≤63 Days (All)	89	1	(1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	1	(3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Center: WESTHOFF (#24)

	<del></del>					·····						•		
Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Numb of I w/Ev		Fisher's exact p value	Number of Events	Mi	1d		Severity erate		ere	Unl	known
NAME TO LEAD TO				,								,		
ANY EVENT	≤63 Days (All)	175		(86%)	0.0366	428	184	(43%)	176	(41%)	66	(15%)	2	(<1%
	≤49 Days (Group 1)	71	5 <b>6</b>	(79%)		136	55	(40%)	57	(42%)	24	(18%)	0	
	50-56 Days (Group 2)	72		(89%)		202	94	(47%)	80	(40%)	27	(13%)	1	(<1%
	57-63 Days (Group 3)	32	31	(97%)		90	35	(39%)	39	(43%)	15	(17%)	1	(1%
SKIN AND APPENDAGES DISORDERS														
ANY EVENT	≤63 Days (All)	175	1	(<1%)	1.0000	1	0		1	(100%)	0		0	
	≰49 Days (Group 1)	71	0			0	0		0	(1001)	n		٥	
	50-56 Days (Group 2)	72	1	(1%)		1	0		-	(100%)	0		٥	
	57-63 Days (Group 3)	32	0			0	0		0	(1001)	0		0	
SWEATING INCREASED	≤63 Days (All)	175	1	(<1%)	1.0000	1	0		,	(100%)	0		•	
	≤49 Days (Group 1)	71	0	( /	2.0000	0	0		0	(100%)			0	
	50 56 Days (Group 2)	72	1	(1%)		1	0			(1008)	0		0	
'	57-63 Days (Group 3)	32	0	(**)		0	0		0	(100%)	0		0	
CENTR & PERIPH NERVOUS SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	175	2	/18)	0 3331		_	/ <b></b> .						
	≤49 Days (Group 1)		2	(1%)	0.3331	2		(100%)	0		0		0	
		71	0	(10)		0	0		0		0		0	
	50 56 Days (Group 2)	72	1	(1%)		1		(100%)	0		0		0	
	57-63 Days (Group 3)	32	1	(3%)		1	1	(100%)	0		0		0	

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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·	Gestational Age	Total Number	Numb of P		Fisher's exact	Number				Severit			
Body System/Event [2]	Group [3]	of Pts	w/Ev		p-value	of Events		i ld		erate	•	/ere	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISORD	ERS(cont.)									*			
DIZZINESS	≤63 Days (All)	175	1	(<1%)	0.1829	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	71	0			0	0		0		0	•	0
	50-56 Days (Group 2)	72	0			0	0		0		0		0
	57-63 Days (Group 3)	32	1	(3%)		1	1	(100%)	0		0		0
HEADACHE	≤63 Days (All)	175	1	(<1%)	1.0000	1	1	(100%)	0		0		0
•	≤49 Days (Group 1)	71	0			0	0		0	•	0		0
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	175	65	(37%)	0.0658	103	65	(63%)	35	(34%)	3	(3%)	0
	≤49 Days (Group 1)	71	19	(27%)		27	15	(56%)	10		2	(7%)	0
	50-56 Days (Group 2)	72	32	(44%)	•	55	36	(65%)	18	(33%)	1	(2%)	0
	57-63 Days (Group 3)	32	14	(44%)		21	14	(67%)	7	(33%)	0		0
DIARRHEA	≤63 Days (All)	175	25	(14%)	0.0108	25	18	(72%)	7	(28%)	0		0
	≤49 Days (Group 1)	71	4	(6%)		4	4	(100%)	0		0		0
	50-56 Days (Group 2)	72	13	(18%)		13	9	(69%)	4	(31%)	0		0
	57-63 Days (Group 3)	32	8	(25%)		8	5	(63%)	3	(38%)	0		0
		32		(23)		J	3	(034)	,	(30%)	U		U

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>(2)</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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ļ i.	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severit		4	
Body System/Event [2]	Group [3]	of Pts	w/Event	p·value	of Events	Mi	1d	Mode	rate	Sev		Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)										,	
NAUSEA	≤63 Days (All)	175	45 (26%)	0.4964	45	27	(60%)	16	(36%)	2	(4%)	0
	≤49 Days (Group 1)	71	15 (21%)		15	8	(53%)	6	(40%)	1	(7%)	0
	50-56 Days (Group 2)	72	20 (28%)		20	12	(60%)	7		1	(5%)	0
	57-63 Days (Group 3)	32	10 (31%)		10	7	(70%)	3		0	(34)	0
VOMITING	≤63 Days (All)	175	33 (19%)	0.0055	33	20	(61%)	12	(36%)	1	(3%)	0
1	≤49 Days (Group 1)	71	8 (11%)		8	3	(38%)	4	(50%)	1	(13%)	0
	50-56 Days (Group 2)	72	22 (31%)		22	15	(68%)	7		0	(130)	0
	57-63 Days (Group 3)	32	3 (9%)		3	2	(67%)	1		0		0
RED BLOOD CELL DISORDERS												
ANY EVENT	≤63 Days (All)	175	2 (1%)	1.0000	2	0		0		2	(100%)	0
	≤49 Days (Group 1)	71	1 (1%)		1	0		0			(100%)	0
	50-56 Days (Group 2)	72	1 (1%)	*	1	o		0			(100%)	0
	57-63 Days (Group 3)	32	0		0	0		0		0	, , , , ,	0
ANAEMIA	≤63 Days (All)	175	2 (1%)	1.0000	2	0		0		2	(100%)	0
	≤49 Days (Group 1)	71	1 (1%)		1	0		0			(100%)	0
	50-56 Days (Group 2)	72	1 (1%)		1	0		0			(100%)	0
	57-63 Days (Group 3)	32	0		0	ō		0		0	(1004)	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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	Gestational	Total Number	Number of Pts	Fisher's exact			Severi		
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
FRINARY SYSTEM DISORDERS	· · · · · · · · · · · · · · · · · · ·								,
ANY EVENT	≤63 Days (All)	175	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	ο .	0
	50-56 Days (Group 2)	72	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
DYSURIA	≤63 Days (All)	175	1 (<1%)	1.0000	1	0	1 (100%)	0	0
1	s49 Days (Group 1)	71	0		0	0	0 '	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	175	9 (5%)	0.7388	11	1 (9%)	0	10 (91%)	0
	s49 Days (Group 1)	71	3 (4%)		4	0	0	4 (100%)	0
	50-56 Days (Group 2)	72	5 (7%)	•	5	1 (20%)	0	4 (80%)	0
	57-63 Days (Group 3)	32	1 (3%)		2	0	0	2 (100%)	0
ENDOMETRITIS	≤63 Days (All)	175	1 (<1%)	0.1829	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	0	0	1 (100%)	0

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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1.	Gestational	Total	Numb	oer	Fisher's									
Body System/Event [2]	Age Group [3]	Number of Pts	of I	Pts	exact p-value	Number of Events		1d		Severit rate	•	ere	Unk	known
REPRODUCTIVE DISORDERS, FEMALE	(cont.)			.,	· · · · · · · · · · · · · · · · · · ·							,	,	
UTERINE DISORDER NOS	≤63 Days (All)	175	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	71	0			0	0		0		0		0	
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	32	0			0	0		0		0		0	
UTERINE HAEMORRHAGE	≤63 Days (All)	175	8	(5%)	1.0000	9	0		0		9	(100%)	0	
ı	≤49 Days (Group 1)	71	3	(4%)		4	0		0		4	(100%)	0	
	50-56 Days (Group 2)	72	4	(6%)		4	0		0		4	(100%)	0	
	57 63 Days (Group 3)	32	1	(3%)		1	0		0		1	(100%)	0	
BODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	175	149	(85%)	0.0539	308	116	(38%)	139	(45%)	51	(17%)	2	(<1%)
	≤49 Days (Group 1)	71	55	(77%)		104	40	(38%)	47	(45%)	17	(16%)	0	
	50-56 Days (Group 2)	72	64	(89%)		138	56	(41%)	60	(43%)	21	(15%)	1	(<1%)
	57-63 Days (Group 3)	32	30	(94%)		66	2,0	(30%)	32	(48%)	13	(20%)	1	(2%)
ABDOMINAL PAIN	≤63 Days (All)	175	147	(84%)	0.0920	300	112	(37%)	135	(45%)	51	(17%)	2	(<1%)
	≤49 Days (Group 1)	71	55	(77%)		102	39	(38%)	46	(45%)	17	(17%)	0	
	50-56 Days (Group 2)	72	62	(86%)		134	54	(40%)	58	(43%)	21	(16%)	1	(<1%)
	57-63 Days (Group 3)	32	30	(94%)		64	19	(30%)	31	(48%)	13	(20%)	1	(2%)

<sup>[1]</sup> Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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