Center: DEAN (#27)

	Gestational	Total Number	Number of Pts		sher's	Number				Severi	•			
Body System/Event [2]	Age Group [3]	of Pts	w/Even		act value	of Events	Mi	14	Mod	erate	•	ere	Unkı	nown
•														
ANY EVENT	≤63 Days (All)	191	190 (>9	) 0.5	5340	1456	498	(34%)	578	(40%)	343	(24%)	37	(3%
	≤49 Days (Group 1)	29	29 (10	<b>(\$</b> )		203	65	(32%)	99	(49%)	39	(19%)	0	
	50-56 Days (Group 2)	73	72 (9	11)		541	201	(37%)	215	(40%)	110	(20%)	15	(3%
	57-63 Days (Group 3)	89	89 (10	14)		712	232	(33%)	264	(37%)	194	(27%)	22	(3≹
SKIN AND APPENDAGES DISORDERS														
ANY EVENT	≤63 Days (All)	191	4 (	( <b>1</b> ) 0.1	8085	<b>! 4</b>	3	(75%)	0		1	(25%)	0	
	≤49 Days (Group 1)	29	1 (	(1)		<b>' 1</b>	1	(100%)	0	:	0.		0	
	50 56 Days (Group 2)	73	1 (	. \$ )		1	1	(100%)	0	1	0		0	
	57-63 Days (Group 3)	89	2 (:	<b>!</b> *)		2	1	(50%)	0		1	(50%)	0	
PRURITUS	≤63 Days (All)	191	1 (<	.*) 1.0	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		1 0		0		0	
	57-63 Days (Group 3)	89	1 (	.*)		1	1	(100%)	0		0		0	
RASH	≤63 Days (All)	191	1 (<	.*) 0.:	1518	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	29	1 (	*)		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	
SWEATING INCREASED	\$63 Days (All)	191	1 (<	.1.0	0000	1	0		o		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	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

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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Center: DEAN (#27)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Markon		Commit		
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	Number of Events	Mild	Moderate	Severe	Unknow
SKIW AND APPENDAGES DISORDERS (cont.)		····							• • • • • • • • • • • • • • • • • • • •
URTICARIA	≤63 Days (All)	191	1 (<1%)	0.5340	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	! <b>o</b>	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
rusculo-skeletal system disorders									
ANY EVENT	≤63 Days (All)	191	2 (1%)	0.4261	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0 1	0.	0
	50-56 Days (Group 2)	73	2 (3%)		3	0	3 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
MYALGIA	s63 Days (All)	191	1 (<1%)	0.5340	2	0	2 (100%)	0	0
1	≤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
SKELETAL PAIN	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	1 (100%)	0	. 0
	≤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	0		0	0	o	0	0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	65 (34%)	0.9565	119	29 (24%)	69 (58%)	18 (15%)	3 (3
	s49 Days (Group 1)	29	9 (31%)		. 17	3 (18%)	13 (76%)	1 (6%)	
	50-56 Days (Group 2)	73	25 (34%)	1	41	12 (29%)	23 (56%)	4 (10%)	
	57-63 Days (Group 3)	89	31 (35%)		61	14 (23%)	33 (54%)	13 (21%)	

<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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Center: DEAN (#27)

	Gestational	Total		ber	Fisher's					
Body System/Event [2]	Age Group (3)	Number of Pts		Pts vent	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDER	RS (cont.)									
DIZZINESS	≤63 Days (All)	191	16	(8%)	0.2497	20	3 (15%)	11 (55%)	6 (30%)	0
	≤49 Days (Group 1)	29	1	(3%)		1	0	1 (100%)	0	Ō
	50-56 Days (Group 2)	73	4	(5%)		5	1 (20%)	3 (60%)	1 (20%)	0
	57-63 Days (Group 3)	89	11	(12%)		14	2 (14%)	7 (50%)	5 (36%)	0
HEADACHE	≤63 Days (All)	191	58	(30%)	0.9766	97	25 (26%)	58 (60%)	11 (111)	3 (31
1	. s49 Days (Group 1)	29	9	(31%)		16	3 (19%)	12 (7,5%)	1 (6%)	0 (3.
	50-56 Days (Group 2)	73	23	(32%)		35	10 (29%)	20 (57%)	3 (91)	2 (61
	57-63 Days (Group 3)	89	26	(29%)		46	12 (26%)	26 (57%)	7 (15%)	1 (2)
MENINGITIS	≤63 Days (All)	191	1	(<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	ō	1-4-7	1.0000	0	ŏ	0	0	0
	50-56 Days (Group 2)	73	0			0	o o	o o	0	0
	57-63 Days (Group 3)	89	1	(1%)		1	ŏ ,	ō	1 (100%)	ō
MUSCLE CONTRACTIONS INVOLUNTARY	≤63 Days (All)	191	1	(<1%)	0.5340	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	ō			0	0	Ö	Ö	Ô
	50-56 Days (Group 2)	73	1	(1%)		1	1 (100%)	Ō	0	Ô
	57-63 Days (Group 3)	89	0			0	0	0	0	0
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

<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: DEAN (#27)

	Marine Inc.	-5 00-	Fisher's	M				
Age Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknowr
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
50-56 Days (Group 2)	73	0		0	0	0	0	o
57-63 Days (Group 3)	89	0		0	0	0	0	0
≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	29	0		0	0	0 ;		0
	73	0		0	0	o '	0	0
57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
		0		0	0	0	=	o
		0		0	0	o	0	. 0
57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
≤63 Days (All)	191	4 (2%)	0.8085	6	0	3 (50%)	3 (50%)	0
		0		0	0	0	0	ō
	73	1 (1%)		3	0	1 (33%)	2 (67%)	0
57-63 Days (Group 3)	89	3 (3%)		3	o	2 (67%)	1 (33%)	0
	<pre>s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  s63 Days (Group 3)  s63 Days (Group 1) 50-56 Days (Group 3)</pre>	<pre>\$63 Days (All)</pre>	<pre> s63 Days (All)</pre>	*63 Days (All)       191       1 (<1%)	#63 Days (All)			

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

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

Center: DEAN (#27)

	Gestational	Total		ber	Fisher's	M								
ANOREXIA  DEPRESSION  INSOMNIA	Age Group [3]	Number of Pts		Pts vent	exact p-value	Number of Events	Mi			Severi	•	ere	Unk	tnown
SYCHIATRIC 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	
DEPRESSION	≤63 Days (All)	191	1	(<1%)	0.5340	1	0		0		1	(100%)	0	
4	≤49 Days (Group 1)	29	0			0	0		0		0		0	
	50:56 Days (Group 2)	73	1	(1%)		1	0		0	:	1.	(100%)	0	
	57163 Days (Group 3)	89	0			0	0		0		0		0	
INSOMNIA	s63 Days (All)	191	3	(2%)	1.0000	4	0		2	(50%)	2	(50%)	0	
	s49 Days (Group 1)	29	0			O,	0		0		0		0	
	50-56 Days (Group 2)	73	1	(1%)		2	0		1	(50%)	1	(50%)	0	
	57-63 Days (Group 3)	89	2	(2%)		2	0	,	1	(50%)	1	(50%)	0	
ASTRO-INTESTINAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	191	141	(74%)	0.1370	454	159	(35%)	180	(40%)	113	(25%)	2	(<19
	≤49 Days (Group 1)	29	17	(59%)		55	20	(36%)	23	(42%)	12	(22%)	0	
	50-56 Days (Group 2)	73	55	(75%)		159	60	(38%)	71	(45%)	28	(18%)	0	
	57-63 Days (Group 3)	89	69	(78%)		240	79	(33%)	86	(36%)	73	(30%)	2	(<1
DIARRHEA	≰63 Days (All)	191	56	(29%)	0.3786	72	37	(51%)	26	(36%)	9	(13%)	0	
	≤49 Days (Group 1)	29	6	(21%)		7	5	(71%)	1	(14%)	1	(14%)	0	
	50-56 Days (Group 2)	73	20	(27%)		. 27	16	(59%)	8	(30%)	3	(11%)	0	
	57-63 Days (Group 3)	89	30	(34%)		38	16	(42%)	17	(45%)	5	(13%)	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.

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

Center: DEAN (#27)

	Gestational Age	Total Numb <b>e</b> r	Numi of		Fisher's exact	Number				Severit	v		<b></b>	
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	1 <b>d</b>	Mode	rate	•	ere	Unk	nown
JASTRO-INTESTINAL SYSTEM DISORDERS (cont.)		· · · · · · · · · · · · · · · · · · ·									•			
DYSPEPSIA	≤63 Days (All)	191	3	(2%)	0.7499	3	0		0		2	(67%)	1	(33%)
	≤49 Days (Group 1)	29	0			. 0	0		0		0		0	
	50-56 Days (Group 2)	73	2	(3%)		2	0		0		2	(100%)	0	
	57-63 Days (Group 3)	89	1	(1%)		1	0		0		0		1	(100%)
FLATULENCE	≤63 Days (All)	191	3	(2%)	0.3805	4	0		2	(50%)	1	(25%)	1	(25%)
•	≤49 Days (Group 1)	29	0			0	0		0		0		0	
•	50-56 Days (Group 2)	73	0	i		0	0		0		0.		0	
	57-63 Days (Group 3)	89	3	(3%)		4	0		2	(50%)	1	(25%)	1	(25%)
NAUSEA	≤63 Days (All)	191	122	(64%)	0.1784	259	101	(39%)	99	(38%)	59	(23%)	0	
	≤49 Days (Group 1)	29	14	(48%)		37	13	(35%)	18	(49%)	6	(16%)	0	
	50-56 Days (Group 2)	73	48	(66%)		90	38	(42%)	40	(44%)	12	(13%)	0	
	57-63 Days (Group 3)	89	60	(67%)		132	50	(38%)	41	(31%)	41	(31%)	0	
TOOTH ACHE	≤63 Days (All)	191	1	(<1%)	0.1518	1	,o		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	
VOMITING	≤63 Days (All)	191	66	(35%)	0.3144	115	21	(18%)	52	(45%)	42	(37%)	0	
	≤49 Days (Group 1)	29	7	(24%)		10	2	(20%)	3	(30%)	5	(50%)	0	
	50-56 Days (Group 2)	73	24	(33%)		40	6	(15%)	23	(58%)	11	(28%)	0	
	57-63 Days (Group 3)	89	35	(39%)		65	13	(20%)	26	(40%)	26	(40%)	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.

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

Center: DEAN (#27)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severit	·v	
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY'SYSTEM DISORDERS			_						
ANY EVENT	≤63 Days (All)	191	7 (4%)	0.8756	9	3 (33%)	3 (33%)	1 (11%)	2 (22%)
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		4	0	1 (25%)	1 (25%)	2 (50%)
	57-63 Days (Group 3)	89	4 (4%)		4	2 (50%)	2 (50%)	0	0
COUGHING	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	0	o	1 (100%)
1	≤49 Days (Group 1)	29	0		, <b>o</b>	0	0	0	0
	50 56 Days (Group 2)	73	1 (1%)		¹ <b>1</b>	0	0 (	0.	1 (100%)
	57-63 Days (Group 3)	89	0		o	0	0	0	0
DYSPNOEA	≤63 Days (All)	191	1 (<1%)	0.1518	1	1 (100%)	0	0	0
	s49 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
HYPERVENTILATION	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	29	0		o	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
PHARYNGITIS	≤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

<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: DEAN (#27)

	Gestational	Total	Number	Fisher's	Mb				
Body System/Event [2]	Age Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
ESPIRATORY SYSTEM DISORDERS (cont.)				<del> </del>		.,			
RHINITIS	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	, 0	0	1 (100%
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	· o	0	1 (100%
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	191	3 (2%)	1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
4	≤49 Days (Group 1)	29	0		0	0	ο .	0	0
·	50-56 Days (Group 2)	73	1 (1%)		2	0	1 (50%)	1' (50%)	0
	57-63 Days (Group 3)	89	2 (2%)		2	2 (100%)	0	0	0
ED BLOOD CELL 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
ANAEMIA	s63 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
<u> </u>	57-63 Days (Group 3)	89	1 (11)		1	0	1 (100%)	0	0
RIMARY SYSTEM 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

<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

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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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Center: DEAN (#27)

	Gestational Age	Total Number	Num of	ber Pts	Fisher's exact	Number	. <b>. .</b>	- <b></b>		···Severit	. <b>v.</b>		. <b></b>
Body System/Event (2)	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	ld	Mode	erate	•	rere	Unknown
URIWARY SYSTEM DISORDERS (cont.)													<del></del>
URINARY TRACT INFECTION	≤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
REPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	191	16	(8%)	0.0115	22	2 :	(9%)	10	(45%)	10	(45%)	0
	≤49 Days (Group 1)	29	3	(10%)		5	1	(20%)	1		13.	(601)	o
	50-56 Days (Group 2)	73	1	(1%)		2	0		2	(100%)	0		o
	57-63 Days (Group 3)	89	12	(13%)		15	1	(7%)	7		7	(47%)	Ō
LEUKORRHOEA	≤63 Days (All)	191	3	(2%)	0.5453	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	29	1	(3%)		1	1	(100%)	0	,,	o		0
	50-56 Days (Group 2)	73	1	(1%)		1	0		1	(100%)	0		ō
	57-63 Days (Group 3)	89	1	(1%)		1	1	(100%)	0	, ,	o		Ō
UTERINE HAEMORRHAGE	≤63 Days (All)	191	11	(6%)	0.0088	15	0		7	(47%)	6	(53%)	0
	s49 Days (Group 1)	29	2	(78)		4	0		1	(25%)	3	(75%)	0
	50-56 Days (Group 2)	73	0			0	0		ō		ō		Ō
	57-63 Days (Group 3)	89	9	(10%)		11	0		6	(55%)	5	(45%)	0
VAGINAL DISCOMFORT	≤63 Days (All)	191	1	(<1%)	1.0000	2	0		0		2	(100%)	0
	≤49 Days (Group 1)	29	0			0	0		Ö		0	, • •	ō
	50-56 Days (Group 2)	73	Ō			0	ō		Ö		ō		Ō
	57-63 Days (Group 3)	89	1	(1%)		• 2	ō		ō		2	(100%)	Ö

<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: DEAN (#27)

	Gestational	Total		ber	Fisher's exact	Number				Caveri	<b>.</b>			
Body System/Event [2]	Age Group (3)	Number of Pts		Pts Event	p-value	of Events	Mi		Mode		•	ere	Uni	known
REPRODUCTIVE DISORDERS, FEMALE (cont.)	······································													
VAGINITIS	≤63 Days (All)	191	2	(1%)	1.0000	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%)		1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	89	1	(1%)		1	0		1	(100%)	0		0	
BODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	191	190	(>99%)	0.5340	830	300	(36%)	304	(37%)	196	(24%)	30	(4%)
	s49 Days (Group 1)	29	29	(100%)		121	38	(31%)	60	(5ġ <b>%</b> )	23 ·	(19%)	0	
	50-56 Days (Group 2)	73	72	(99%)		325	127	(39%)	113	(3Š <b>%</b> )	74	(23%)	11	(3%
	57-63 Days (Group 3)	89	89	(100%)		384	135	(35%)	131	(34%)	99	(26%)	19	(51)
ABDOMINAL PAIN	≤63 Days (All)	191	190	(>99*)	0.5340	772	281	(36%)	280	(36%)	186	(24%)	25	(3%)
	≤49 Days (Group 1)	29	29	(100%)		112	34	(30%)	55	(49%)	23	(21%)	0	
	50-56 Days (Group 2)	73	72	(99%)		298	118	(40%)	99	(33%)	70	(23%)	11	(4%)
	57-63 Days (Group 3)	89	89	(100%)		362	129	(36%)	126	(35%)	93	(26%)	14	(4%)
ALLERGY	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		0		0		1	(100%)
	≰49 Dayş (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		0		1	(100%)
ASTHENIA	≤63 Days (All)	191	5	(3%)	0.4621	6	2	(33%)	4	(67%)	i 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%)	o		0	
	57-63 Days (Group 3)	89	4	(4%)		. 4	2	(50%)	2	(50%)	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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Center: DEAN (#27)

	Gestational Age	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
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)	······································							
BACK PAIN	≤63 Days (All)	191	17 (91	0.8336	31	9 (29%)	13 (42%)	5 (16%)	4 (13%
	≤49 Days (Group 1)	29	3 (101	)	5	3 (60%)	2 (40%)	0	0
	50-56 Days (Group 2)	73	7 (10)	)	16	5 (31%)	9 (56%)	2 (13%)	0
	57-63 Days (Group 3)	89	7 (81	)	10	1 (10%)	2 (20%)	3 (30%)	4 (40%
FATIGUE	≤63 Days (All)	191	7 (41	) 0.1139	7	2 (29%)	5 (71%)	0	0
	≤49 Days (Group 1)	29	3 (10)	)	3	0	3 (100%)	0	Ō
	50:56 Days (Group 2)	73	2 (31	)	2	1 (50%)	1 (50%)	0 -	0
	57163 Days (Group 3)	89	2 (21	)	2	1 (50%)	1 (50%)	0	0
FEVER	≤63 Days (All)	191	4 (21	) 0.3736	5	4 (80%)	1 (20%)	0	0
	≤49 Days (Group 1)	29	0		0,	0	0	0	0
	50-56 Days (Group 2)	73	3 (41	)	4	3 (75%)	1 (25%)	0	Ö
	57-63 Days (Group 3)	89	1 (11	)	1	1 (100%)	0	0	0
HOT FLUSHES	≤63 Days (All)	191	1 (<19	) 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 (14	)	1	0	0	1 (100%)	0
MALAISE	≤63 Days (All)	191	1 (<1	0.5340	1	0	0	1 (100%)	0
	#49 Days (Group 1)	29	0		0	0	0	0	O
	50-56 Days (Group 2)	73	1 (19	)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	89	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.

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Center: DEAN (#27)

	Gestational	Total	Number	Fisher's					
	Age	Number	of Pts	exact	Number		Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (	coat.)								
PAIN	≤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
SYNCOPE	≤63 Days (All)	191	4 (2%)	1.0000	5	1 (20%)	1 (20%)	3 (60%)	0
1	s49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	2 (2%)		3	1 (33%)	0 .*	2 (67%)	0
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	191	5 (3%)	0.0457	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	73	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	89	0		o	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	191	5 (3%)	0.0457	5	2 (40%)	2 (40%)	1 (20%)	0
	s49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	73	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	89	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.

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

Center: CREININ (#28)

	Gestational Age	Total Number	Number of Pts	Fishe exact					Severi	ty		
Body System/Event [2]	Group [3]	of Pts	w/Even	p-val	ue of Events	Mi	14	Mod	erate	Sev	ere	Unknow
•												
ANY EVENT	≤63 Days (All)	115	115 (10			397	(42%)	335		221	(23%)	0
	≤49 Days (Group 1)	23	23 (10		154	64	(42%)	56		34	(22%)	0
	50-56 Days (Group 2)	50	50 (10		432	163	(38%)	160		109	(25%)	0
	57-63 Days (Group 3)	42	42 (10	(*)	367	170	(46%)	119	(324)	78	(21%)	0
KIN AND APPENDAGES DISORDERS												
ANY EVENT	≤63 Days (All)	115	4 (.	( <b>%</b> ) 0.105	9 4	0		3	(75%)	1	(25%)	0
	s49 Days (Group 1)	23	0		0	0		0	:	0 -		0
	50-56 Days (Group 2)	50	4 (	<b>(%)</b>	4	0		3	(75*)	1	(25%)	0
	57-63 Days (Group 3)	42	0		0	0		0		0		0
RASH	≤63 Days (All)	115	1 (<	.%) 1.000	0 1	0		1	(100%)	0		0
	≤49 Days (Group 1)	23	0		0	0		0		0		0
	50-56 Days (Group 2)	50	1 (	· <b>*</b> )	1	0		1	(100%)	0		0
	57-63 Days (Group 3)	42	0		0	0		0		0		0
SKIN DISORDER	≤63 Days (All)	115	1 (<	(%) 1.000	0 1	0		1	(100%)	0		0
	s49 Days (Group 1)	23	0		0	0		0		0		0
	50-56 Days (Group 2)	50	1 (	<b>(%)</b>	1	0		1	(100%)	0		0
	57-63 Days (Group 3)	42	0		0	0		0		0		0
SWEATING INCREASED	≤63 Days (All)	1115	2 (:	(%) 0.679	6 2	0		1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	23	0		0	0		0		0		0
	50-56 Days (Group 2)	50	2 (-	1\$)	; <b>2</b>	0		1	(50%)	1	(50%)	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

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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Center: CREININ (#28)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severity		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	3 (3%	0.7916	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	23	1 (4%		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	50	1 (2%		1	0	; o	1 (100%)	0
	57 63 Days (Group 3)	42	1 (2%		1	0	1 (100%)	0	0
BONE DISORDER	≤63 Days (All)	115	1 (<1%	1.0000	1	0	0	1 (100%)	0
1	≤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
SKELETAL PAIN	≤63 Days (All)	115	2 (28	0.3173	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	23	1 (48		1	0	1 (100%)	Ŏ	0
	50-56 Days (Group 2)	50	0		0	0	0	0	ō
	57-63 Days (Group 3)	42	1 (2%		1	0	1 (100%)	0	0
INTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	54 (47%	0.4374	86	37 (43%)	40 (47%)	9 (10%)	0
	≤49 Days (Group 1)	23	9 (39%		12	7 (58%)	5 (42%)	0	0
· ·	50-56 Days (Group 2)	50	22 (44%		43	15 (35%)	21 (49%)	7 (16%)	0
	57-63 Days (Group 3)	42	23 (55%		31	15 (48%)	14 (45%)	2 (6%)	0
DIZZINESS	≤63 Days (All)	115	19 (17%	0.4389	21	16 (76%)	4 (19%)	1 (5%)	0
	≤49 Days (Group 1)	23	2 (9%		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	50	8 (16%	ļ	10	8 (80%)	2 (20%)	0	0
	57-63 Days (Group 3)	42	9 (21%		٠,	6 (67%)	2 (22%)	1 (11%)	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)

	Gestational	Total		nber	Fisher's								
Body System/Event [2]	Age Group [3]	Number of Pts		Pts Event	exact p-value	Number of Events		ld.		Severit erate	-	ere	Unknown
ENTR & PERSPH NERVOUS SYSTEM DISC	RDERS (cont.)	<del></del>			<u> </u>								<del></del>
HEADACHE	≰63 Days (All)	115	44	(38%)	0.9680	64	21	(33%)	35	(55%)	8	(13%)	0
	≤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	1	0	l l	0		0
	50 56 Days (Group 2)	50	0			0	0		0		þ.		0
	57-63 Days (Group 3)	42	1	(2%)		1	0		1	(100%)	0		0
EARING AND VESTIBULAR DISORDERS													•
ANY EVENT	≤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		0
	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
	≤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
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			. 0	0		0		0		0
	50-56 Days (Group 2)	50	5	(10%)		. 8	2	(25%)	4	(50%)	2	(25%)	0
	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.

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: CREININ (#28)

	Gestational	Total	Number	Fisher's	M		Samani	•	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS (cont.)				<del></del>					
ANOREXIA	≤63 Days (All)	115	1 (<1%)	0.5652	1	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	0	0
ANXIETY	≤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 (2%)		1	0	1 (100%)	O ·	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
	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	o	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	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	Į <b>O</b>	0
	57-63 Days (Group 3)	42	0		0	0	0	ю	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 Age	Total Number		ber Pts	Fisher's exact	Number				Severity	<b>,</b>		
Body System/Event (2)	Group [3]	of Pts	w/E	vent	p value	of Events	Mi	ld	Mode	rate	Se	vere	Unknown
PSYCHIATRIC DISORDERS (cont.)			-										
Insomnia	≤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
PARONIRIA	≤63 Days (All)	115	1	(<1%)	1.0000	2	0		1	(50%)	1	(50%)	0
ı	£49 Days (Group 1)	23	0			0	0		0		0		0
·	50  56 Days (Group 2)	50	1	(2%)		2	0		1	(5 <b>0%</b> )	1	(50%)	0
	57-63 Days (Group 3)	42	0			0	0		0		0		0
LASTRO-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		0		0
	57-63 Days (Group 3)	42	1	(2%)		1	0		0		1	(100%)	0
CONSTIPATION	≤63 Days (All)	115	3	(3%)	0.5960	3	3	(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	2	(5%)		2	2	(100%)	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

<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		1d		Severity	Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
DIARRHEA	≤63 Days (All)	115	45 (	391)	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 (4	40%)		30	14	(47%)	11	(37%)	5	(17%)	0
	57-63 Days (Group 3)	42	16 (	381)		20	16	(80%)	3	(154)	1	(5%)	0
DYSPEPSIA	≤63 Days (All)	115	3	(3%)	0.0967	3	2	(67%)	0		1	(33%)	0
	≤49 Days (Group 1)	23	0			0	0		0		0		0
'	50-56 Days (Group 2)	50	0	i		0	0		0	•	0.		0
	57-63 Days (Group 3)	42	3	(78)		3	2	(67%)	0	•	1	(33%)	0
FLATULENCE	s63 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
NAUSEA	≤63 Days (All)	115	93 (	81%)	0.0320	178	85	(48%)	61	(34%)	32	(18%)	0
	s49 Days (Group 1)	23	14 (	614)		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		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

<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.

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

Center: CREININ (#28)

	Gestational Age	Total Number	Num of		Fisher's exact	Number	<b></b>			Severit	y		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	1 <b>d</b>	Mode	rate	Sev	ere	Unknow
GASTRO-INTESTINAL SYSTEM DISORDERS (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	(33%)	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 DISORDERS													
ANY EVENT	≤63 Days (All)	115	3	(3%)	1.0000	; <b>3</b>	1	(33%)	2	(67%)	0		0
<b>'</b> .	≤49 Days (Group 1)	23	0			¹o	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	≤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	1	0		0		0
	57-63 Days (Group 3)	42	1	(2%)		1	0	,	1	(100%)	0		0
RHINITIS	s63 Days (All)	115	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	s49 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
	≤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		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					
Body System/Event {2}	Age Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
RINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	5 (4)	) 0.5170	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	23	1 (4)	)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	50	1 (2	)	1	1 (100%)	! o	0	0
	57-63 Days (Group 3)	42	3 (7	)	3	1 (33%)	2 (67%)	0	0
DYSURIA	≤63 Days (All)	115	1 (<1	) 0.5652	1	1 (100%)	0	o	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
'	50-56 Days (Group 2)	50	0		0 .	0	О '	<b>O</b> .	0
	57-63 Days (Group 3)	42	1 (2	)	1	1 (100%)	0	0	0
MICTURITION FREQUENCY	≤63 Days (All)	115	1 (<1	) 1.0000	1	1 (100%)	O	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	3	0	3 (100%)	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	2 (5	)	2	0	2 (100%)	0	0
EPRODUCTIVE DISORDERS, FEMALE							!		
ANY EVENT	≰63 Days (All)	115	27 (23	0.8453	30	9 (30%)	12 (40%)	9 (30%)	0
	≤49 Days (Group 1)	23	5 (22	)	6	2 (33%)	2 (33%)	2 (33%)	0
	50-56 Days (Group 2)	50	13 (26)	)	- 13	4 (31%)	6 (46%)	3 (23%)	0
	57-63 Days (Group 3)	42	9 (21)	)	• 11	3 (27%)	4 (36%)	4 (36%)	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)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Carrett	. <b>y</b>	
Body System/Event [2]	Group (3)	of Pts	w/Event	p·value	of Events	Mild	Moderate	Severe	Unknow
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
BREAST DISCHARGE	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
I .	≤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
ENDOMETRITIS	≤63 Days (All)	115	1 (<1%)	0.2000	1	1 (100%)	<b>o</b> ,	0	0
i i	≤49 Days (Group 1)	23	1 (4%)		1	1 (100%)	o !	,0	0
	50-56 Days (Group 2)	50	0		0	0	ο (	0.	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
LEUKORRHOEA	≤63 Days (All)	115	2 (2%)	0.6796	2	1 (50%)	1 (50%)	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	0		0	0	0	0	0
PELVIC INFLAMMATION	≤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
UTERINE HAEMORRHAGE	≤63 Days (All)	115	8 (7%)	0.8972	9	0	1 (11%)	8 (89%)	0
	₫49 Days (Group 1)	23	2 (9%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	50	3 (6%)		3	0	1 (33%)	2 (67%)	0
	57-63 Days (Group 3)	42	3 (7%)		4	0	0	4 (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 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	6	Fisher's exact	Number				Severi	•	<b>.</b> .	
Body System/Event [2]	Group [3]	of Pts	w/Ever	nt	p value	of Events	Mi	.1d	Mode	rate	Sev	ere	Unknow
REPRODUCTIVE DISORDERS, FEMALE (cont.)													
VAGINAL DISCOMFORT	≤63 Days (All)	115	2	(2%)	0.3173	2	1	(50%)	1	(50%)	0		0
	s49 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 (1	10%)	0.9261	13	4	(31%)	8	(62%)	1	(8%)	0
	s49 Days (Group 1)	23	2 (	(9%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	50	6 (1	12%)		6	1	(17%)	4	(67%)	1.	(17%)	0
	57-63 Days (Group 3)	42	4 (1	10%)		5	2	(40%)	3	(60%)	0		0
VULVA DISORDER	≤63 Days (All)	115	1 (<	<11)	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
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	s63 Days (All)	115	115 (10	00%)		493	191	(39%)	154	(31%)	148	(30%)	0
	≤49 Days (Group 1)	23	23 (10	00%)		89	37	(42%)	30	(34%)	22	(25%)	0
	50-56 Days (Group 2)	50	50 (10	00%)		214	78	(36%)	66	(31%)	70	(33%)	0
	57-63 Days (Group 3)	42	42 (10	001)		190	76	(40%)	58	(31%)	56	(29%)	0
ABDOMINAL PAIN	≤63 Days (All)	115	114 (>9	991)	1.0000	419	144	(34%)	135	(32%)	140	(33%)	0
	≤49 Days (Group 1)	23	23 (10	00%)		77	30	(39%)	27	(35%)	20	(26%)	0
	50-56 Days (Group 2)	50	49 (9	98%)		183	59	(32%)	57	(31%)	<b>\$7</b>	(37%)	0
	57-63 Days (Group 3)	42	42 (10	00%)		159	55	(35%)	51	(32%)	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

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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 Age	Total Number	Num of		Fisher's exact	Number				··Severit	V		
Body System/Event [2]	Group (3)	of Pts	w/E	vent	p value	of Events		ild		rate	•	ere	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (co	ont.)												
ASTHENIA	≤63 Days (All)	115	1	(<1%)	0.5652	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	23	0	1		0	0		0		0		0
	50 56 Days (Group 2)	50	0	1		0	0		0		0		0
	57-63 Days (Group 3)	42	1	(2%)		1	1	(100%)	0		0		0
BACK PAIN	≤63 Days:(All)	115	21	(18%)	0.5438	25	10	(40%)	9	(36%)	6	(24%)	0
1	≤49 Days (Group 1)	23	3	(13%)		3	2	(67%)	0	,,,,,	1	(33%)	ō
	50-56 Days (Group 2)	50	8	(16%)		9	2	(221)	5	(56%)	2	(22%)	ō
	57-63 Days (Group 3)	42	10	(24%)		13	6	(46%)	4	(31%)	3	(23%)	o
CHEST PAIN	s63 Days (All)	115	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	23	ō	/		o ·	0	(000)	ŏ		ŏ		n
	50-56 Days (Group 2)	50	ī	(2%)		ī	-	(100%)	Ö		ň		Ŏ
	57-63 Days (Group 3)	42	0			3	0	,,	Ō		ō		o
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		Ö
	57-63 Days (Group 3)	42	15	(36%)		15	13	(87%)	2		0		0
FEVER	≤63 Days (All)	115	2	(2%)	1.0000	2	2	(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	1	(2%)		1		(100%)	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.

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 -		Severi	t <b>v</b>	
Body System/Event [2]	Group (3)	of Pts	w/Event	p·value	of Events	Mild	Moderate	Severe	Unknow
ODY 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
1	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	<b>0</b> ·	0
	57-63 Days (Group 3)	42	0		0	0	o *	0	0
RIGORS	≤63 Days (All)	115	3 (3%)	0.2273	3	2 (67%)	0	1 (33%)	0
	≤49 Days (Group 1)	23	0 1		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	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	o	0
	s49 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
ESISTANCE NECHAMISM 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 (40%)	3 (60%)	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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Center: CREININ (#28)

	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	Unknown
ESISTANCE MECHANISH DISORDERS (cont.)		····	<del> </del>				*		
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)	1	0	1 (100%)	0	0
INFECTION FUNGAL	≤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
i	50-56 Days (Group 2)	50	1 (2	1)	1	0	1 (100%)	0 .	0
'	57-63 Days (Group 3)	42	0		0	0	0	0	0
INFECTION PARASITIC	≤63 Days (All)	115	2 (2	1.0000	2	0	2 (100%)	0	0
	s49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2	1)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	1 (2	1)	1	0	1 (100%)	0	0
INFECTION VIRAL	≤63 Days (All)	115	6 (5	0.6523	6	3 (50%)	3 (50%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	3 (6	1)	3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	42	3 (7	1)	3	2 (67%)	1 (33%)	0	0
SCONDARY TERMS									
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

<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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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 -	Mild	Severi Moderate	ty Severe	Unknown
ECONDARY TERMS (cont.)					1	***************************************			
BITE	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	. 0	1 (100%)	0
	≤49 Days (Group 1)	23	0		0	0	O	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	· · o	1 (100%)	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: SOGOR (#29)

Days (All) Days (Group 1) 56 Days (Group 2)	of Pts		vent	p value	of Events	Mi	ıa	Mode	erate	Sev	ere	Unki	
Days (Group 1)		70											nown
Days (Group 1)		20											
-		79	(95%)	1.0000	379	85	(22%)	160	(42%)	133	(35%)	1	(<11
56 Days (Group 2)	26	27	(96%)		124	25	(20%)	68	(55%)	30	(24%)	1	(<11)
	37	35	(95%)		165	34	(21%)	64	(39%)	67	(41%)	0	
63 Days (Group 3)	18	17	(94%)		90	26	(29%)	28	(31%)	36	(40%)	0	
Days (All)	83	1	(1%)	0.5542	1	0	1	1	(100%)	.0		0	
Days (Group 1)	28	1	(4%)		1	0		1	(100%)	0		0	
56 Days (Group 2)	37	0			0	0		0	.,	0		0	
63 Days (Group 3)	18	0			0	0		0		0		0	
Days (All)	83	1	(1%)	0.5542	1	0		1	(100%)	0		0	
Days (Group 1)	28	1	(4%)		1	0		1	(100%)	0		0	
56 Days (Group 2)	37	0			0	0		0		0.,	•••	0	
63 Days (Group 3)	18	0			0	0		0		0		0	
Days (All)	83	22	(27%)	0.6226	31	9	(29%)	15	(48%)	7	(23%)	0	
Days (Group 1)	28	8	(29%)		11	3	(27%)	7	(64%)	1	(9%)	0	
66 Days (Group 2)	37	8	(22%)		8	2	(25%)	5	(63%)	1	(13%)	0	
63 Dave (Group 3)	18	6	(33%)		12	4	(33%)	2	(25\$)	=	(428)	۸	
5	6 Days (Group 2) 3 Days (Group 3) Days (All) Days (Group 1) 6 Days (Group 2) 3 Days (Group 3) Days (All) Days (Group 1)	6 Days (Group 2) 37 3 Days (Group 3) 18  Days (All) 83 Days (Group 1) 28 6 Days (Group 2) 37 3 Days (Group 3) 18  Days (All) 83 Days (Group 1) 28 6 Days (Group 1) 28 6 Days (Group 2) 37	6 Days (Group 2) 37 0 3 Days (Group 3) 18 0 Days (All) 83 1 Days (Group 1) 28 1 6 Days (Group 2) 37 0 3 Days (Group 3) 18 0 Days (All) 83 22 Days (Group 1) 28 8 6 Days (Group 2) 37 8	6 Days (Group 2) 37 0 3 Days (Group 3) 18 0  Days (All) 83 1 (1%) Days (Group 1) 28 1 (4%) 6 Days (Group 2) 37 0 3 Days (Group 3) 18 0  Days (All) 83 22 (27%) Days (Group 1) 28 8 (29%) 6 Days (Group 2) 37 8 (22%)	6 Days (Group 2) 37 0 3 Days (Group 3) 18 0  Days (All) 83 1 (1% 0.5542  Days (Group 1) 28 1 (4%) 6 Days (Group 2) 37 0 3 Days (Group 3) 18 0  Days (All) 83 22 (27% 0.6226  Days (Group 1) 28 8 (29%) 6 Days (Group 2) 37 8 (22%)	6 Days (Group 2) 37 0 0 3 Days (Group 3) 18 0 0  Days (All) 83 1 (1%) 0.5542 1 Days (Group 1) 28 1 (4%) 1 6 Days (Group 2) 37 0 0 3 Days (Group 3) 18 0 0  Days (All) 83 22 (27%) 0.6226 31 Days (Group 1) 28 8 (29%) 11 6 Days (Group 2) 37 8 (22%) 8	6 Days (Group 2) 37 0 0 0 0 3 Days (Group 3) 18 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 Days (Group 2) 37 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 Days (Group 2) 37 0 0 0 0 0 3 Days (Group 3) 18 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 Days (Group 2) 37 0 0 0 0 0 0 3 Days (Group 3) 18 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 Days (Group 2) 37 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 Days (Group 2) 37 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 Days (Group 2) 37 0 0 0 0 0 0 0 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

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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: SOGOR (#29)

	Gestational Age	Total Number	Num of		Fisher's exact	Number	<b></b>	· · · · ·		Severi	ty		
Body System/Event [2]	Group [3]	of Pts	w/Event		p value	of Events	Mild		Mode	rate	-	ere	Unknow
PSYCHIATRIC DISORDERS (cont.)													
DEPRESSION	≤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		0		0		0
	57-63 Days (Group 3)	18	0			0	0		0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	83	48	(58%)	0.8080	115	18	(16%)	43	(37%)	54	(47%)	0
:	≤49 Days (Group 1)	28	15	(54%)		29	3	(10%)	12	(41%)	14	(48%)	o
	50-56 Days (Group 2)	37	23	(621)		55	6	(11%)	23	(42%)	26	(47%)	ō
	57-63 Days (Group 3)	18	10	(56%)		31	9	(29%)	8	(26%)	14	(45%)	ō
DIARRHEA	≤63 Days (All)	83	13	(16%)	0.7334	16	3	(19%)	. 6	(38%)	7	(44%)	0
	≤49 Days (Group 1)	28	3	(11%)	011221	3	0	(2) 2)	1	(33%)	2		0
	50-56 Days (Group 2)	37	7	(19%)		9	1	(11%)	5	(56%)	3		. 0
	57-63 Days (Group 3)	18	3			4	2	(50%)	ő	(300)	2		0
DYSPEPSIA	≤63 Days (All)	83	2	(2%)	0.0450	2	2	(100%)	0		0		o
	≤49 Days (Group 1)	28	0	•		0	0		o		0		ō
	50-56 Days (Group 2)	37	0			0	0		ō		0		ō
	57-63 Days (Group 3)	18	2	(11%)		2	2	(100%)	ō		0		ō
NAUSEA	≤63 Days (All)	83	39	(47%)	0.5120	55	10	(18%)	23	(42%)	22	(40%)	0
	s49 Days (Group 1)	28	12	(43%)		16	3	(19%)	7	(44%)	. 6	(38%)	ō
	50-56 Days (Group 2)	37	20	(54%)		27	5	(19%)	11	(41%)	111	(41%)	0
	57-63 Days (Group 3)	18	7	(39%)		12	2	(17%)	5		1 5	(42%)	ō

<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: SOGOR (#29)

Age Group [3]  s63 Days (All) s49 Days (Group 1)	of Pts	of Pts w/Event	exact p-value	Number of Events	Mild '	Severity Moderate	Severe	Unknown
s49 Days (Group 1)	83						_	Unknowr
s49 Days (Group 1)	83							
		1 (19	0.5542	1	0	0	1 (100%)	0
	28	1 (41	)	1	0	0	1 (100%)	0
50-56 Days (Group 2)	37	0		0	0	0	0	0
57-63 Days (Group 3)	18	0 .		0	0	0	<b>o</b>	0
≤63 Days (All)	83	28 (34)	) 0.7612	41	3 (7%)	14 (34%)	24 (59%)	0
≤49 Days (Group 1)	28	8 (29	)	9	0	4 (44%)	5 (56%)	' o
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
≤63 Days (All)	83	1 (1	1.0000	1	0	. 1 (100%)	0	0
s49 Days (Group 1)	28	0		, <b>o</b>	0	o '	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
≤63 Days (All)	83	1 (1	) 1.0000	1	0	1 (100%)	0	0
s49 Days (Group 1)	28	0		0	0	0	0	0
50-56 Days (Group 2)	37	1 (31	)	1	0	1 (100%)	0	0
57-63 Days (Group 3)	18	0		0	0	0	0	0
≤63 Days (All)	83	1 (19	0.5542	1	0	1 (100%)	0	0
s49 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
	57-63 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 3)  s63 Days (Group 1) 50-56 Days (Group 3)  s63 Days (Group 1) 50-56 Days (Group 3)	\$63 Days (All) 83  \$49 Days (Group 1) 28  \$50-56 Days (Group 2) 37  \$7-63 Days (Group 3) 18   \$63 Days (All) 83  \$49 Days (Group 1) 28  \$50-56 Days (Group 1) 28  \$50-56 Days (Group 2) 37  \$7-63 Days (Group 3) 18  \$63 Days (All) 83  \$49 Days (Group 3) 18  \$63 Days (All) 83  \$49 Days (Group 1) 28  \$50-56 Days (Group 2) 37  \$7-63 Days (Group 3) 18  \$63 Days (All) 83  \$49 Days (Group 3) 18	57-63 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  s63 Days (All) s49 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  s63 Days (All) s49 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 3)  s63 Days (All) s49 Days (Group 3)  s63 Days (Group 1) 50-56 Days (Group 3)  s63 Days (Group 3)  s63 Days (Group 3)  s63 Days (Group 3)  s64 Days (Group 3)  s65 Days (Group 3)  s65 Days (Group 3)  s66 Days (Group 3)  s67 Days (Group 3)  s68 Days (All) s69 Days (Group 3)	\$63 Days (All)	57-63 Days (Group 3) 18 0 0 0  s63 Days (All) 83 28 (34%) 0.7612 41 s49 Days (Group 1) 28 8 (29%) 9  50-56 Days (Group 2) 37 14 (38%) 19 57-63 Days (Group 3) 18 6 (33%) 13  s63 Days (All) 83 1 (1%) 1.0000 1 s49 Days (Group 1) 28 0 0 50-56 Days (Group 2) 37 1 (3%) 1 57-63 Days (Group 3) 18 0 0  s63 Days (All) 83 1 (1%) 1.0000 1 s49 Days (Group 3) 18 0 0  s63 Days (All) 83 1 (1%) 1.0000 1 s49 Days (Group 1) 28 0 0 50-56 Days (Group 2) 37 1 (3%) 1 57-63 Days (Group 3) 18 0 0  s63 Days (All) 83 1 (1%) 1.0000 1 s49 Days (Group 3) 18 0 0  s63 Days (Group 3) 18 0 0 0	57-63 Days (Group 3) 18 0 0 0 0  s63 Days (All) 83 28 (34%) 0.7612 41 3 (7%) s49 Days (Group 1) 28 8 (29%) 9 0  50-56 Days (Group 2) 37 14 (38%) 19 0  57-63 Days (Group 3) 18 6 (33%) 13 3 (23%)  s63 Days (All) 83 1 (1%) 1.0000 1 0  s49 Days (Group 1) 28 0 0 0 0  50-56 Days (Group 2) 37 1 (3%) 1 0  57-63 Days (Group 3) 18 0 0 0 0  s63 Days (All) 83 1 (1%) 1.0000 1 0  s63 Days (Group 3) 18 0 0 0 0  s63 Days (Group 1) 28 0 0 0 0  50-56 Days (Group 2) 37 1 (3%) 1 0  57-63 Days (Group 3) 18 0 0 0 0  s63 Days (Group 3) 18 0 0 0 0  s63 Days (Group 3) 18 0 0 0 0  s63 Days (Group 3) 18 0 0 0 0  s649 Days (Group 3) 18 0 0 0 0  s650 Days (Group 3) 18 0 0 0 0 0	57-63 Days (Group 3)       18       0       0       0       0         s63 Days (Al1)       83       28       (34%)       0.7612       41       3       (7%)       14       (34%)         s49 Days (Group 1)       28       8       (29%)       9       0       4       (44%)         50-56 Days (Group 2)       37       14       (38%)       19       0       7       (37%)         57-63 Days (Group 3)       18       6       (33%)       13       3       (23%)       3       (23%)         s63 Days (Al1)       83       1       (1%)       1.0000       1       0       1       (100%)         s49 Days (Group 1)       28       0       0       0       0       0       0         s63 Days (Al1)       83       1       (1%)       1.0000       1       0       1       (100%)         s49 Days (Group 1)       28       0       0       0       0       0       0       0       0         57-63 Days (Group 2)       37       1       (3%)       1       0       1       (100%)       1       (100%)       0       0       0       0       0       0 <t< td=""><td>57-63 Days (Group 3) 18 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td></t<>	57-63 Days (Group 3) 18 0 0 0 0 0 0 0 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 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SOGOR (#29)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severit	y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
HEART RATE, AND RHYTHM DISORDERS (cont.)									
TACHYCARDIA	≤63 Days (All)	83	1 (19	0.5542	1	0	1 (100%)	0	0
	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
ESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	2 (2)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	28	1 j(41	)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (31	)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	o <sup>!</sup>		0	0	0	0	0
ASTHMA	≤63 Days (All)	83	1 (1	0.5542	1	0	1 (1004)	0	0
	≤49 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
SINUSITIS	≤63 Days (All)	83	1 (19	) 1.0000	1	0	1 (100%)	<b>0</b> :	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
LATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤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 (31	)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	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 5a (Continued) Adverse Events [1] By Center (Safety Evaluable Patients)

Center: SOGOR (#29)

	Gestational	Total	Numb		Fisher's	N.,_b			Caucauit		
Body System/Event [2]	Age Group [3]	Number of Pts	of E		exact p·value	Number of Events	Mild '		·-·-Severit Noderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORD	ERS (cont.)						· . — · · · · · · · · · · · · · · · · ·				
EPISTAXPS	≤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
URINARY SYSTEM DISORDERS											
ANY EVENT	≤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	0	0
URINARY TRACT INFECTION	≤63 Days (All)	83	1	(1%)	1.0000	1	0		1 (100%)	0	0
	#49 Days (Group 1)	28	0			0	0		о ′	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	1	0	0	0
REPRODUCTIVE DISORDERS, PEMALE											
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	(6%)		1	0		0	1 (100%)	0

<sup>[11]</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.

Center: SOGOR (#29)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Onune de				
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild		Mode	Severit rate	•	/ere	Unk	known
EPRODUCTIVE DISORDERS, FEMALE (cont.)													
BREAST DISCHARGE	≤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		0		0	
BREAST PAIN FEMALE	s63 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		0		0		0	
	57-63 Days (Group 3)	18	0		0	0		0		0		0	
UTERINE HAEMORRHAGE	≤63 Days (All)	83	2 (2%)	0.6956	2	0		0		2	(100%)	0	
ı	≤49 Days (Group 1)	28	0		0	0	•	0	1	0		0	
	50-56 Days (Group 2)	37	1 (3%)		1	0		0		1	(100%)	0	
1	57-63 Days (Group 3)	18	1 (6%)		1	0		0		1	(100%)	0	
DDY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	83	74 (89%)	0.5331	214	58 (	27%)	86	(40%)	69	(32%)	1	(<11
	≤49 Days (Group 1)	28	26 (93%)		75	19 (	25%)	40	(53%)	15	(20%)	1	(11
	50-56 Days (Group 2)	37	33 (89%)		94	26 (	28%)	30	(32%)	38	(40%)	0	
ş.	57-63 Days (Group 3)	18	15 (83%)		45	13 (	29%)	16	(36%)	16	(36%)	0	
ABDOMINAL PAIN	≤63 Days (All)	83	74 (89%)	0.5331	198	53 (	27%)	77	(39%)	67	(34%)	1	(<11
	≤49 Days (Group 1)	28	26 (93%)	1	70	17 (	24%)	37	(53%)	15	(21%)	1	(11
	50-56 Days (Group 2)	37	33 (89%)	i	87	25 (	29%)	26	(30%)	36	(41%)	0	
	57-63 Days (Group 3)	18	15 (83%)	;	41	11 (	271)	14	(34%)	16	(39%)	0	

<sup>[1]</sup> Includes all adverse event's 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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Center: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p·value		Mild '	Severit	y Severe	Unknow
	0.000 (0)		,	<b>P</b>					
ODY AS A WHOLE - GENERAL DISORDERS	•								
ALLERGY *	≤63 Days (All)	83	1 (1%	1.0000	1	0	1 (100%)	0	0
	s49 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
BACK PAIN	s63 Days (All)	83	4 (5%	0.8173	5	1 (20%)	3 (60%)	1 (20%)	0
	s49 Days (Group 1)	28	2 (7%	)	2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	37	1 (3%	)	2	Ø	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	18	1 (6%	)	1	0	1 (100%)	i o	0
CHEST PAIN	≰63 Days (All)	83	1 (1%	0.2169	1	o	1 (100%)	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
	57-63 Days (Group 3)	18	1 (6%	)	1	0	1 (100%)	0 .	0
FEVER	≤63 Days (All)	83	4 (5%	0.8173	4	2 (50%)	2 (50%)	o	0
1	s49 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%)	0	0
	57-63 Days (Group 3)	18	1 (6%	)	1	1 (100%)	0	O	0
MALAISE	≤63 Days (All)	83	2 (2%	1.0000	2	0	2 (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	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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FINAL

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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.

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

Center: SOGOR (#29)

Parks Guatan / Purant 121	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severity-		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ODY AS A WHOLE - GENERAL DISORDERS (cont	.)								
OEDEMA	≤63 Days (All)	83	1 (1%)	0.2169	1	1 (100%)	0	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
	57-63 Days (Group 3)	18	1 (6%)		1	1 (100%)	0	0	0
PAIN	≤63 Days (All)	83	1 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	83	4 (5%)	1.0000	5	0	5 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		2	0	2 (100%)	0	Ŏ
	50-56 Days (Group 2)	37	2 (5%)		2	0	2 (100%)	0	Ō
	57-63 Days (Group 3)	18	1 (6%)		1	0	1 (100%)	0	0
INFECTION	≤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%)	o	0
	57-63 Days (Group 3)	18	0 ,		0	0	0	0	0
INFECTION PARASITIC	s63 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	0	0	0
	57-63 Days (Group 3)	18	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: SOGOR (#29)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			··Severit	·v	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ESISTANCE NECHANISM DISORDERS (cont.)							· · · · · · · · · · · · · · · · · · ·		
INFECTION VIRAL	≤63 Days (All)	83	3 (4	1.0000	3	0	3 (100%)	0	0
	s49 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	ō
	· · · · · ·								

<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: POINDEXTER (#21)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severit	<b>y</b>		
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events	Mi	1d '		rate	•	ere	Unknow
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	(00)	Ô
	50-56 Days (Group 2)	26	18	(691)		36	18	(50%)	14	(391)	4	(11%)	Ô
	57-63 Days (Group 3)	17	11	(65%)		29	13	(45%)	12		4		ŏ
ENTR & PERIPH MERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	71	12	(17%)	0.0639	16	7	(44%)	7	(44%)	2	(13%)	0
	≤49 Days (Group 1)	28	7	(25%)		, 7	4	(57%)	3	(43%)	0	·	0
	50-56 Days (Group 2)	26	1	(4%)		3	1	(33%)	1	(33%)	1	(33%)	0
!	57-63 Days (Group 3)	17	4	(24%)		6	2	(33%)	3		1	(17%)	0
DIZZINESS	≤63 Days (All)	71	3	(4%)	0.0119	4	1	(25%)	. 2	(50,8)	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 Days (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
SYCHIATRIC DISORDERS													
ANY EVENT	≤63 Days (All)	71	2	(3%)	0.7070	3	0		2	(67%)	1	(33%)	0
	≤49 Days (Group 1)	28	1	(4%)		1	0			(100%)	ō		0
	50-56 Days (Group 2)	26	0			0	0		0		0		0
	57-63 Days (Group 3)	17	1	(6%)		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 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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Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Numb of P w/Ev	Pts .	Fisher's exact p-value	Number of Events				Severit erate	•	ere	Unknown
PSYCHIATRIC DISORDERS	(cont.)			<del></del>								- <del></del>	
INSOMNIA	≤63 Days (All)	71	2	(3%)	0.7070	3	0		2	(67%)	1	(33%)	0
	≤49 Days (Group 1)	28	1	(4%)		1	Ó			(100%)	ō		0
	50-56 Days (Group 2)	26	0			0	0		0	,	ō		0
	57-63 Days (Group 3)	17	1	(6%)		2	0		1	(50%)	1	(50%)	o
LASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	71	32	(45%)	0.3338	44	22	(50%)	19	(43%)	3	(7%)	0
	≤49 Days (Group 1)	28	10	(36%)		14	7	(50%)	7	(50%)	0		0
	50-56 Days (Group 2)	26	12	(46%)		16	10	(63%)	5	(31%)	1	(6%)	0
	57-63 Days (Group 3)	17	10	(59%)		14	5	(36%)	7		2	(14%)	0
DIARRHEA	≤63 Days (All)	71	2	(3%)	0.1855	2	2	(100%)	. 0	,	0		0
	≤49 Days (Group 1)	28	0			0	0		0		. 0		0
	50-56 Days (Group 2)	26	2	(8%)		2	2	(100%)	0		0		Ö
•	57-63 Days (Group 3)	17	0			0	0		0		0		0
FLATULENCE	≤63 Days (All)	71	. 2	(3%)	1.0000	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	28	1	(4%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	26	1	(4%)		1	1	(100%)	0		0		0
!	57-63 Days (Group 3)	17	0			0	0	}	0		0		0
NAUSEA	≤63 Days (All)	71	23	(32%)	0.1340	25	11	(44%)	13	(521)	1	(4%)	0
	≤49 Days (Group 1)	28	7	(25%)	1	8	4	(50%)	4	(50%)	0		0
	50-56 Days (Group 2)	26	7	(27%)		7	4	(57%)	3	(43%)	0		0
	57-63 Days (Group 3)	17	9	(53%)	ţ	10	3	(30%)	6	(60%)	1	(10%)	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.

Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Numb of E w/E	Pts	Fisher's exact p-value	Number of Events		, 1 <b>d</b>		Severity- lerate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)											
VOMITING	≤63 Days (All)	71	14	(20%)	0.9300	15	7	(47%)	•	(40%)	2 (13%)	0
	≤49 Days (Group 1)	28	5	(18%)		5	2	(40%)	1 3	(60%)	0	0
	50-56 Days (Group 2)	26	5	(19%)		6	3	(50%)	! :	(33%)	1 (17%)	0
	57-63 Days (Group 3)	17	4	(24%)		4	2	(50%)	1	(25%)	1 (25%)	0
VASCULAR (EXTRACARDIAC) DISORDERS												
ANY EVENT	≤63 Days (All)	71	1	(1%)	0.6056	1	0		1	(100%)	0	0
	≤49 Days (Group 1)	28	0			0	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
FLUSHING	≤63 Days (All)	71	1	(1%)	0.6056	1	0		. ,	(100%)	0	0
	≤49 Days (Group 1)	28	0			0	Ó			)	0	0
	50-56 Days (Group 2)	26	1	(4%)		1	Ö		1	(100%)	Ō	0 .
1	57-63 Days (Group 3)	17	0			0	0		(	)	0	0
RESPIRATORY SYSTEM DISORDERS	/											
ANY EVENT	≤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
İ	50-56 Days (Group 2)	26	0			0	0	1		)	0	0
:	57-63 Days (Group 3)	17	0			0	. 0	i		)	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.

Center: POINDEXTER (#21)

	Gestational	Total	Number		Fisher's								
Body System/Event	Age Group [2]	Number of Pts	of Pti w/Eve		exact   p-value	Number of Events		1d '	Mode	Severi rate	•	ere	Unknow
RESPIRATORY SYSTEM DISORDERS	(cont.)												
PULMONARY CONGESTION	≤63 Days (All)	71	1	(1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	28		(4%)		1	0			(100%)	0		0
	50-56 Days (Group 2)	26	ō	,		n	ŏ		Ô	(1004)	0		0
	57-63 Days (Group 3)	17	Ō			ō	ō		o		ō		o
REPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	71	1	(1%)	0.6056	1	1.	(100%)	0		D		0
	≤49 Days (Group 1)	28	0			ō	0	,	ō	1	ō		0
	50-56 Days (Group 2)	26	1	(4%)		1	-	(100%)	ō		Ιō		Ô
	57-63 Days (Group 3)	17	0			0	0	, ,	0		0		ō
LEUKORRHOEA	≤63 Days (All)	71	1	(1%)	0.6056	1	1	(100%)	. 0		0		0
	≤49 Days (Group 1)	28	0			0	ō		ō	•	ō		ň
	50-56 Days (Group 2)	26	1	(4%)		1	1	(100%)	Ŏ		ō		ň
	57-63 Days (Group 3)	17	0			Ō	ō	,,	ō		ŏ	!	ŏ
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	s63 Days (All)	71	33 (4	46%)	0.2664	37	21	(57%)	14	(38%)	2	(5%)	0
	≤49 Days (Group 1)	28		54%)		15	9	(60%)	6	(40%)	-	,	Ô
	50-56 Days (Group 2)	26		50%)		15	6	(40%)	7	(47%)	2	(13%)	ō
	57-63 Days (Group 3)	17		29%)		7	6	(861)	i	(14%)	ō	3 • /	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)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Numi of i w/E		Fisher's exact p.value	Number of Events	 Mi	, i1d	Mode	Severit	y····· Sev		Unknow
DANY NO A WHALL ADVENTAGE DECARRAGE					•								
ODY AS A WHOLE - GENERAL DISORDERS ABDOMINAL PAIN	(cont.) ≤63 Days (All)	71	20	(205)				/== <b>4</b> \			_		_
ADDOMINAD FAIN	•	_	28	(39%)	0.2916	30	17		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	į	. 0
ASTHENIA	≤63 Days (All)	71	1	(1%)	0.2394	1	,	(100%)	0		0	•	0
	≤49 Days (Group 1)	28	Ô	(14)	0.2354	•	ò	(1004)	0		•		. 0
	50-56 Days (Group 2)	26	0			•	۰		0		•		0
	57-63 Days (Group 3)	17	1	(6%)		1	1	(100%)	0		0		0
	0 00 00 00 00 00 00 00 00 00 00 00 00 0		-	(0,0)		•	-	(1000)	٠		•		v
BACK PAIN	≤63 Days (All)	71	2	(3%)	1.0000	2	1	(50%)	1	(50%)	0		0
	s49 Days (Group 1)	28	1	(4%)		1	1	(100%)	. 0	1	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	s63 Days (All)	71	1	(1%)	0.2394	2	2	(100%)	0		0		0
	s49 Days (Group 1)	28	0			0	0		ō		Ô		Ô
	50-56 Days (Group 2)	26	0			0	Ó		ō		ō		Ô
	57-63 Days (Group 3)	17	1	(6%)		2	2	(100%)	Ō		ō		ŏ
FEVER	≤63 Days (All)	71		(14)	0.6056	,			•	(1008)	•		_
1 0 1 0 1	-		,	(14)	0.6056	1	0			(100%)	0		0
	s49 Days (Group 1)	28	0	/483		0	0		0		0		0
	50-56 Days (Group 2)	26	1	(4%)		1	0			(100¥)	0		0
	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.

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severit	· <b>V</b>	
Body System/Event	Group (2)	of Pts	w/Event	p-value	of Events	Mild '	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cost.)								
RIGORS 4	≤63 Days (All)	71	1 (1%)	1.0000	1	0 .	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (1001)	0	Ó
	50-56 Days (Group 2)	26	0 .		0	0	0	0	0
	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.

Center: VARGAS (#22)

	Gestational	Total		ber	Fisher's								
Body System/Event	Age Group [2]	Number of Pts	of w/E	Pts vent	exact p-value	Number of Events		1d		Severit erate	•	ere	Unknown
							-						
ANY EVENT	≤63 Days (All)	151	122	(81%)	0.9300	278	108	(39%)	139	(50%)	31	(11%)	0
	≤49 Days (Group 1)	70	57	(81%)		132	52	(39%)	69	(52%)	11	(8%)	0
	50-56 Days (Group 2)	43	35	(81%)		83	31	(37%)	41	(49%)	11	(13%)	0
	57-63 Days (Group 3)	38	30	(79%)		63	25	(40%)	29	(46%)	9	(14%)	0
USCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	≤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	ļ		0	0		0		0		0
ARTHRALGIA	≤63 Days (All)	151	1.	(<1%)	0.5364	1	0		. 1	(100%)	0		0
	s49 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
ENTR & PERIPH MERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	151	43	(28%)	0.8219	50	24	(48%)	21	(42%)	5	(10%)	0
	≤49 Days (Group 1)	70	19	(27%)		22	13	(59%)	8	(36%)	1	(5%)	0
	50-56 Days (Group 2)	43	14	(33%)		16	7	(44%)	8	(50%)	1	(61)	0
	57-63 Days (Group 3)	38	10	(26%)		12	4	(33%)	5		3	(25%)	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

 $\label{local_sas_general} \textbf{J}: \texttt{\sc 30NOV98:10:58}$ 

<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		ber Pts	Fisher's exact	Number			••••	Severit	v		
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events	M:	ild '	Mode		•	ere	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISORI	DERS (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%)	ō		ō
	50-56 Days (Group 2)	43	4	(9%)		4	1	(25%)	3	(75%)	ō		ň
	57-63 Days (Group 3)	38	4	(11%)		4	1	(25%)	2	(50%)	1	(25%)	ō
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		0
HYPOAESTHESIA	≤63 Days (All)	151	1	(<1%)	1.0000	•		(100%)					
,	≤49 Days (Group 1)	70	1	(11)	1.0000			1	0		0		0
	50-56 Days (Group 2)	43	ō	(10)		•		(1004)	. 0	,	0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
BARING AND VESTIBULAR DISORDERS		1						ĺ					
ANY EVENT	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0		0
	s49 Days (Group 1)	70	0			0	0		0	,,	0		Ô
	50-56 Days (Group 2)	43	0			0	0		0		ō		ň
	57-63 Days (Group 3)	38	1	(3%)		1	0		1	(100%)	ō		ŏ
TINNITUS	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0		0
	s49 Days (Group 1)	70	0		_	ō	ō		ō	(2007)	0		0
	50-56 Days (Group 2)	43	0			Ó	ō		Ô		n		Õ
	57-63 Days (Group 3)	38	1	(3%)		1	ō		•	(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)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Numb of I w/Ev	Ptø	Fisher's exact p-value	Number of Events		, 11d			Severit		vere	Unknown
PSYCHIATRIC DISORDERS					•									OII.TIOWI
ANY EVENT	≤63 Days (All)	151	8	(5%)	0.8096		,	(13%)			(638)		(255)	•
	≤49 Days (Group 1)	70	4	(6%)	0.0090	4	•	(25%)	1	5	(63%) (75%)	2	(25%)	0
	50-56 Days (Group 2)	43	3	(7%)		,	0	(234)	i	-		0	(226)	0
	57.63 Days (Group 3)	38	1	(3%)		1	0		;	2	(67%)		(33%) (100%)	0
			_	(30)		-	٠			•		•	(1004)	U
ANOREXIA	≤63 Days (All)	151	2	(1%)	0.2861	2	0			1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	70	0			0	0			0	(555)	0	(300)	ŏ
	50 56 Days (Group 2)	43	1	(21)		1	0			1	(100%)	ō		n
	57-63 Days (Group 3)	38	1	(3%)		1	0			ō	(2000)	1	(100%)	ŏ
EMOTIONAL LABILITY	≤63 Days (All)	151	_	(3.8.)	1.0000		_			_				
and to the land to	s49 Days (Group 1)	70	2	(1%)	1.0000	2	1		_	0		1	(50%)	0
	50-56 Days (Group 2)			(1%) (2%)		1		(100%)	•	0	t	0		0
	57-63 Days (Group 3)	43 38	1	(24)		ī	0			0			(100%)	0
İ	37-03 Days (Gloup 37	30	0			0	U			0		0		0
INSOMNIA	≤63 Days (All)	151	4	(3%)	0.6950	4	0				(100%)	0		0
	≤49 Days (Group 1)	70	. 3	(4%)		3	Ô				(100%)	ō		Ô
	50-56 Days (Group 2)	43	1	(2%)		1	0				(100%)	ō		Ô
	57-63 Days (Group 3)	38	0			0	0			0	(000)	ō		o :
ASTRO-INTESTINAL SYSTEM DISORDERS														
ANY EVENT	s63 Days (All)	151	75	(50%)	0.8332	95	30	(32%)	9	2	(55%)	13	(14%)	0
	≤49 Days (Group 1)	70	34	(49%)	!	40	12	(30%)		14	(60%)	4	(10%)	ō
	50-56 Days (Group 2)	43		(53%)	į	31	8	(26%)		7	(55%)	6		Ö
	57-63 Days (Group 3)	38		(47%)	1	24	10	(42%)		1	(46%)		(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

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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)

Age	Total Number		ber Pts	Fisher's exact	Number	<b></b>	<b></b>		Severit	y		
Group [2]	of Pts	w/E	vent	p-value	of Events	Mi	1 <b>d</b> '	Mode	rate	Sev	ere	Unknown
(cont.)												
≤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		0		o
50-56 Days (Group 2)	43	2	(5%)		2	1	(50%)	1		0		Ö
57-63 Days (Group 3)	38	0			0	0	,,,,,	0	,	0		ō
≤63 Days (All)	151	1	(<1%)	1.0000	1	0		1	(100%)	0		0
•	70	1	(1%)		1	0			•	-		ő
	43	0			0	0 '		0	, , ,	-		ō
57-63 Days (Group 3)	38	0			0	0		0		lo		ō
≤63 Days (All)	151	65	(43%)	0.7560	65	25	(38%)	30	(46%)	10	(15%)	0
• • • • • • • • • • • • • • • • • • •	70									4		ŏ
•	43	20							•	4		Ö
57-63 Days (Group 3)	38	17	(45%)		17	9	(53%)	6	(35%)	2		ō
≤63 Days (All)	151	26	(17%)	0.6197	26	4	(15%)	19	(73%)	3	(121)	0
s49 Days (Group 1)	70	10	(14%)		10	1		9		0	,,	ō
50-56 Days (Group 2)	43	9	(21%)		9	2		5		2	(221)	0
57-63 Days (Group 3)	38	7	(18%)		7	1	(14%)	5	(71%)	1	•	0
≤63 Days (All)	151	1	(<1%)	0.5364	1	0		1	(100%)	0		0
s49 Days (Group 1)	70	0			0	0		0		0		ō
50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	Ō		Ö
57-63 Days (Group 3)	38	0			0	0		o	•	ō		ō
-	Group [2]  (comt.) <pre> 463 Days (All)  489 Days (Group 1)  50-56 Days (Group 3)  463 Days (All)  489 Days (Group 1)  50-56 Days (Group 1)  50-56 Days (Group 3)  463 Days (All)  489 Days (Group 1)  50-56 Days (Group 1)  50-56 Days (Group 2)  57-63 Days (Group 3)  463 Days (All)  489 Days (Group 1)  50-56 Days (Group 3)  463 Days (All)  489 Days (Group 3)  463 Days (Group 1)  50-56 Days (Group 3)  463 Days (Group 1)  50-56 Days (Group 3)</pre>	Group [2] of Pts  (cost.)  s63 Days (All) 151  s49 Days (Group 1) 70  50-56 Days (Group 2) 43  57-63 Days (Group 3) 38  s63 Days (All) 151  s49 Days (Group 1) 70  50-56 Days (Group 2) 43  57-63 Days (Group 3) 38  s63 Days (All) 151  s49 Days (Group 3) 38  s63 Days (All) 151  s49 Days (Group 1) 70  50-56 Days (Group 2) 43  57-63 Days (Group 3) 38  s63 Days (All) 151  s49 Days (Group 1) 70  50-56 Days (Group 3) 38  s63 Days (All) 151  s49 Days (Group 1) 70  50-56 Days (Group 3) 38  s63 Days (All) 151  s49 Days (Group 3) 38	Group [2] of Pts w/E  (cont.)  s63 Days (All) 151 3 s49 Days (Group 1) 70 1 50-56 Days (Group 2) 43 2 57-63 Days (Group 3) 38 0  s63 Days (All) 151 1 s49 Days (Group 1) 70 1 50-56 Days (Group 2) 43 0 57-63 Days (Group 3) 38 0  s63 Days (All) 151 65 s49 Days (Group 3) 38 0  s63 Days (All) 151 65 s49 Days (Group 1) 70 28 50-56 Days (Group 2) 43 20 57-63 Days (Group 3) 38 17  s63 Days (All) 151 26 s49 Days (Group 3) 38 7  s63 Days (All) 151 26 s49 Days (Group 1) 70 10 50-56 Days (Group 2) 43 9 57-63 Days (Group 3) 38 7	Group [2]   of Pts   w/Event	Group [2]   Of Pts   W/Event   p-value	Group [2]         of Pts         w/Event         p-value         of Events           {cont.}         #63 Days (All)         151         3 (2%)         0.4489         3           #49 Days (Group 1)         70         1 (1%)         1           50-56 Days (Group 2)         43         2 (5%)         2           57-63 Days (Group 3)         38         0         0           #63 Days (All)         151         1 (1%)         1.0000         1           #49 Days (Group 1)         70         1 (1%)         1         1           50-56 Days (Group 2)         43         0         0         0           #63 Days (All)         151         65 (43%)         0.7560         65           #49 Days (Group 1)         70         28 (40%)         28           50-56 Days (Group 2)         43         20 (47%)         20           57-63 Days (Group 3)         38         17 (45%)         0.6197         26           #49 Days (Group 1)         70         10 (14%)         10         10           50-56 Days (Group 2)         43         9 (21%)         9         7           #63 Days (All)         151         1 (1%)         0.5364         1	Group [2]         of Pts         w/Event         p-value         of Events         Mi           (cont.)         #63 Days (All)         151         3 (2%)         0.4489         3         1           #49 Days (Group 1)         70         1 (1%)         1         0           50-56 Days (Group 2)         43         2 (5%)         2         1           57-63 Days (Group 3)         38         0         0         0           #49 Days (Group 1)         70         1 (1%)         1.0000         1         0           #49 Days (Group 1)         70         1 (1%)         1         0         0         0           #50-56 Days (Group 2)         43         0	Group [2]         of Pts         w/Event         p-value         of Events         Mild           (cont.)         #63 Days (All)         151         3 (2%)         0.4489         3         1 (33%)           #49 Days (Group 1)         70         1 (1%)         1         0           50-56 Days (Group 2)         43         2 (5%)         2         1 (50%)           57-63 Days (Group 3)         38         0         0         0           #49 Days (Group 1)         70         1 (1%)         1 0         0           #49 Days (Group 1)         70         1 (1%)         1 0         0         0           #57-63 Days (Group 2)         43         0         0         0         0         0         0           #63 Days (All)         151         65 (43%)         0.7560         65         25 (38%)         11 (39%)         0	Group [2]         of Pts         w/Event         p-value         of Events         Mild         Mode           (coat.)         x63 Days (All)         151         3 (2%)         0.4489         3 1 (33%)         2           x49 Days (Group 1)         70         1 (1%)         1 0         1           50-56 Days (Group 2)         43         2 (5%)         2 1 (50%)         1           57-63 Days (Group 3)         38         0         0         0         0           x63 Days (All)         151         1 (<1%)	Group [2]         of Pts         w/Event         p-value         of Events         Mild         Moderate           (cost.)         #63 Days (All)         151         3 (2%)         0.4489         3 1 (33%)         2 (67%)           #49 Days (Group 1)         70         1 (1%)         1 0 1 (100%)           50-56 Days (Group 2)         43 2 (5%)         2 1 (50%)         1 (50%)           57-63 Days (Group 3)         38 0         0 0 0         0 0           #63 Days (All)         151         1 (<1%)	Group [2]         of Pts         w/Event         p-value         of Events         Mild         Moderate         Sev           (cont.)         # 63 Days (All)         151         3         (2%)         0.4489         3         1 (33%)         2 (67%)         0           ±49 Days (Group 1)         70         1 (1%)         1         0         1 (100%)         0           50-56 Days (Group 2)         43         2 (5%)         2         1 (50%)         1 (50%)         0           ±63 Days (Group 3)         38         0         0         0         0         0         0           ±63 Days (All)         151         1 (<1%)	Group [2]         of Pts         w/Event         p.value         of Events         Mild         Moderate         Severe           (cost.)         #63 Days (All)         151         3 (2%)         0.4489         3 1 (33%)         2 (67%)         0           #49 Days (Group 1)         70         1 (1%)         1 0 1 (100%)         0         1 (50%)         0           50-56 Days (Group 2)         43         2 (5%)         2 1 (50%)         1 (50%)         1 (50%)         0           #63 Days (Group 3)         38         0         0 0         0         0         0           #63 Days (Group 1)         70         1 (1%)         1.0000         1 0         1 (100%)         0           #63 Days (Group 1)         70         1 (1%)         1 0         1 (100%)         0           #63 Days (Group 3)         38         0         0 0         0         0         0           #63 Days (Group 3)         38         0         0 0         0         0         0         0           #63 Days (Group 3)         38         0         0.7560         65         25 (38%)         30 (46%)         10 (15%)           #64 Days (Group 1)         70         28 (40%)         28

<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.

Center: VARGAS (#22)

	Gestational	Total	Number	Fisher's		1			
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknow
METABOLIC AND NUTRITIONAL DISORDERS	(cont.)								
THIRST .	≤63 Days (All)	151	1 (<1%)	0.5364	1	0	1 (100%)	0	0
	s49 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								:	į
ANY EVENT	≤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
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	ō
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	151	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	70	1 (1%)		1	0	1 (100%)	0	ō
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38	o ',		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.

Center: VARGAS (#22)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number		;		Severit	y		• • • • • • • •
Body System/Event	Group [2]	of Pts	w/Ev	ent/	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknown
REPRODUCTIVE DISORDERS, FEMALE	(cont.)				<del>,</del>								
LEUKORRHÕEA	≤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		Ó		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%)	0.5619	120	52	(43%)	57	(48%)	11	(9%)	0
	≤49 Days (Group 1)	70	48	(69%)		65	26	(40%)	33	(51%)	6	(9%)	ō
	50-56 Days (Group 2)	43	28	(65%)		30	15	(50%)	12	(40%)	3	(10%)	Ö
	57-63 Days (Group 3)	38		(58%)		25	11	(44%)	12	(48%)	2	(81)	Ō
ABDOMINAL PAIN	≤63 Days (All)	151	94	(62%)	0.4483	98	39	(40%)	. 48	(491)	11	(11%)	0
	≤49 Days (Group 1)	70		(67%)	0.4403	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		(55%)		21	9	(434)	10	(48%)	2		0
BACK PAIN	≤63 Days (All)	151	8	(5%)	1.0000	8	6	(75%)	2	(25%)	0		0
	s49 Days (Group 1)	70	4	(6%)		4	3	(75%)	1	(25%)	0	, 1	Ŏ
	50-56 Days (Group 2)	43	2	(5%)		2	-	(100%)	ō	(250)	0		ō
	57-63 Days (Group 3)	38	2	(5%)		2	1	(50%)	1	(50%)	ŏ		Ö
FATIGUE	≤63 Days (All)	151	7	(5%)	0.8873	7	2	(29%)	5	(71%)	0		0
	≤49 Days (Group 1)	70	4	(6%)		4	2	(50%)	2		0		o
	50-56 Days (Group 2)	43	2	(5%)		2	0		_	(100%)	Ŏ		ō
	57-63 Days (Group 3)	38	1	(3%)		1	ō			(100%)	ō		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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Center: VARGAS (#22)

<b>∛</b>	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severi	t <b>v</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
	≤49 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	0	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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FINAL

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

Center:

	Gestational Age	Total Number	of		Fisher's exact	Number		•		Severity-			
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events	Mi	.1d	Mode	rate	Sev	ere	Unknow
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%)	0.7073	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	(104)	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	ō		0		o		Ō
<b>;</b>	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
RTHRALGIA	≤63 Days (All)	89	1	(1*)	0.2247	1	1	(100%)	. о	1	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	(52%)	1	(3%)	0
	≤49 Days (Group 1)	35	11	(31%)		12	8	(67%)	4	(33%)	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%)	2	(40%)	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.

Center:

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	<del></del> .	Severity-	· <b></b>	
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ENTR & PERIPH MERVOUS SYSTEM DISORD	ERS (cont.)		·						
DIZZINESŠ	≤63 Days (All)	89	10 (11%)	0.0281	12	8 (67%)	4 (33%)	0	0
	≤49 Days (Group 1)	35	8 (23%)		9	7 (78%)	2 (22%)	0	0
	50-56 Days (Group 2)	34	1 (3%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0
HEADACHE	s63 Days (All)	89	15 (17%)	0.2145	19	6 (32%)	12 (63%)	1 (5%)	0
	≤49 Days (Group 1)	35	3 (9%)		3	1 (33%)	2 (67%)	0	ō
	50-56 Days (Group 2)	34	8 (24%)		12	3 (25%)	8 (67%)	1 (81)	ŏ
	57-63 Days (Group 3)	20	4 (20%)		4	2 (50%)	2 (50%)	0	ŏ
SYCHIATRIC DISORDERS								:	
ANY EVENT	≤63 Days (All)	89	3 (31)	0.1772	3	1 (33%)	1 (33\$)	1 (33%)	0
	s49 Days (Group 1)	35	3 (91)	******	3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	34	0		o	0	0	0	0
I	57-63 Days (Group 3)	20	o		0	ō	ō	Ö	ŏ
ANOREXIA	≤63 Days (All)	89	. 2 (21)	0.3437	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	35	2 (6%)	0.3.37	2	1 (50%)	1 (50%)	Ŏ	0
	50-56 Days (Group 2)	34	0		0	0	0	ŏ	Ö
ļ	57-63 Days (Group 3)	20	ō		ō	0	o	o	0
	• • •					-	•	•	•
INSOMNIA	<63 Days (All)	89	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	1 (3%)	1	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	ļ	0	0	0	0	ō

<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.

e2*	Gestational Age	Total Number		ber Pts	Fisher's	Number	<b>-</b>			Severit	V	. <b></b>	
Body System/Event	Group [2]	of Pts		vent	p value	of Events		.1d		rate	Seve		Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS					*** **						<del></del>		
ANY EVENT	≤63 Days (All)	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%)	ō
	57-63 Days (Group 3)	20	9	(45%)		17	11	(65%)	6	(35%)	0	, ,	o
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	1	0		0
	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0	ł	. 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		Ó
	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%)	7	(54%)	0		0
	50-56 Days (Group 2)	34	17	(50%)		23	10	(43%)	13	(57%)	0		0
	57-63 Days (Group 3)	20	8	(40%)		11	7	(64%)	4	(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 Age	Total Number	Numb		Fisher's exact	Number				Sever	itv	<b></b>	
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events		.14		rate	•	evere	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	ō
	50-56 Days (Group 2)	34	9	(26%)		11	3	(27%)	6			2 (18%)	0
	57-63 Days (Group 3)	20	4	(20%)		5	4	(80%)	1	(20%)		0	0
REPRODUCTIVE DISORDERS, FEMALE													i
ANY EVENT	≤63 Days (All)	89	1	(1%)	1.0000	1	0		0			1 (100%)	, O
· ·	≤49 Days (Group 1)	35	1	(3%)		1	0		0			1 (100%)	ō
	50-56 Days (Group 2)	34	0			0	0		0			0	ō
	57-63 Days (Group 3)	20	0			0	0		0			Ö	ō
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		Ô	·		1 (100%)	ō
	50-56 Days (Group 2)	34	0			0	0		ō			0	ŏ
	57-63 Days (Group 3)	20	0			0	ō		0			0	0
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	89	61	(69%)	0.9566	94	57	(61%)	29	(31%)		B (9%)	0
	s49 Days (Group 1)	35	23	(66%)		40	24	(60%)	13	(33%)		3 (8%)	0
	50-56 Days (Group 2)	34	24	(71%)		32	19	(59%)	A .	(25%)		5 (16%)	o
	57-63 Days (Group 3)	20		(70%)		22	14	(64%)	8	(36%)		0	ő

<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.

Center:	•	

	Gestational Age	Total Number	Num of		Fisher's exact	Number				Consult			
Body System/Event	Group [2]	of Pts		vent	p-value	of Events		11 <b>d</b>		Severit rate	-	ere	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cost.)												
ABDOMINAL PAIN	s63 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		6	(24%)	3	(12%)	0
	57-63 Days (Group 3)	20	13	(65%)		18	13	• •	5	(28%)	ō	(120)	ō
BACK PAIN	≤63 Days (All)	89	2	(2%)	1.0000	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	35	1	(3%)		1		(100%)	ŏ		Ů		ů
	50-56 Days (Group 2)	34	1	(3%)		1		(100%)	ō		0		0
	57-63 Days (Group 3)	20	0			0	0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	ō		ŏ		ő
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)	ī	(111)	0
	50-56 Days (Group 2)	34	4	(12%)		:5	2	(40%)	1	(20%)	2	(40%)	Ů
	57-63 Days (Group 3)	20	3	(15%)		4	1	(25%)	3	(75%)	ō	(404)	0
FEVER	≤63 Days (All)	89	2	(2%)	1.0000	2	1	(50%)	1	(501)	0		0
	≤49 Days (Group 1)	35	1	(3%)		1	_	(100%)	Ô	(301)	ő		0
	50-56 Days (Group 2)	34	1	(3%)		1	0	(2000)		(100%)	o	1	0
	57-63 Days (Group 3)	20	0			0	0		ō	(1000)	ŏ		0
LEG PAIN	≤63 Days (All)	89	1	(1%)	1.0000	1	0		,	(100%)	0		0
	≤49 Days (Group 1)	35	1	(3%)		1	ō			(100%)	0		0
	50-56 Days (Group 2)	34	ō			ō	0		ō	,	0		0
	57-63 Days (Group 3)	20	Ö			Ö	ŏ		o		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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	Gestational Age	Total Number	Number of Pts	Fisher's exact		· · · · · · · · · · · · · · · · · · ·	Severi	tv	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)						<del></del>		
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	Ŏ	ŏ
	50-56 Days (Group 2)	34	0		0	0	0	Ō	Ö
	57-63 Days (Group 3)	20	0		0	0	0	Ō	ō
SISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	89	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	1 (3%)		i	Ö	Ö	1 (100%)	0
	50-56 Days (Group 2)	34	0		0	Ö	Ö	0	n
	57-63 Days (Group 3)	20	0		0	0	0	o	ŏ
HERPES SIMPLEX	≤63 Days (All)	89	1: (1%)	1.0000	1	0	. 0 .	1 (100%)	0
	≤49 Days (Group 1)	35	1 (3%)		i	0	o ,	1 (100%)	0
	50:56 Days (Group 2)	34	0		0	0	ō	0	Õ
	57-63 Days (Group 3)	20	0		0	0	0	. 0	ő

<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.

Center: WESTHOFF (#24)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severi	t <b>v</b>			
Body System/Event	Group (2)	) of Pts				p-value of Events				Moderate		Severe		Unknow
ANY EVENT	≤63 Days (All)	175	112	(64%)	0.2663	182	91	(50%)	69	(381)	22	(12%)	0	
	≤49 Days (Group 1)	71	46			72	33	(46%)	28	(39%)	11	(15%)	Ö	
	50-56 Days (Group 2)	72	42	(58%)		73	43	(59%)	22	(30%)	8	(11%)	ō	
	57-63 Days (Group 3)	32	24	(75%)		37	15	(41%)	19	(51%)	3	(8%)	ō	
EMTR & PERIPH NERVOUS SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	175	5	(3%)	0.6146	5	2	(40%)	3	(60%)	0		0	
	s49 Days (Group 1)	71	1	(11)		. 1	ō	,,,,		(100%)	ŏ		ō	
	50-56 Days (Group 2)	72	3	(4%)		3	2	(67%)		(33%)	ō		n	
1	57-63 Days (Group 3)	32	1	(3%)		1	0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(100%)	0		ŏ	
ZZINESS	s63 Days (All)	175	1	(<1%)	1.0000	1	1	(100%)	. 0		0		D	
	s49 Days (Group 1)	71	0			ō	0	(2000)	ō	•	0		ŏ	
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	ō		0		ñ	
	57-63 Days (Group 3)	32	0			0	0	1	o		ō		ō	
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	
	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	
STRO-INTESTIMAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	175	41	(23%)	0.7746	65	24	(37%)	27	(42%)	14	(22%)	0	
	≤49 Days (Group 1)	71	16	(23%)		26	10	(38%)	9	(35%)	7	(27%)	Ŏ	
	50-56 Days (Group 2)	72	16	(22%)		28	12	(43%)	11	(39%)	5	(18%)	Ö	
	57-63 Days (Group 3)	32	9	(28%)		11	2	(18%)	7	(64%)	2		ō	

<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	Numb of P	-	Fisher's exact	Number				Severity	<b>/</b>		
Body System/Event	Group [2]	of Pts	w/Ev	ent	p-value	of Events	iМ	.1 <b>d</b>	Mode	erate	Sev	ere	Unknow
ASTRO-INTESTIMAL 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		o
	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	<b>(75</b> ♦)	0		0
	≤49 Days (Group 1)	71	2	(3%)		2	0			(100%)	ō		0
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0	,	ō		0
	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		o
TSPEPSIA	≤63 Days (All)	175	3	(21)	0.4032	3	1	(33%)	2	(67%)	0		0
	s49 Days (Group 1)	71	0			0	0		. 0	,	0		Ō
	50-56 Days (Group 2)	72	2	(3%)		2	1	(50%)	1	(50%)	ō		ō
1	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		ō
NAUSEA	≤63 Days (All)	175	32	(18%)	0.9035	36	15	(42%)	13	(36%)	8	(22%)	0
	s49 Days (Group 1)	71	14	(20%)		17	9	(53%)	5	(29%)	3	(18%)	0
	50-56 Days (Group 2)	72	13	(18%)		14	6	(43%)	5	(36%)	3	(21%)	0
	57-63 Days (Group 3)	32	5	(16%)		5	0		3	(60%)	2	(40%)	0
								1					
VOMITING	≤63 Days (All)	175	20	(11%)	0.7771	21	, 7	(33%)	8	(38%)	6	(29%)	0
	<pre>s49 Days (Group 1)</pre>	71	7	(10%)		7	1	(14%)	2	(29%)	4	(57%)	0
	50-56 Days (Group 2)	72	10	(14%)	i	11	4	(36%)	5	(45%)	2	(18*)	0
	57-63 Days (Group 3)	32	3	(9%)		3	2	(67%)	1	(33%)	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 Sb (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Numb of F		Fisher's exact	Number	<b></b>			Severit	t <b>v</b>		
Body System/Event	Group [2]	of Pts	w/Event		p-value	of Events		14		rate	Sev	ere	Unknow
REPRODUCTIVE DISORDERS, FEMALE				·····								<del></del>	
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	≤63 Days (All)	175	1	(<1%)	0.5886	1	0		0		1	(100%)	o
	s49 Days (Group 1)	71	1	(1%)		1	0 -		0			(100%)	0
	50-56 Days (Group 2)	72	0			O	0 '		0	1	0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	175	96	(55%)	0.0655	111	65	(59%)	. 39	(35%)	7	(6%)	0
	≤49 Days (Group 1)	71	39	(55%)		44	23	(52%)	18	(41%)	3	(7%)	0
	50-56 Days (Group 2)	72	34	(47%)		42	29	(69%)	10	(24%)	3	(7%).	0
	57-63 Days (Group 3)	32	23	(72%)		25	13	(52%)	11	(44%)	1	(4%)	0
ABDOMINAL PAIN	≤63 Days (All)	175	93	(53%)	0.0947	102	61	(60%)	35	(34%)	6	(6%)	0
	≤49 Days (Group 1)	71	38	(54%)		41	22	(54%)	16	(39%)	3	(78)	o
	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%)	10	(43%)	1	(4%)	0
BACK PAIN	≤63 Days (All)	175	5	(3%)	0.7278	5	2	(40%)	2	(40%)	1	(20%)	0
	≰49 Days (Group 1)	71	3	(4%)		3	1	(33%)	2	(67%)	0		0
	50-56 Days (Group 2)	72	2	(3%)		2	1	(50%)	0		1	(50%)	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.

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact		1			
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Severit Moderate	Severe	Unknow
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)			· •					
FEVER *	≤63 Days (All)	175	1 (<1%)	0.1829	1	1 (100%)	0	n	0
	≤49 Days (Group 1)	71	0		0	0	Ŏ	0	0
	50-56 Days (Group 2)	72	0		0	ō	Ŏ	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	1 (100%)	0	0	Ö
MALAISE	≤63 Days (All)	175	2 (1%)	0.3331	2	1 (50%)	1 (50%)	0 '	0
	<pre>s49 Days (Group 1)</pre>	71	0		0	0	0	ō	ō
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	o
	57-63 Days (Group 3)	32	1 (3%)		1	0	1 (100%)	0	ō
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	175	1 (<1%)	1.0000	1	0	1 (100%)	0	0
•	s49 Days (Group 1)	71	0		0	o	0	Ö	Ŏ
	50-56 Days (Group 2)	72	1 (1%)		1	0	1 (100%)	ŏ	Ô
	57-63 Days (Group 3)	32	0		0	o	0	. 0	Ď

<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.

Center: NICHOLS (#25)

	Gestational Age	Total Number	-	ber Pts	Fisher's exact	Number				Severit	. <b>y</b>	• • • • • • •	
Body System/Event	Group (2)	of Pts	w/E	vent	p-value	of Events	Mi	14		rate	•	ere	Unknow
ANY EVENT	462 Payer (111)	170	60	(202)	0.0176			(544)					_
WII EASTI	≤63 Days (All)	178 72	52	(29%)	0.0176	72	40	(56%)	21	(29%)	11	•	0
	≤49 Days (Group 1)		13	(18%)		19	9	(47%)	5	(26%)	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	(37%)	3	(10%)	0
ECIAL SEMSES OTHER, DISORDERS													
ANY EVENT	≤63 Days (All)	178	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	s49 Days (Group 1)	72	1	(1%)		1	0		Ó			(100%)	Ö
	50-56 Days (Group 2)	54	0			0	0		0		0		Ö
	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	,	,	(100%)	0
	s49 Days (Group 1)	72	1	(1%)		i	ŏ		Ô	•		(100%)	Ö
	50-56 Days (Group 2)	54	0			6	ō		ň		ō	(2000)	Ö
	57-63 Days (Group 3)	52	o			6	ō		ō		ŏ		ō
STRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	178	27	(15%)	0.4218	36	16	(44%)	13	(36%)	7	(194)	0
	≤49 Days (Group 1)	72	8	(11%)		12	6	(50%)	1	(25%)	,	(25%)	Ö
	50-56 Days (Group 2)	54	9	(17%)		10	6	(60%)	2	(20%)	2	(20%)	0
	57-63 Days (Group 3)	52	10	(19%)		14	4	(29%)	8	(57%)	2		
	37-03 Days (Group 3)	32	10	(134)		14	•	(274)	8	(5/4)	2	(148)	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.

Center: NICHOLS (#25)

	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		1d	Mode		•	ere	Unknown
JASTRO-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)	52	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
	#49 Days (Group 1)	72	3	(4%)		4	2	(50%)	1	(25%)	1	(25%)	0
	50-56 Days (Group 2)	54	0	1		0	0		0		0		0
	57-63 Days (Group 3)	52	2	(4%)		2	0		1	(50%)	1	(50%)	0
ODY 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	(69%)	8	(23%)	3	(9%)	0
	≤49 Days (Group 1)	72	4	(6%)		6	3	(50%)	2	(331)	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		(29%)		16	12	(75%)	3	(19%)	1	(61)	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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Center: SHEEHAN (#26)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severit				
Body System/Event	Group (2)	of Pts		vent	p-value	of Events	Mi			rate	Sev		Unk	nown
ANY EVENT	≤63 Days (All)	179	164	(92%)	0.1663	359	161	(45%)	149	(42%)	47	(13%)	•	(<11
	≤49 Days (Group 1)	63	55	(87%)	0.1003	120	59	(49%)	45	(38%)	15	(13%)	1	
	50-56 Days (Group 2)	59	57	(97%)		126	51	(40%)	57	(45%)	17		1	
	57-63 Days (Group 3)	57	52	(91%)		113	51	(45%)	47	(42%)	15		ō	( 1 )
KIN 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%)		į <b>1</b>	0			(100%)	Ō		ō	
	50-56 Days (Group 2)	59	0			0	Ö		ō	,,	ō		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		Ö	
SWEATING INCREASED	≤63 Days (All)	179	1	(<1%)	1.0000	1	0		. 1	(100%)	0		0	
	s49 Days (Group 1)	63	1	(2%)		1	0			(100%)	Ō		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	0			0	0	- (	0		0		ō	
ENTR & PERIPH MERVOUS SYSTEM DISORDERS						1								
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	

<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 Age	Total Number	Number of Pts	Fisher's exact	Number		····Severity	•	
Body System/Event	Group (2)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DIS	ORDERS (cont.)				· · · · · · · · · · · · · · · · · · ·				
DIZZINESŜ	≤63 Days (All)	179	10 (6%)	0.0008	11	5 (45%)	3 (27%)	3 (27%)	0
	s49 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
	s49 Days (Group 1)	63	5 (8%)		6	2 (33%)	4 (67%)	0	Ō
	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%)	o	ō
VISION 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
F .	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
	s49 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
SYCHIATRIC DISORDERS						1			
ANY EVENT	≤63 Days (All)	179	3 (2%)	0.7746	3	2 (67%)	0	1 (33%)	0
	≤49 Days (Group 1)	63	2 (3%)		2	1 (50%)	0	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

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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	Numi		Fisher's								
Body System/Event	Age Group [2]	Number of Pts	of : w/E	rcs vent	exact p-value	Number of Events	Mild		Severit rate	Sev	ere	Unkn	own
PSYCHIATRIÇ DISORDERS (	cont.)			····									
ANOREXIA	s63 Days (All)	179	1	(<1%)	1.0000	1	1 (100%)	0		0		0	
	≤49 Days (Group 1)	63	1	(2%)		1	1 (100%)	ō		Ô		Ô	
	50-56 Days (Group 2)	59	0			0	0	0		ō		Ô	
	57-63 Days (Group 3)	57	0			0	0	ō		ō		ō	
DEPRESSION	≤63 Days (All)	179	1	(<11)	0.6480	1	1 (100%)	0		0		0	
	£49 Days (Group 1)	63	0			0	0	0	1	0		ō	
	50-56 Days (Group 2)	59	1	(2%)		1	1 (100%)	ō	· ·	0		ō	
	57-63 Days (Group 3)	57	0			0	0	0		0		ō	
EMOTIONAL LABILITY	s63 Days (All)	179	1	(<1%)	1.0000	1	0	0		1	(100%)	0	
•	≤49 Days (Group 1)	63	1	(2%)		1	0	. 0			(100%)	Ö	
	50-56 Days (Group 2)	59	0			0	0	0		ō	(2007)	ō	
	57-63 Days (Group 3)	57	0			0	0	0		ō	1	ō	
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	179	123	(69%)	0.0422	192	86 (45%)	78	(41%)	27	(14%)	1	(<1%
	≤49 Days (Group 1)	63	36	(57%)		54	28 (52%)	22	(41%)	4	(7%)	ō	,
	50-56 Days (Group 2)	59	46	(78%)		75	30 (40%)	31	(41%)	13	(17%)	i	(1%
	57-63 Days (Group 3)	57	41	(72%)		63	28 (44%)	25	(40%)	10	(16%)	ō	, -
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		ō	
	50-56 Days (Group 2)	59	0			0	0	0		0		0	
	57-63 Days (Group 3)	57	1	(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

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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 Age	Total Number		ber Pts	Fisher's exact	Number	<b>-</b> -		<b>-</b>	···Severit	y			
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events	Mi	1 <b>1</b> d	Mode	rate	Sev	ere	Unk	known
MASTRO-INTESTIMAL SYSTEM DISORDERS	(cont.)													
DIARRHEA *	≤63 Days (All)	179	4	(2%)	1.0000	5	1	(20%)	4	(80%)	0		0	
	s49 Days (Group 1)	63	2	(3%)		2	1	(50%)	1	(50%)	ō		ō	
	50-56 Days (Group 2)	59	1	(2%)		2	0	,,	2	(100%)	ō		ō	
	57-63 Days (Group 3)	57	1	(2%)		1	0			(100%)	0	į.	ō	
DYSPEPSIA	≤63 Days (All)	179	3	(21)	0.5336	3	1	(33%)	1	(33%)	1	; (33%)	0	
	≤49 Days (Group 1)	63	1	(2%)		1	1	(100%)	0		0		΄ ο	
	50-56 Days (Group 2)	59	2	(3%)		2	0		1	(50%)	1	(50%)	0	
	57-63 Days (Group 3)	57	0			0	0		0		Ō	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	ō	
NAUSEA	≤63 Days (All)	179	114	(641)	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%)	ō	,
	50-56 Days (Group 2)	59	44	(75%)		56	24	(43%)	23	(41%)	8	(14%)	1	(21
	57-63 Days (Group 3)	57	37	(65%)		43	20	(47%)	16	(37%)	7	(16%)	ō	,,
VOMITING .	≤63 Days (All)	179	36	(20%)	0.1848	41	15	(37%)	18	(44%)	8	(20%)	0	
	s49 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%)	ō	
	57-63 Days (Group 3)	57	14	(25%)		18	8	(44%)	8	(44%)	2	(11%)	o	
ETABOLIC AND NUTRITIONAL DISORDERS				1;										
ANY EVENT	≤63 Days (All)	179	1	(<1%)	1.0000	1	1	(100%)	0	i	0		0	
	s49 Days (Group 1)	63	1	(2%)		1	1	(100%)	0		. 0		ō	
	50-56 Days (Group 2)	59	0			0	0		0		o		ō	
	57-63 Days (Group 3)	57	0			0	0		0		10		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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Center: SHEEHAN (#26)

	Gestational	Total	Number	Fisher's					
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
CETABOLIC AND NUTRITIONAL DISORDERS	(cont.)						· · · · · · · · · · · · · · · · · · ·		
DEHYDRATION	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	1 (21)		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
/ASCULAR (EXTRACARDIAC) DISORDERS									
ANY EVENT	≤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	o	0	0	0
VEIN DISORDER	≤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
RED BLOOD CELL DISORDERS								i	
ANY EVENT	≤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

<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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Center: SHEEHAN (#26)

	Gestational Age	Total Number	Numl of		Fisher's exact					Severi	ty			
Body System/Event	Group (2)	of Pts	w/E	vent	p-value	of Events		.1 <b>d</b>	Mode		•	ere	Unk	mown
RED BLOOD CELL DISORDERS	(cont.)								<del></del>					
ANAEMIA 4	s63 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	
	s49 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	
	s49 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	(<11
	#49 Days (Group 1)	63	40	(63%)		44	22	(50%)	15	(34%)	6	(14%)	1	(21
	50-56 Days (Group 2)	59	40	(68%)		43	18	(42%)	21	(49%)	4	(9%)	0	
	57-63 Days (Group 3)	57	37	(65%)		41	20	(49%)	16	(39%)	5	(12%)	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: SHEEHAN (#26)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number	<b></b> -			Severit	.y			
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unk	nown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)													
ABDOMINAL PAIN	≤63 Days (All)	179	116	(65%)	0.9800	122	58	(48%)	51	(42%)	12	(101)	1	(<11
	≤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)	57	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	
	s49 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	t	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		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		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: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	· <b>v</b>	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS	(cont.)							FIR 8 11 1 241 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
INFECTION VIRAL	≤63 Days (All)	179	1 (<1%)	0.6480	1	0	1 (100%)	0	0
	s49 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

<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.

Center: DEAN (#27)

	Gestational Age	Total Number		ber Pts	Fisher's exact i	Number				Severit				
Body System/Event	Group (2)	of Pts		vent	p-value	of Events		.1d		erate	•	ere	Unkı	nown
ANY EVENT	≤63 Days (All)	191	138	(72%)	0.2852	385	136	(35%)	170	(448)		(100)		/24
	≤49 Days (Group 1)	29	24	(83%)	0.2032	68	24	(35%)	37	(44%) (54%)		(18%)	8	(2%)
	50-56 Days (Group 2)	73	49			142	47	(33%)	68		7	(10%) (18%)	0	/15
	57-63 Days (Group 3)	89	65			175	65	(37%)	65		25 39	(22%)	2 6	(1%)
SKIN AND APPENDAGES DISORDERS														
ANY EVENT	≤63 Days (All)	191	1	(<1%)	1.0000	1	1	(100%)	0	1	0		0	
	s49 Days (Group 1)	29	0			0	0	,	ō	١	. 0		ō	
	50-56 Days (Group 2)	73	0			0	ō		0		0		ŏ	
	57-63 Days (Group 3)	89	1	(11)		1	1	(100%)	0		0		0	
PRURITUS	≤63 Days (All)	191	1	(<1%)	1.0000	1	1	(100%)	. о	•	0		0	
	≤49 Days (Group 1)	29	0			0	0		0		0		0	
	50-56 Days (Group 2)	73	0			0	0		0		Ó	1	Ö	
	57-63 Days (Group 3)	89	1	(1%)		1	1	(100%)	0		0		0	
NUSCULO-SKELETAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	191	1	(<1%)	0.5340	2	0		2	(100%)	0		0	
	s49 Days (Group 1)	29	0			0	Ö		0		0		ŏ	
	50-56 Days (Group 2)	73	1	(1%)		2	0		2	(100%)	0		ō	
	57-63 Days (Group 3)	89	0			0	0		0		ō		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.

Center: DEAN (#27)

	Gestational	Total		ber	Fisher's			4		_					
Body System/Event	Age Group [2]	Number of Pts		Pts vent	exact p-value	Number of Events	M	11d	Mode	Sever	rity.		ere	Unk	nown
MUSCULO-SKELETAL SYSTEM DISORDERS	(cont.)								······································						
MYALGIA 4	≤63 Days (All)	191	1	( <b>&lt;1</b> %)	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 DISORDS	TRS													i	
ANY EVENT	≤63 Days (All)	191	33	(17%)	0.9010	49	14	(29%)	29	(59%)		5	(10%)	1	(2%
	s49 Days (Group 1)	29	5	(17%)		7	1	(14%)	6	(86%)		ō	1-0-7	0	,
·	50-56 Days (Group 2)	73	14	(19%)		18	7	(39%)	9	(50%)		1	(6%)	1	(61
	57-63 Days (Group 3)	89	14	(16%)		24	6	(25%)	14	(581)		4	(17%)	0	,,,,
DIZZINESS	≤63 Days (All)	191	10	(5%)	0.7536	11	2	(18%)	. 8	(731)		1	(91)	0	
	£49 Days (Group 1)	29	1	(3%)		1	0	• •		(100%)		ō		0	
	50-56 Days (Group 2)	73	3	(4%)		3	1	(33%)	2	(67%)		ō		ō	
	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		ō	
	50-56 Days (Group 2)	73	12	(16%)		14	5	(36%)	7	(50%)		1	(7%)	1	(78)
	57-63 Days (Group 3)	89	12	(13 <b>%</b> )		17	5	(29%)	9	(53%)		3	(18%)	0	, .
MUSCLE CONTRACTIONS INVOLUNTARY	≤63 Days (All)	191	1	(<1%)	0.5340	1	1	(100%)	0		1	0		0	
	≤49 Days (Group 1)	29	0			0	0	,	0			0		0	
	50-56 Days (Group 2)	73	1	(1%)		1	1	(100%)	0			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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Center: DEAN (#27)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	NumberSeverity				
					of Events	Mild	Moderate	Severe	Unknown
VISION DISORDERS		<del></del>							
any event	≤63 Days (All)	191	1 (<1%)	0.1518	1	<b>o</b> .	1 (100%)	0	O
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	ō	ő
	50-56 Days (Group 2)	73	0		ō	0	0	ō	Ö
	57-63 Days (Group 3)	89	0		0	0	o	ō	ō
MYDRIASIS	≤63 Days (All)	191	1 (<1%)	0.1518	1	0	1 (100%)	0	•
	s49 Days' (Group 1)	29	1 (3%)	0.1510	1	Ö	1 (100%)	0	0
	50-56 Days (Group 2)	73	0		0	o o	0	0	0
	57-63 Days (Group 3)	89	ō		ō	o	Ö	0	0
PECIAL SEMSES OTHER, DISORDERS	1								
ANY EVENT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	29	0		ō	Ō	0	o o	0
	50-56 Days (Group 2)	73	ō		Ď	Ô	Ô	Ô	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	ŏ	0
TASTE PERVERSION	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0 .	0
	#49 Days (Group 1)	29	0		0	ő	0	0	0
	50-56 Days (Group 2)	73	0		o	Ô	0	o	Ö
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	ő	ō
SYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	191	2 (1%)	0.6419	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	Ö
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	2 (2%)		2	0	2 (100%)	0	Ô

<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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Center: DEAN (#27)

	Gestational	Total	Numb		Fisher's									
Body System/Event	Age Group (2)	Number of Pts	of i		exact p-value	Number of Events	Mi	ld	Mode	Severit rate	•	ere	Unk	known
PSYCHIATRIC DISORDERS	(cont.)													
ANOREXIA	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		1	(100%)	o		0	
	≤49 Days (Group 1)	29	0	, ,		. 0	ō		ō	(1004)	Ô		Ö	
	50-56 Days (Group 2)	73	ō			0	0		Ô		Ô		ō	
	57-63 Days (Group 3)	89	1	(1%)		1	ŏ		1	(100%)	ō		o	
INSOMNIA	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	29	0			0	0		0	(100-7	ō		ō	
	50-56 Days (Group 2)	73	0	1		Ö	ō		ō		ō		ō	
	57-63 Days (Group 3)	89	1	(1%)		1	0		1	(100%)	ō		ō	
LASTRO-INTESTINAL SYSTEM DISORDERS				,										
ANY EVENT	≤63 Days (All)	191	80	(42%)	0.9796	161	42	(26%)	74	(46%)	44	(27%)	1	(<1%
	s49 Days (Group 1)	29	12	(41%)		30	11	(37%)	15	(50%)	4	(13%)	ō	
	50-56 Days (Group 2)	73	30	(41%)		57	12	(21%)	31	(54%)	14	(25%)	ō	
	57-63 Days (Group 3)	89	38	(43%)		74	19	(26%)	28	(38%)	26	(35%)	1	
DIARRHEA	s63 Days (All)	191	3	(2%)	0.1818	3	1	(33%)	1	(33%)	1	(33%)	0	
	≤49 Days (Group 1)	29	1	(3%)		4		(100%)	0		ō	,,,	ō	
	50-56 Days (Group 2)	73	2	(3%)		2	0		1	(50%)	1	(50%)	ō	
	57-63 Days (Group 3)	89	0			0	0		0		0	, ,	0	
DYSPEPSIA	s63 Days (All)	191	1	(<1%)	0.5340	1	0		0		1	(100%)	0	
	#49 Days (Group 1)	29	0			0	ō		Ŏ		0		0	
	50-56 Days (Group 2)	73	1	(1%)		1	ō		0			(100%)	ō	
	57-63 Days (Group 3)	89	0			0	Ô		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.

# 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	<b></b>			Severit	. <b>y</b>			
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events	Mi	1 <b>d</b>	Mode	rate	Sev	ere	Unk	nown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)													
FLATULENĈE	≤63 Days (All)	191	2	(1%)	0.6419	2	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	(35%)	0.9566	99	33	(33%)	46	(46%)	20	(20%)	0	
	≤49 Days (Group 1)	29	10	(34%)		22	8	(36%)	12	(55%)	2	(9%)	0	
	50-56 Days (Group 2)	73	24	(33%)		;33	9	(27%)	10	(55%)	6	(18%)	0	
	57-63 Days (Group 3)	89	32	(36%)		<sup>i</sup> 44	16	(36%)	16	(36%)	12	(27%)	0	
VOMITING	≤63 Days (All)	191	38	(20%)	0.9103	56	8	(14%)	26	(46%)	22	(39%)	0	
•	s49 Days (Group 1)	29	5	(17%)		7	2	(29%)	. 3	(43)	2	(29%)	0	
	50-56 Days (Group 2)	73	14	(19%)		21	3	(14%)	12	(57%)	6	(29%)	0	
	57-63 Days (Group 3)	89	19	(21%)		28	3	(11%)	11	(39%)	14	(50%)	0	
RESPIRATORY SYSTEM DISORDERS		1						1						
ANY EVENT	≤63 Days (All)	191	1	(<1%)	0.1518	1	1	(100%)	0		0		0	
	s49 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	
	50-56 Days (Group 2)	73	0			υ	0		0		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	Number of Pt	-	Fisher's exact	Number	<b></b>	,	<b></b>	Severit	y			
Body System/Event	Group [2]	of Pts	w/Eve		p-value	of Events	Mi			erate	•	ere	Unkr	10WN
EPRODUCTIVE DISORDERS, FEMALE														
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	
	≤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		O		0		0	
UTERINE HAEMORRHAGE	≤63 Days (All)	191	1 (	(<1%)	0.1518	1	0		1	(100%)	0		0	
,	s49 Days (Group 1)	29	1	(3%)		1	0		1	(1004)	0		0	
	50-56 Days (Group 2)	73	0			0	0		0		0		0	
1	57-63 Days (Group 3)	89	0			0	0		O		0		0	
VAGINAL DISCOMFORT	s63 Days (All)	191	1 (	(<1%)	1.0000	1	0		o		1	(100%)	0	
	≤49 Days (Group 1)	29	. 0			0	0		C		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	
DY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	191	105	(55%)	0.7532	164	77	(47%)	60	(37%)	21	(13%)	6	(
	≤49 Days (Group 1)	29	18	(62%)	1	27	10	(37%)	14	(52%)	3	(11%)	0	
	50-56 Days (Group 2)	73	39	(53%)		65	28	(43%)	26	(40%)	10	(15%)	1	
	57-63 Days (Group 3)	89	48	(54%)	ŗ	72	39	(54%)	20	(28%)	8	(11%)	5	

<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)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Num of w/E		Fisher's exact   p value	Number of Events		1d		Severity	Sev		Unkr	
2007 By Ocean, 20010	0104p (2)				F									<del></del>
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)													
ABDOMINAL PAIN	≤63 Days (All)	191	103	(54%)	0.6419	147		(48%)	50	(34%)	20		6	(4%
	≤49 Days (Group 1)	29	18	(62%)		23	8	(35%)	12	(52%)	3		0	
	50-56 Days (Group 2)	73	38	(521)		58	27	(47%)	21	(36%)	9	(16%)	1	(21
	57-63 Days (Group 3)	89	47	(53%)		66	36	(55%)	17	(26%)	8	(12%)	5	(84
ASTHENIA	≤63 Days (All)	191	4	(21)	0.8085	4	1	(25%)	3	(75%)	0		0	
	s49 Days (Group 1)	29	0			0	0,		0		0		0	
	50-56 Days (Group 2)	73	1	(11)		1	O <sup>i</sup>		1	(100%)	0		0	
	57-63 Days (Group 3)	89	3	(31)		3	1	(33%)	2	(67%)	<u>:</u> 0		0	
BACK PAIN	≤63 Days (All)	191	8	(41)	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	
4	≤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	(11)		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	
	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	

<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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Center: CREININ (#28)

	Gestational	Total		ber	Fisher's			,					
Body System/Event	Age Group [2]	Number of Pts	of w/E	Pts Vent	exact p-value	Number of Events	Mi		Mode	Severi Prate	•	rere	Unknown
	• • • • • • • • • • • • • • • • • • • •												
ANY EVENT	≤63 Days (All)	115	94	(82%)	0.4921	216	110	(51%)	68	(31%)	38	(18%)	•
	s49 Days (Group 1)	23	19	(83%)	0.4321	46	24	(52%)	16		6	(13%)	0
	50-56 Days (Group 2)	50	43	(86%)		97	42	(43%)	34		21	(22%)	0
	57-63 Days (Group 3)	42	32	(76%)		73	44	(60%)	18			(15%)	0
	37-03 Days (Gloup 3)	72	32	(/04/		73	77	(604)	10	(454)	11	;(154)	: 0
IN AND APPENDAGES DISORDERS												•	1
ANY EVENT	≤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	(21)		1	0		1	(100%)	O		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	(106%)	0		0
	≤49 Days (Group 1)	23	0	• • • •		0	ō		0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Ô		Ô
	50-56 Days (Group 2)	50	1	(2%)		i	ŏ		•	(100%)	o		Ô
	57-63 Days (Group 3)	42	ō	, , , ,		0	ō		ō	(2000)	ō		ō
TTR & PERIPH MERVOUS SYSTEM DISORDERS													
NY EVENT	≤63 Days (All)	115	21	(18%)	0.7389	25	15	(60%)	7	(28%)	3	(12%)	0
	s49 Days (Group 1)	23	3	(13%)	2302	3		(100%)	0	(200)	,	( /	0
	50-56 Days (Group 2)	50	9	(18%)		12	5	(42%)	5	(42%)	2	(17%)	ů
				į			-		_		,	(10%)	0
	57-63 Days (Group 3)	42	9	(21∜)		10	7	(70%)	2		1	(10	*)

<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 Pt		Fisher's exact	Number				Severit	. <b>v</b> -	<b></b>	
Body System/Event	Group [2]	of Pts	w/Eve		p-value	of Events	Mi	.1d '	Mode	rate	Sev	ere	Unknow
ENTR & PERIPH MERVOUS SYSTEM DISORDERS	(cont.)												
DIZZINESS	≤63 Days (All)	115	7	(6%)	1.0000	7	6	(86%)	1	(14%)	0		0
	s49 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	(78)		3	2	(67%)	1	(33%)	0		0
HEADACHE	≤63 Days (All)	115	15	(13%)	0.8756	18	9	(50%)	6	(33%)	3	(17%)	0
	s49 Days (Group 1)	23	2	(9%)		2	2	(100%)	0		0		0
	50-56 Days (Group 2)	50	7	(14%)		9	2	(22%)	5	(56%)	2	(22%)	0
	57-63 Days (Group 3)	42	6	(14%)		7	5	(71%)	1	(14%)	1	(14%)	0
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	115	49	(43%)	0.6670	72	31	(43%)	. 25	(35%)	16	(221)	0
	≤49 Days (Group 1)	23	11	(48%)		19	7	(37%)	8	(421)	4	(21%)	0
	50-56 Days (Group 2)	50	19	(38%)		28	11	(39%)	8	(29%)	9	(32%)	0
	57-63 Days (Group 3)	42	19	(45%)		25	13	(52%)	9	(36%)	3	(12%)	0
CONSTIPATION	≤63 Days (All)	115	2	(2%)	1.0000	2	2	(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	1	(2%)		1	1	(100%)	0		0		0
DIARRHEA	s63 Days (All)	115	7	(6%)	0.3142	10	6	(60%)	3	(30%)	1	(10%)	o
	≤49 Days (Group 1)	23	3	(13%)		4	3	(75%)	1	(25%)	0		0
	50-56 Days (Group 2)	50	2	(4%)		4	2	(50%)	1	(25%)	1	(25%)	0
	57-63 Days (Group 3)	42	2	(5%)		2	1	(50%)	1	(50%)	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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Center: CREININ (#28)

	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	Number		<b></b>		Severit	y		
Body System/Event	Group [2]	of Pts	w/Eve	ent	p-value	of Events	M	ild	Mode	rate	Sev	ere	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												
DYSPEPSIA	≤63 Days (All)	115	2	(21)	0.1699	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	23	0			0	0	, ,	Ō		o		o
	50-56 Days (Group 2)	50	0			0	Ö		ō		o		Ô
	57-63 Days (Group 3)	42	2	(5%)		2	2	(100%)	0		0		Ō
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	(251)	6	(50%)	3	(25%)	0
	50-56 Days (Group 2)	50		(24%)		14	4	(291)	4	(29%)	6	(43%)	Ö
	57-63 Days (Group 3)	42	11 (	26%)		13	6		5	(38%)	2		0
VOMITING	≤63 Days (All)	115	17 (	(15%)	0.7018	19	8	(42%)	7	(37%)	4	(21%)	0
'	s49 Days (Group 1)	23		(9%)		3	1	(33%)	1	(33%)	1	(33%)	Ö
	50-56 Days (Group 2)	50		16%)		9	4	(44%)	3	(33%)	2	(221)	ō
	57-63 Days (Group 3)	42	7 (	17%)		7	3	(43%)	3		1		Ö
EPRODUCTIVE DISORDERS, 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	s63 Days (All)	115	1 (	<11)	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		Ō		1	(100%)	Ö
	57-63 Days (Group 3)	42	0			0	0		ō		0		ŏ

<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.

Center: CREININ (#28)

	Gestational Age	Total Number	Num of		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	Unknow
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	s63 Days (All)	115 .	85	(74%)	0.4191	117	64	(55%)	35	(30%)	18	(15 <b>%</b> )	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
	≤49 Days (Group 1)	23	16	(70%)		19	10	(53%)	7	(37%)	2	(111)	0
	50-56 Days (Group 2)	50	39	(78%)		. 47	24	(51%)	15	(32%)	8	(17%)	0
,	57-63 Days (Group 3)	42	28	(67%)		36	23	(64%)	7	(19%)	6	(17%)	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	s63 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
	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

<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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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 Moderate	ty Severe	Unknown
ODY AS A MHOLE - 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	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: SOGOR (#29)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number				Severit	. <b>v</b>	. <b></b> . <b>.</b>		
Body System/Event	Group [2]	of Pts		vent	p-value	of Events		1 <b>d</b>		rate	Sev		Unk	nown
ANY EVENT	≤63 Days (All)	83	55	(66%)	0.9552	107	28	(26%)	50	(47%)	28	(26%)	1	(<1
	≤49 Days (Group 1)	28	18	(64%)		35	10	(29%)	18	(51%)	6	(17%)	1	(31
	50-56 Days (Group 2)	37	25	(68%)		42	10	(24%)	16	(38%)	16	(38%)	0	
	57-63 Days (Group 3)	18	12	(67%)		30	8	(27%)	16	(53%)	6	(20%)	0	
ENTR & PERIPH MERVOUS SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	83	9	(11%)	1.0000	9	3	(33%)	4	(448)	2	(22%)	0	
	≤49 Days (Group 1)	28	3	(11%)		3	1	(33%)	2	(67%)	, 0		0	
	50-56 Days (Group 2)	37	4	(11%)		4	2	(50%)	1	(25%)	1	(25%)	0	
	57-63 Days (Group 3)	18	2	(11%)		2	0		1	(50%)	1	(50%)	0	
DIZZINESS	≤63 Days (All)	83	5	(6%)	0.7091	5	2	(40%)	. 2	(40%)	1	(20%)	0	
	≤49 Days (Group 1)	28	2	(7%)		2	0		2	(100%)	0		0	
	50-56 Days (Group 2)	37	3	(8%)		3	2	(67%)	0		1	(33%)	0	
	57-63 Days (Group 3)	18	0			0	0		0		0		0	
HEADACHE	≤63 Days (All)	83	3	(4%)	1.0000	3	1	(33%)	2	(67%)	0		0	
	≤49 Days (Group 1)	28	1	(4%)		1	1	(100%)	0		0		0	
	50-56 Days (Group 2)	37	1	(3%)		1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	18	1	(61)		1	0		1	(100%)	0		0	
MIGRAINE	≤63 Days (All)	83	1	(1%)	0.2169	1	0		0		1	(100%)	0	
	<pre>s49 Days (Group 1)</pre>	28	0			0	0		0		0		0	
	50-56 Days (Group 2)	37	0			0	0		0		0		0	
	57-63 Days (Group 3)	18	1	(6%)		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

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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 Age	Total Number	Numb of P		Fisher's exact	Number				Severit	; <b>y</b>		
Body System/Event	Group (2)	of Pts	w/Ev		p-value	of Events	Mi	.1d	Mode	rate	Sev	ere	Unknow
JASTRO-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	9	(321)		13	3	(23%)	7	(54%)	3	(23%)	0
	50-56 Days (Group 2)	37	14	(38%)		20	3	(15%)	8	(40%)	9	(45%)	0
	57-63 Days (Group 3)	18	7	(39%)		15	5	(33%)	7	(47%)	3	(20%)	. 0
DIARRHEA	≤63 Days (All)	83	3	(4%)	1.0000	3	1	(33%)	2	(67%)	0		i o
	≤49 Days (Group 1)	28	1	(4%)		1	0			(100%)	0		ō
	50-56 Days (Group 2)	37	1	(3%)		1	0			(100%)	0		o
	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		(32%)		10	3	(30%)	· 5		2	(20%)	0
	50-56 Days (Group 2)	37		(27%)		11	3	(27%)	4		4	(36%)	0
	57-63 Days (Group 3)	18		(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%)	0
	≤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
EART RATE AND RHYTHM DISORDERS	•			1,									
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
	50-56 Days (Group 2)	37	0			0	0		0		0		0
	57-63 Days (Group 3)	18	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: SOGOR (#29)

	Gestational Age	Total Number	Number of Pt		Fisher's exact	Number		,		Severit	y			
Body System/Event	Group [2]	of Pts	w/Eve	ent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unk	nown
HEART RATE AND RHYTHM DISORDERS	(cont.)											· · · · · · · · · · · · · · · · · · ·		
TACHYCARDIA	≤63 Days (All)	83	1	(11)	0.5542	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	28	1	(4%)		1	0			(100%)	Ó		Ō	
	50-56 Days (Group 2)	37	0	1		0	0		0		0		ō	
	57-63 Days (Group 3)	18	0	4		0	0		0		0		0	
BODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	83	42 (	(51%)	0.7469	49	14	(29%)	23	(47%)	11	(22%)	1	(2%
	≤49 Days (Group 1)	28		(54%)		18	6	(33%)	8	(44%)	3	1 1	î	(6%
	50-56 Days (Group 2)	37		(46%)		18	5	(28%)	7	(39%)	6	(33%)	ō	,,,,
	57-63 Days (Group 3)	18		(56%)		13	3	(23%)	8		_	(15%)	ŏ	
ABDOMINAL PAIN	≤63 Days (All)	83	42 (	(51%)	0.7469	46	14	(30%)	. 20	(434)	11	(24%)	1	(28
	s49 Days (Group 1)	28		(54%)		17	6	(35%)	7		3	(18%)	i	(61
	50-56 Days (Group 2)	37		(46%)		18	5	(28%)	7		6	(33%)	Ô	(00
	57-63 Days (Group 3)	18		(56%)		11	3	(27%)	6		2		ō	
BACK PAIN	≤63 Days (All)	83	1	(1%)	0.2169	1	0		1	(100%)	0	• i	0	
	s49 Days (Group 1)	28	ō	,,,,,		0	0		0	,,,,,,,	ō	11	ŏ	
	50-56 Days (Group 2)	37	0			ō	ō		ō		ō		ŏ	
	57-63 Days (Group 3)	18	-	(6%)		1	0		•	(100%)	o		ŏ	
CHEST PAIN	≤63 Days (All)	83	1	(1%)	0.2169	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	28	ō	•		0	Ō		ō	, - • • • •	ő		0	
	50-56 Days (Group 2)	37	ō			Ō	Ō		Ô		Ö		ō	
	57-63 Days (Group 3)	18		(6%)		i	0		•	(100%)	Ö		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.

#### 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 MHOLE - GENERAL DISORDERS	(cont.)								
FEVER *	≤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	0	0	0
	57-63 Days (Group 3)	18	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.

Appendix D, Table 5c

Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: POINDEXTER (#21)

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			Severity-		ere į	Unknow
•													
ANY EVENT	≤63 Days (All)	71	61	(86%)	0.5665	213	76	(36%)	109	(51%)	28	(13%)	0
	≤49 Days (Group 1)	28	24	(86%)		64	24	(38%)	38	(59%)	2	(3%)	0
	50-56 Days (Group 2)	26	21	(81%)		73	22	(30%)	! 34	(47%)	17	(23%)	0
	57-63 Days (Group 3)	17	16	(94%)		76	30	(39%)	37	(49%)	9	(12%)	0
IN AND APPENDAGES DISORDERS													
ANY EVENT	s63 Days (All)	71	1	(1%)	0.2394	1	0		1	(100%)	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	0		1	(100%)	0		0
SWEATING INCREASED	≤63 Days (All)	71	1	(1%)	0.2394	1	0		1	(100%)	0		0
	s49 Days (Group 1)	28	0	•		0	0		0		0		0
	50-56 Days (Group 2)	26	ō			0	o		0		0		0
i	57-63 Days (Group 3)	17	1	(6%)		1	0		1	(100%)	0		0
MTR & PERIPH MERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	71	14	(20%)	0.3532	21	7	(33%)	11	(52%)	3	(14%)	0
	s49 Days (Group 1)	28	6	(21%)		6	2	(33%)	4	(67%)	0		0
!	50-56 Days (Group 2)	26	3	(12%)		4	0	1	2	(50%)	2	(50%)	0
· ·	57-63 Days (Group 3)	17	5	(29%)		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 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: POINDEXTER (#21)

	Gestational Age	Total Number		ber Pts	Fisher's exact:	Number				Severi	tv		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	M:	ila '		rate	•	ere	Unknow
ENTR & PERIPH MERVOUS SYSTEM DISORDERS (CO	ont.)										·		
HEADACHB	≤63 Days (All)	71	14	(20%)	0.3532	20	7	(35%)	10	(50%)	3	(15%)	٥
	s49 Days (Group 1)	28	6	(21%)		6	2	(33%)	4	(67%)	0	(134)	ň
	50-56 Days (Group 2)	26	3	(12%)		4	0	(202,	2	(50%)	2	(50%)	0
	57-63 Days (Group 3)	17	5	(29%)		10	5	(50%)	4	(40%)	1		ō
MIGRAINE	s63 Days (All)	71	,	(1%)	0.2394	1	0		•	(100%)	0		•
	≤49 Days (Group 1)	28	0	,	0.233.	ō	0		ō	(1004)	0		0
	50-56 Days (Group 2)	26	ō			ň	ō			1	·		0
	57-63 Days (Group 3)	17	1	(6%)		1	0		1	(100%)	0		0
STRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	71	35	(49%)	0.7211	66	23	(35%)	. 31	(47%)	12	(18%)	^
	#49 Days (Group 1)	28	12	(43%)		14	6	(43%)	7		1	(7%)	0
	50-56 Days (Group 2)	26	14	(54%)		28	7	(25%)	13	(46%)	ā	(29%)	0
	57-63 Days (Group 3)	17	9	(53%)		24	10	-	11	(46%)	3		0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	71	1	(1%)	1.0000	1	1	(100%)	0				_
·	±49 Days (Group 1)	28	1	(4%)	2.0000	;		(100%)			0		0
	50-56 Days (Group 2)	26	ô	,		Ô		(1004)	0		0		0
	57-63 Days (Group 3)	17	ō			n	0		0		0		0
	3. 33 22/3 (Group 3)	.,	v			U	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 Sc (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Numb of P w/Ev	Pt s	Fisher's exact p-value	Number of Events		; : :1d		Severity		vere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)						•						
DIARRHEÀ	≤63 Days (All)	71	6	(8%)	0.5594	6	3	(50%)	3	(50%)	0		0
	s49 Days (Group 1)	28	1	(4%)		1	1	(100%)	ō	(200)	0		Ô
	50-56 Days (Group 2)	26	3	(12%)		3	1	(33%)	2	(67%)	ō		n
	57-63 Days (Group 3)	17		(12%)		2	1	(50%)	ī		o	1	o
DYSPEPSIA	≤63 Days (All)	71	2	(3%)	0.5155	2	1	(50%)	0		1	(50%)	0
	≤49 Days (Group 1)	28	0			0	0		0		ō		Ô
	50-56 Days (Group 2)	26	1	(4%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	17	1	(6%)		1	1	(100%)	Ō		0	(1000)	Ö
NAUSEA	≤63 Days (All)	71	27	(38%)	0.7787	34	11	(32%)	15	(44%)	8	(24%)	0
•	s49 Days (Group 1)	28	9	(32%)		9	3	(33%)	. 5	(56%)	1	(11%)	0
	50-56 Days (Group 2)	26		(42%)		14	4	(29%)	5		5	(36%)	0
	57-63 Days (Group 3)	17	7	(41%)		11	4	(36%)		(45%)	2		Ô
VOMITING .	≤63 Days (All)	71	16	(23%)	0.1143	23	7	(30%)	13	(57%)	3	(13%)	0
	s49 Days (Group 1)	28	3	(11%)		3	1	(33%)	2		ō	(220)	Ô
	50-56 Days (Group 2)	26	7	(27%)		10	2	(20%)	6	(60%)	2	(20%)	Ô
	57-63 Days (Group 3)	17		(35%)		10	4	(40%)		(50%)	1		0
LATELET, BLEEDING & CLOTTING DISORDERS	i			1									
ANY EVENT	≤63 Days (All)	71	1	(1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	28	1	(4%)		1	0			(100%)	Ô		0
	50-56 Days (Group 2)	26	0			0	0		ō	,	0		n
	57-63 Days (Group 3)	17	0			0	ō		ō		0		Ö

<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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Center: POINDEXTER (#21)

	Gestational	Total	Numb		Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of I	Pts vent	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISOR	DERS (cont.)									
<b>EPISTAXÍS</b>	≤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
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
	\$0-56 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
	≤49 Days (Group 1)	28	1	(4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	0			0	O .	0	0	0
	57-63 Days (Group 3)	17	0			<b>'</b> 0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	71	1	(11)	0.6056	1	0	0	1 (100%)	0
	s49 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

<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: POINDEXTER (#21)

	Gestational Age	Total Number	Numi of 1		Fisher's exact	Number				Severit	<b>v</b> -	<b>-</b>	
Body System/Event [2]	Group (3)	of Pts	w/E	vent	p-value	of Events	Mi	14	Mode		Sev	ere	Unknow
BODY AS A WHOLE - GENERAL DISORDERS										·····			
ANY EVENT	≤63 Days (All)	71	59	(83%)	0.6130	122	46	(38%)	64	(52%)	12	(10%)	0
	<pre>s49 Days (Group 1)</pre>	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
	≤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
1	s49 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	≤63 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%)	O		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
	≤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

<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: VARGAS (#22)

ody System/Event [2]	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severi	tv	<b></b>	
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events		14	Mode		•	ere	Unknow
ANY EVENT	≤63 Days (All)	151	137	(91%)	0.1014			()					
	≤49 Days (Group 1)	70	131	(86%)	0.1814	513	162	(32%)	201	(39%)	150	(29%)	0
	50-56 Days (Group 2)	43				187	59	(32%)	82	(44%)	46	(25%)	О
			41			174	58	(33%)	64	(37%)	52	(30%)	0
	57-63 Days (Group 3)	38	36	(95%)		152	45	(30%)	55	(36%)	52	(34%)	0
IN 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	ō	,	ŏ		Ů		0
	50-56 Days (Group 2)	43	1	(2%)		' 1	-	(100%)	ō		Ô		0
	57-63 Days (Group 3)	38	0			0	ō	(2000)	ŏ		ŏ		0
RASH	s63 Days (All)	151	1	(<1%)	0.5364	•		(****					
		70	0	(<14)	0.3364	1		(100%)	. 0	1	0		0
	≤49 Days (Group 1)			(0.0)		0	0		0		0		0
	50-56 Days (Group 2)	43	1	(2%)		1		(100%)	0		0		0
SCULO-SKELETAL SYSTEM DISORDERS	57-63 Days (Group 3)	38	0			•	0	ı	0		0		0
ANY EVENT	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0		0
	s49 Days (Group 1)	70	0		<del>-</del> -	Ö	ō		ō	12000	'n		0
	50-56 Days (Group 2)	43	0			ō	ñ		n		0		0
	57-63 Days (Group 3)	38	ì	(3%)			0		v	(100%)	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: VARGAS (#22)

	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	Mí			ierate	•	ere	Unknow
USCULO-SEPLETAL SYSTEM DISORDERS	(cont.)								•			····	
MYALGIA	≤63 Days (All)	151	1	(<1%)	0.2517	1	0			(100%)	0		0
	≤49 Days (Group 1)	70	0			0	0		1 (	)	0		0
	50-56 Days (Group 2)	43	0			0	0		-! (	)	0		0
	57-63 Days (Group 3)	38	1	(3%)		1	0			(100%)	0		0
ENTR & PERIPH NERVOUS SYSTEM DISORD	ERS												
ANY EVENT	≤63 Days (All)	151	29	(19%)	0.0650	37	9	(24%)	2	5 (68%)	3	(8%)	0
	s49 Days (Group 1)	70	8	(11%)		11	2	(18%)	1	(73%)	1	(9%)	0
	50-56 Days (Group 2)	43	11	(26%)		13	6	(46%)		7 (54%)	0		0
	57-63 Days (Group 3)	38	10	(26%)		13	1	(8%)	1	(77%)	2	(15%)	0
DIZZINESS	≤63 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%)	:	(50%)	0		0
•	57-63 Days (Group 3)	38	2	(5%)		2	0			(100%)	0		0
HEADACHE	s63 Days (All)	151	20	(13%)	0.0182	24	5	(21%)	10	5 (67%)	3	(13%)	0
	s49 Days (Group 1)	70	4	(6%)		4	0		:	(75%)	1	(25%)	0
	50-56 Days (Group 2)	43	7	(16%)		9	4	(44%)		(56%)	0		0
	57-63 Days (Group 3)	38		(24%)		11	1	(9%)		3 (73%)	2	(18%)	Ō

<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 of Pt		Fisher's exact	Number		Sever		· · · · · · · · · · · · · · · · · · ·
Body System/Event [2]	Group [3]	of Pts	w/Eve		p-value	of Events	Mild	Moderate	Severe	Unknown
ISION DISORDERS		<del></del>					<del></del>			
ANY EVENT	≤63 Days (All)	151	1 (	(<1%)	0.5364	1	1 (100%)	•	_	_
	≤49 Days (Group 1)	70	ō	,	0.3301	•	0	0	0	0
	50-56 Days (Group 2)	43		(2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	ō	,		0	0	0	0	0
	,		•			U	U	0	0	0
VISION ABNORMAL	≤63 Days (All)	151	1 (	(<1%)	0.5364	,	1 (1001)	Ā	_	
	≤49 Days (Group 1)	70	ō,	, /	0.5504		1 (100%) d	0	0	0
	50-56 Days (Group 2)	43	-	(21)		1	•	0 '	, <b>0</b>	0
	57-63 Days (Group 3)	38	ō	(20)		1	1 (100%)	0	! O	0
		30	·			U	0	0	0	0
ASTRO-INTESTINAL SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	151	99 (	(661)	0.0669	211	02 (444)			
	≤49 Days (Group 1)	70	•	(561)	0.0003	76	93 (44%)	76 (36%)	42 (20%)	0
	50-56 Days (Group 2)	43		(74%)		72	31 (41%)	33 (43%)	12 (16%)	0
	57-63 Days (Group 3)	38		(74%)		63	33 (46%)	23 (32%)	16 (22%)	0
4	11 11 11 11 11 11	30		(/11/		63	29 (46%)	20 (32%)	14 (22%)	0
CONSTIPATION	s63 Days (All)	151	1 (	(<1%)	0.5364	•				
	≤49 Days (Group 1)	70	ō,	,	0.5304	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	43	-	(21)		0	0	0	0	0
	57-63 Days (Group 3)	38	0	(41)		1	0	1 (100%)	0	0
	s. as says (Group 3)	20	U			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 which the relationship was not assessed.

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

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**О** 

<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: VARGAS (#22)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severit	·v		
Body System/Event (2)	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	ild '	Mode		Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)	-											
DIARRHEA <sup>®</sup>	≤63 Days (All)	151	47	(31%)	0.2075	65	33	(51%)	23	(35%)	9	(14%)	0
	≤49 Days (Group 1)	70	17	(24%)		23	11	(48%)	9	(39%)	3	(13%)	o
	50-56 Days (Group 2)	43	17	(40%)		22	10	(45%)	9	(41%)	3	(14%)	Ô
	57-63 Days (Group 3)	38	13	(34%)		20	12	(60%)	5		3	(151)	ō
NAUSEA	≤63 Days (All)	151	80	(53%)	0.2462	95	44	(46%)	33	(35%)	18	(19%)	0
	≤49 Days (Group 1)	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%)	Ŏ
	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	(534)	4	(24%)	ō
	50-56 Days (Group 2)	43	15	(35%)		17	7	(41%)	3	(18%)	7	(41%)	Ö
	57-63 Days (Group 3)	38	13	(34%)		16	5	(31%)	7	(44%)	4	(25%)	ō
ETABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	s63 Days (All)	151	1	(<1%)	0.2517	1	1	(100%)	0		n		0
	s49 Days (Group 1)	70	0			0	ō		ō		Ô		n
	50-56 Days (Group 2)	43	0			0	Ó		0		Ô		Ô
	57-63 Days (Group 3)	38	1	(3%)		1	1	(100%)	0		n		ó

<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.

### 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			19		
	Age	Number	of Pts	exact	Number		Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	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
	s49 Days (Group 1)	70	0 '		0	0	0	0	0
	50-56 Days (Group 2)	43	Ο,		0	0	0	0	0
	57-63 Days (Group 3)	38	1 (3%)		1	1 (100%)	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	0
	s49 Days (Group 1)	70	0		0	0	0	0	0
	\$0-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
MICTURITION DISORDER	≤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	1 0	0
REPRODUCTIVE DISORDERS, PENALE									
ANY EVENT	≤63 Days (All)	151	7 (5%)	1.0000	7	1 (14%)	2 (29%)	4 (57%)	0
	≤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	0	0	2 (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.

Center: VARGAS (#22)

Body System/Event [2]	Gestational Age Group [3]	Total Number	of	ber Pts	Fisher's exact	Number				Severi	ty		
	G104P (3)	of Pts	W/E	vent	p-value	of Events	Mi	1 <b>d</b>	Mod	erate	Se	vere	Unknown
REPRODUCTIVE DISORDERS, PENALE	(cont.)					-							
LEUKORRĤOEA	≤63 Days (All)	151	1	(<1%)	1.0000			/1001\	_				
	s49 Days (Group 1)	70	1	(1%)	1.0000	,		(100%)	0		0		0
	50-56 Days (Group 2)	43	ō	(/		•		(100%)	0		0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
	•		v			0	0		0		0		0
UTERINE HAEMORRHAGE	≤63 Days (All)	151	5	(3%)	0.7184	_							
	#49 Days (Group 1)	70	2	(3%)	0.7184	5	0		1	(20%)	4	(80%)	0
	50-56 Days (Group 2)	43	i	(21)		2	0		1	(50%)	1	(50%)	0
	57-63 Days (Group 3)	38	2	(5%)		1	0		0		1	(100%)	0
	= == ; = (szcup 3)	20	-	(34)		2	0		0		2	(100%)	0
VAGINITIS	s63 Days (All)	151	,	(<1%)	0.5364	_							
	±49 Days (Group 1)	70		(<14)	0.5364	1	0		. 1	(100%)	0		0
	50-56 Days (Group 2)	43		/mas		0	0		0	•	0		0
	57-63 Days (Group 3)	38	1	(2%)		1	0		1	(100%)	0		0
	37 03 Days (Group 3)	38	0			0	0		0		0		0
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	161											
			137	(91%)	0.1814	253	55	(22%)	97	(38%)	101	(40%)	0
	\$49 Days (Group 1)	70	60	(86%)		97	25	(26%)	40	(41%)	32	(33%)	0
	50-56 Days (Group 2)	43	41	(95%)		84	16	(19%)	33	(39%)	35	(42%)	o o
	57-63 Days (Group 3)	38	36	(95%)		72	14	(19%)	24	(33%)	34	(47%)	Ô

<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 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)

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	Severityseverityseveritys						
	Group (3)	OL PUS		·····	b. varue	or Evencs	P14	.14	Mode	tace			Unknow
ODY AS A MHOLE - GENERAL DISORDERS	(cont.)												
ABDOMINAL PAIN	≤63 Days (All)	151	137	(91%)	0.1814	236	47	(20%)	88	(37%)	101	(43%)	0
	s49 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
	≤49 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	(50%)	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			1			ň
	50-56 Days (Group 2)	43	2	(5%)		2	0		2	(100%)	0		0
	57-63 Days (Group 3)	38	0			0	0	l	0	,,,,,	ō		ō
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
	s49 Days (Group 1)	70	0			0	0		0		0		Ö
	50-56 Days (Group 2)	43	0			0	0		o		0		0
	57-63 Days (Group 3)	38	1	(3%)		1	0		1	(100%)	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)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event		Fisher's exact  p-value	Number -	 Mi			Severit erate	y Severe	Unknow
ODY AS A MHOLE - GENERAL DISORDERS	(cont.)				<del></del>							
RIGORS	≤63 Days (All)	151	3	(2%)	0.1517	3	2	(67%)	1	(33%)	0	0
	≤49 Days (Group 1)	70	0			0	Ö	, ,	0	,	0	Ô
	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	≤63 Days (All)	151	2	(1%)	1.0000	2	1	(50%)	1	(50%)	0	0
	≤49 Days (Group 1)	70	1	(1%)		1	Ō		1	(100%)	o	ō
	50-56 Days (Group 2)	43		(2%)		1	1	(100%)	ō		ō	ō
	57-63 Days (Group 3)	38	0			0	0		0		ō	Ô

<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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Center:	-

Body System/Event [2]	Gestational Age	Total Number			Fisher's exact	Number		<b></b> .!		Severi	ty		<b>.</b>	
	Group [3]	of Pts			p-value	of Events	Mild		Moderate		Severe		Unknown	
•														
ANY EVENT	≤63 Days (All)	89	88	(991)	1.0000	505	165	(33%)	204	(40%)	135	(27%)	1	(<11
	≤49 Days (Group 1)	35	34	(971)		175	59	(34%)	66	(38%)	49	(28%)	1	(<11
	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	
KIN AND APPENDAGES DISORDERS												1	İ	
ANY EVENT	≤63 Days (All)	89	1	(1%)	1.0000	1	0		0	1	1	(100%)	0	
	≤49 Days (Group 1)	35	1	(3%)		1	0		0	,		(100%)	ō	
	50-56 Days (Group 2)	34	0			0	0		0		. 0	,	Ŏ	
	57-63 Days (Group 3)	20	0			0	0		0		0		o	
SWEATING INCREASED	≤63 Days (All)	89	1	(1%)	1.0000	1	0		. 0		1	(100%)	0	
	s49 Days (Group 1)	35	1	(3%)	2.0000	1	0		0			(100%)	Ö	
	50-56 Days (Group 2)	34	0	,,,,,		ō	ō		ň		0	(1001)	0	
	57-63 Days (Group 3)	20	0			ō	ŏ		Ô		0		0	
USCULO-SKELETAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	89	1	(1%)	0.6067	1	0		0		1	(100%)	0	
	≤49 Days (Group 1)	35	ō	/	,	ō	ō		0			(1004)	0	
	50-56 Days (Group 2)	34	1	(3%)		í	ō		o		1	(100%)	o	
	57-63 Days (Group 3)	20	ō	, ,		0	n		0		0	. 2000/	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.