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

Center: MALLOY (#7)

	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	Number -		Severi	.ty	
Body System/Event [2]	Group [3]	of Pts	w/Eve		p-value	of Events	Mild	Moderate	Severe	Unknow
ODY AS A WHOLE - GENERAL DISORDERS (cor	t.)									
FATIGUE	≤63 Days (All)	52	5 (10%)	0.8328	5	1 (20%)	3 (60%)	1 (20%)	0
	≰49 Days (Group 1)	19	1	(5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	1	(9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	3 (14%)		3	0	2 (67%)	1 (33%)	0
FEVER	≤63 Days (All)	52	3	(6%)	0.7919	3	1 (33%)	2 (67%)	0	0
1	≤49 Days (Group 1)	19	1	(5%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	11	0		1	0	0	0	0	0
	57-63 Days (Group 3)	22	2	(91)		2	0	2 (100%)	0	0
HOT FLUSHES	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	0	0	0
LEG PAIN	≤63 Days (All)	52	2	(4%)	1.0000	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	19	1	(5%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	0	1 (100%)	0	0
RIGORS	≤63 Days (All)	52	2	(4%)	0.6848	2	1 (50%)	0	1 (50%)	0
	≰49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	1	(9%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	22	1,	(5%)		. 1	1 (100%)	° t	o ´	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

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

^[4] 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: MALLOY (#7)

	Gestational	Total	Numbe		Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pt w/Eve		exact p·value	Number of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)					<u> </u>				
SYNCOPE	≤63 Days (All)	52	1	(2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	0	0	1 (100%)	0
RESISTANCE MECHANISM DISORDERS										
ANY EVENT	≤63 Days (All)	52	2	(4%)	0.1704	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	19	2 ((11%)		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	0			0	0	0	0	0
INFECTION BACTERIAL	≤63 Days (All)	52	1	(2%)	0.5769	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	1	(5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	0			0	0	0	0	0
INFECTION PARASITIC	≤63 Days (All)	52	1	(2%)	0.5769	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	1	(5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	0			0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	52	1	(2%)	0.5769	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	19	1	(5%)		1	0	0	1 . (100%)	0
	50-56 Days (Group 2)	11	0			, 0	0	0 ,	O .	0
	57-63 Days (Group 3)	22	O.			0	0	0 t	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

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

^[4] 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: ROTHENBERG (#8)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severi	ty	.	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mi	1 d	Mode	rate	Sev	ere	Unknow
ANY EVENT	s63 Days (All)	21	21 (100%)		98	38	(39%)	37	(38%)	23	(23%)	o
ANI EVENI	≤49 Days (Group 1)	13	13 (100%)		48	25	(52%)	17	(35%)	6	(13%)	0
	50-56 Days (Group 2)	5	5 (100%)		31	7	(23%)	16	(52%)	8	(26%)	0
	57-63 Days (Group 3)	3	3 (100%)		19	6	(32%)	4	(21%)	9	(47%)	0
ENTR & PERIPH MERVOUS SYSTEM DISORDERS												_
ANY EVENT	≤63 Days (All)	21	9 (43%)	0.3870	16	0		13	(81%)	3	(19%)	0
	≤49 Days (Group 1)	13	4 (31%)	•	8	0		7	(88%)	1	(13%)	0
	50-56 Days (Group 2)	5	3 (60%)		6	0		5	(83%)	1		0
	57-63 Days (Group 3)	3	2 (67%)		2	0		1	(50%)	1	(50%)	0
DIZZINESS	≤63 Days (All)	21	1 (5%)	1.0000	2	0			(100%)	0		0
	≤49 Days (Group 1)	13	1 (8%)		2	0		2	(100%)	0		0
	50-56 Days (Group 2)	5	0		0	0		0		0		0
	57-63 Days (Group 3)	3	0		0	0		0		0		0
HEADACHE	≤63 Days (All)	21	9 (43%)	0.3870	14	0		11	(79%)	3		0
	≤49 Days (Group 1)	13	4 (31%)		6	0		5	(83%)	1	(17%)	0
	50-56 Days (Group 2)	5	3 (60%)		6	0		5	(83%)	1	(17%)	0
	57-63 Days (Group 3)	3	2 (67%)		2	0		1	(50%)	1	(50%)	0
ASTRO-INTESTINAL SYSTEM DISORDERS	1											_
ANY EVENT	≤63 Days (All)	21	16 (76%)	0.7892	. 37	19	(51%)		(27%)	8	• •	0
	≤49 Days (Group 1)	13	9 (69%)		. 18	12	(67%)		(17%)	3		0
	50-56 Days (Group 2)	5	4 (80%)		12	3	(25%)		"(50%)	3	(25%)	0
	57-63 Days (Group 3)	3	3 (100%)		7	4	(57%)	1	(14%)	2	(29%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

^[2] NOS = Not otherwise specified

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

^[4] Events in this body system occurred during the study blood sampling.

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: ROTHENBERG (#8)

	Gestational	Total	Number	Fisher's			Severi		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS (CODt.)						_	. (1001)		•
CONSTIPATION	≤63 Days (All)	21	1 (5%)	0.3810	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	-
	57-63 Days (Group 3)	3	0		· O	0	0	0	0
DIARRHEA	≤63 Days (All)	21	5 (24%)	0.7892	7	5 (71%)	2 (29%)	0	0
DIARREA	≤49 Days (Group 1)	13	4 (31%)		5	3 (60%)	2 (40%)	0	0
'	50-56 Days (Group 2)	5	1 (20%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	3	0	·	0	0	0	0	0
FLATULENCE	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
FLATULENCE	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	ō		0	0	0	0	0
NAMES	≤63 Days (All)	21	11 (52%)	0.0383	18	10 (56%)	4 (22%)	4 (22%)	0
NAUSEA	s49 Days (Group 1)	13	4 (31%)		8	5 (63%)	1 (13%)	2 (25%)	0
	50-56 Days (Group 2)	5	4 (80%)		6	1 (17%)	3 (50%)	2 (33%)	0
	57-63 Days (Group 3)	3	3 (100%)		4	4 (100%)	0	0	0
1001787110	≤63 Days (All)	21	7 (33%)	0.4466	10	3 (30%)	3 (30%)	4 (40%)	0
VOMITING	s49 Days (Group 1)	13	3 (23%)		4	3 (75%)	0	1 (25%)	0
	50-56 Days (Group 2)	5	2 (40%)		3	0	2 (67%)	1, (33%)	0
	57-63 Days (Group 3)	3	2 (67%)		3	0	1 (33%)	2 (67%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

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

^[4] 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: ROTHENBERG (#8)

	Gestational	Total	Number	Fisher's	N. mb a m		Sever	i e	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS			1111						
ANY EVENT	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	21	20 (95%)	1.0000	44	18 (41%)	14 (32%)	12 (27%)	0
	≤49 Days (Group 1)	13	12 (92%)		21	12 (57%)	7 (33%)	2 (10%)	0
	50-56 Days (Group 2)	5	5 (100%)		13	4 (31%)	5 (38%)	4 (31%)	0
	57-63 Days (Group 3)	3	3 (100%)		10	2 (20%)	2 (20%)	6 (60%)	0
ABDOMINAL PAIN	≤63 Days (All)	21	20 (95%)	1.0000	38	17 (45%)	12 (32%)	9 (24%)	0
	≤49 Days (Group 1)	13	12 (92%)		19	11 (58%)	6 (32%)	2 (11%)	0
	50-56 Days (Group 2)	5	5 (100%)		12	4 (33%)	4 (33%)	4 (33%)	0
	57-63 Days (Group 3)	3	3 (100%)		7	2 (29%)	2 (29%)	3 (43%)	0
BACK PAIN	s63 Days (All)	21	3 (14%)	0.3158	5	0	2 (40%)	3 (60%)	0
	≤49 Days (Group 1)	, 13	1 (8%)		1	0	1 (100%)	O ·	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0 .	0
	57-63 Days (Group 3)	3	1 (33%)		3	0	o 4	3 (100%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

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

^[4] 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: ROTHENBERG (#8)

	Gestational		Numb of F		Fisher's exact	Number -		Seve1	-itv	
Body System/Event [2]	Age Group [3]	Number of Pts	w/Ev		p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont.								_	_	•
LEG PAIN	≤63 Days (All)	21	1	(5%)	1.0000	1	1 (100%)	0	O	0
	≤49 Days (Group 1)	13	1	(8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0			0	0	0	0	0
	57-63 Days (Group 3)	3	0			0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

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

^[4] Events in this body system occurred during the study blood sampling.

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

Center: MISHELL (#1)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number	 -			Severi	ty		
Body System/Event [2]	_	of Pts		vent	p-value	of Events	Mi	1đ	Mode	rate	Sev	ere	Unknown
ANY EVENT	≤63 Days (All)	204	146	(72%)	0.0301	279	99	(35%)	110	(39%)	70	(25%)	0
ANI EVENI	≤49 Days (Group 1)	145	99	(68%)		199	74	(37%)	78	(39%)	47	(24%)	0
	50-56 Days (Group 2)	40	35	(88%)		57	17	(30%)	25	(44%)	15	(26%)	0
	57-63 Days (Group 3)	19	12	(63%)		23	8	(35%)	7	(30%)	8	(35%)	0
SKIN AND APPENDAGES DISORDERS													_
ANY EVENT	≤63 Days (All)	204	1	(<1%)	1.0000	1	0			(100%)	0		0
	≤49 Days (Group 1)	145	1	(<1%)	•	1	0		1	(100%)	0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
SWEATING INCREASED	≤63 Days (All)	204	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	145	1	(<1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	204	18	(9%)	0.6062	19	9	(47%)	7		3	(16%)	0
	≤49 Days (Group 1)	145	15	(10%)		16	7	(44%)	6	(38%)	3	(19%)	0
	50-56 Days (Group 2)	40	2	(5%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	19	1	(5∜)		1	1	(100%)	0		0		0
	•												

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: MISHELL (#1)

	Gestational	Total	Number of Pts	Fisher's exact			Severi	tv	
Body System/Event [2]	Age Group [3]	Number of Pts	w/Event		of Events	Mild	Moderate	Severe	Unknown
ENTR & PERIPH NERVOUS SYSTEM DIS	ORDERS(cont.)								
DIZZINESS	≤63 Days (All)	204	7 (3	0.4317	8	4 (50%)	2 (25%)	2 (25%)	0
	≤49 Days (Group 1)	145	7 (9	*)	8	4 (50%)	2 (25%)	2 (25%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HEADACHE	≰63 Days (All)	204	11 ((%) 1.0000	11	5 (45%)	5 (45%)	1 (9%)	0
HEADACHE	≤49 Days (Group 1)	145	8 ((4)	8	3 (38%)	4 (50%)	1 (13%)	0
	50-56 Days (Group 2)	40		(%)	. 2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	19		(*)	1	1 (100%)	0	0	0
SYCHIATRIC DISORDERS									_
ANY EVENT	≤63 Days (All)	204	2 (<	.*) 1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	145	2 (.*)	3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	204	1 (<	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<	L %)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	204	1 (<	1.0000	1	0	1 (100%)	0	0
DEL VOOC 1011	≤49 Days (Group 1)	145	1 (<	L %)	1	0	1 (100%)	0 !	0
	≤49 Days (Group 1) 50-56 Days (Group 2)	40	o .		. 0	0	0	0	0
	57-63 Days (Group 3)	19	o .		0	0	o "	0	0

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

Appendix A.1, Table 25

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^[2] NOS - Not otherwise specified

^[3] 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: MISHELL (#1)

	Gestational Age	Total	Numb		Fisher's					6			
Body System/Event [2]	_	Number of Pts	of I		exact p-value	Number of Events		1 d		Severi rate	•	ere	Unknowr
PSYCHIATRIC DISORDERS	(cont.)	• •											
INSOMNIA	≤63 Days (All)	204	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	145	1	(<1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
GASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	204	84	(41%)	0.2197	127	34	(27%)	42	(33%)	51	(40%)	0
•	≤49 Days (Group 1)	145	57	(39%)		86	25	(29%)	27	(31%)	34	(40%)	0
	50-56 Days (Group 2)	40	21	(53%)	•	32	8	(25%)	12	(38%)	12	(38%)	0
	57-63 Days (Group 3)	19	6	(32%)		9	1	(11%)	3	(33%)	5	(56%)	0
ABDOMINAL PAIN	s63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≰49 Days (Group 1)	145	1	(<1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
DIARRHEA	≤63 Days (All)	204	2	(<1%)	0.0450	3	1	(33%)	1	(33%)	1	(33%)	0
	≤49 Days (Group 1)	145	0			0	0		0		0		0
	50-56 Days (Group 2)	40	1	(3%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	19	1	(5%)		1	0		0		1	(100%)	0
DYSPEPSIA	≤63 Days (All)	204	2	(<1%)	1.0000	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	145	2	(1%)		2	1	(50%)	1	(50%)	0 ,		0
	50-56 Days (Group 2)	40	0			; 0	0		0		0 -		0
	57-63 Days (Group 3)	19	0.			• 0	0		0	į.	0		0

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

Appendix A.1, Table 25

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^[2] NOS - Not otherwise specified

^[3] 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: MISHELL (#1)

	Gestational	Total	Number		Fisher's					_			
Body System/Event (2)	-	Number of Pts	of Pts w/Even		exact p-value	Number of Events	Mi	1d	Mode	Severi rate	-	ere	Unknow
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												
FLATULENCE	≤63 Days (All)	204	1 (<	1%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	145	1 (<	1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	204	79 (3	91)	0.0539	89	25	(28%)	23	(26%)	41	(46%)	0
1	≰49 Days (Group 1)	145	54 (3	7%)		62	20	(32%)	14	(23%)	28	(45%)	0
	50-56 Days (Group 2)	40	21 (5	3%)		23	5	(221)	8	(35%)	10	(43%)	0
	57-63 Days (Group 3)	19	4 (2	11)		4	0		1	(25%)	3	(75%)	0
VOMITING	≤63 Days (All)	204	27 (1	3*)	0.2676	31	5	(16%)	17	(55%)	9	(29%)	0
	≤49 Days (Group 1)	145	16 (1	11)		20	2	(10%)	12	(60%)	6	(30%)	0
	50-56 Days (Group 2)	40	7 (1	81)		7	2	(29%)	3	(43%)	2	(29%)	0
	57-63 Days (Group 3)	19	4 (2	1*)		4	1	(25%)	2	(50%)	1	(25%)	0
RESPIRATORY SYSTEM DISORDERS							!						
ANY EVENT	≤63 Days (All)	204	1 (<	11)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	145	1 (<	1%)		1	0		1	(100%)	0		0
•	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
RHINITIS	≤63 Days (All)	204	1 (<	1%)	1.0000	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	145	1 (<	1%)		, 1	0		1	(100%)	0	1	0
	50-56 Days (Group 2)	40	0.			• 0	0		0	Ł	0		0
	57-63 Days (Group 3)	19	0			0	0		0	μ	0		0

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

Appendix A.1, Table 25

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^[2] NOS - Not otherwise specified

^[3] 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: MISHELL (#1)

	Gestational	Total	Numb of F		Fisher's	No contra a co				0		
Body System/Event [2]	Age Group [3]	Number of Pts	w/Ev		exact p-value	Number of Events	Mi	1d	Moder	Severi ate	Severe	Unknow
EPRODUCTIVE DISORDERS, PEMALE												
ANY EVENT	≤63 Days (All)	204	3	(1%)	0.3435	3	1	(33%)	1	(33%)	1 (33%	0
	≤49 Days (Group 1)	145	2	(1%)		2	1	(50%)	1	(50%)	0	0
	50-56 Days (Group 2)	40	0			0	0		0		0	0
	57-63 Days (Group 3)	19	1	(5%)		1	0		0		1 (100%	0
LEUKORRHOEA	≤63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		0	0
	≤49 Days (Group 1)	145	1	(<1%)		1	1	(100%)	0		0	0
'	50-56 Days (Group 2)	40	0			0	0		0		0	0
	57-63 Days (Group 3)	19	0		,	0	0		0		0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	204	1	(<1%)	0.0931	1	0		0		1 (100%	0
	≤49 Days (Group 1)	145	0			0	0		0		0	0
	50-56 Days (Group 2)	40	0			0	0		0		0	0
	57-63 Days (Group 3)	19	1	(5%)		1	0		0		1 (100%	0
VAGINITIS	≤63 Days (All)	204	1	(<1%)	1.0000	1	0		1 (100%)	0	0
	≤49 Days (Group 1)	145	1	(<1%)		1	0		1 (100%)	0	0
	50-56 Days (Group 2)	40	0			0	0		0		0	0
	57-63 Days (Group 3)	19	0			0	0		0		0	0
ODY AS A WHOLE - GENERAL DISORDERS												
ANY EVENT	≤63 Days (All)	204	106	(52%)	0.8520	125	54	(43%)	56	(45%)	15 (12%	0
	≰49 Days (Group 1)	145	75	(52%)		90	40	(44%)	40	(44%)	10 (11%	0
	50-56 Days (Group 2)	40	22	(55%)		· 23	8	(35%)	12	(52%)	3 (13%	0
	57-63 Days (Group 3)	19	9.	(47%)		12	6	(50%)	4 1	(33%)	2 (17%	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: MISHELL (#1)

	Gestational Age	Total Number	Num of		Fisher's exact	Number				Severi	tv		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	.1d	Mode	rate	•	ere	Unknow
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)												
ABDOMINAL PAIN	≤63 Days (All)	204	103	(50%)	0.8503	109	46	(42%)	51	(47%)	12	(11%)	0
	≤49 Days (Group 1)	145	72	(50%)		77	34	(44%)	35	(45%)	8	(10%)	0
	50-56 Days (Group 2)	40	22	(55%)		22	8	(36%)	12	(55%)	2	(9%)	0
	57-63 Days (Group 3)	19	9	(47%)		10	4	(40%)	4	(40%)	2	(20%)	0
ASTHENIA	≤63 Days (All)	204	1	(<1%)	1.0000	1	0		1	(100%)	0		0
I I	≤49 Days (Group 1)	145	1	(<1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	40	0		•	0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
BACK PAIN	s63 Days (All)	204	6	(3%)	0.3678	6	4	(67%)	2	(33%)	0		0
	≤49 Days (Group 1)	145	5	(3%)		5	3	(60%)	2	(40%)	0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
!	57-63 Days (Group 3)	19	1	(5≹)		1	1	(100%)	0		0		0
CHEST PAIN	s63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	£49 Days (Group 1)	145	1	(<1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
FATIGUE	≤63 Days (All)	204	4	(2%)	0.7159	4	2	(50%)	1	(25%)	1	(25%)	0
	≤49 Days (Group 1)	145	4	(3%)		4	2	(50%)	1	(25%)	1	(25%)	0
	50-56 Days (Group 2)	40	0			. 0	0		0		0 '		0
	57-63 Days (Group 3)	19	Q			• 0	0		0	t	0		0

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

Appendix A.1, Table 25

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⁽²⁾ NOS = Not otherwise specified

^[3] 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: MISHELL (#1)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Cover	i ty -	
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
SODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
MALAISE	≰63 Days (All)	204	1 (<1%)	0.0931	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
RIGORS	≤63 Days (All)	204	1 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
ı	≤49 Days (Group 1)	145	1 (<1%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	40	0	4	0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	204	1 (<1%)	0.2892	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total		ber	Fisher's	Monthson				Sever:	. 		
Body System/Event [2]	Age Group [3]	Number of Pts		Pts Event	exact p·value	Number of Events	Mi			rate	Sev	ere	Unknown
												4	_
ANY EVENT	≤63 Days (All)	238	201	(84%)	0.8111	553	260	(47%)	214	(39%)	79	(14%)	0
	≤49 Days (Group 1)	81	67	(83%)		177	81	(46%)	66	(37%)	30	(17%)	0
	50-56 Days (Group 2)	89	75	(84%)		201	104	(52%)	72	(36%)	25	(12%)	0
	57-63 Days (Group 3)	68	59	(87%)		175	75	(43%)	76	(43%)	24	(14%)	0
BEIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	238	4	(2%)	0.8345	4	0		2	(50%)	2	(50%)	0
'	≤49 Days (Group 1)	81	2	(2%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	89	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	68	1	(1%)		1	0		0		1	(100%)	0
SWEATING INCREASED	≤63 Days (All)	238	4	(2%)	0.8345	4	0		2	(50%)	2	(50%)	0
	≤49 Days (Group 1)	81	2	(2%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	89	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	68	1			1	0		0		1	(100%)	0
MUSCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	238	2	(<1%)	0.0808	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	0			0	0		0		0		0
	57-63 Days (Group 3)	68	2	(3%)		2	1	(50%)	1	(50%)	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total Number		ber Pts	Fisher's exact	Number				Severi	***		
Body System/Event [2]	Age Group [3]	of Pts		vent	p value	of Events		ld	Mode		•	/ere	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS	(cont.)									•			
ARTHRALGIA	≤63 Days (All)	238	2	(<1%)	0.0808	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	0			0	0		0		0		0
	57-63 Days (Group 3)	68	2	(3%)		2	1	(50%)	1	(50%)	0		0
CENTR & PERIPH NERVOUS SYSTEM DIS	ORDERS												
ANY EVENT	≤63 Days (All)	238	41	(17%)	0.3182	55	22	(40%)	26	(47%)	7	(13%)	0
	≤49 Days (Group 1)	81	18	(22%)	,	23	7	(30%)	13	(57%)	3	(13%)	0
	50-56 Days (Group 2)	89	12	(13%)		15	7	(47%)	5	(33%)	3	(20%)	0
	57-63 Days (Group 3)	68	11	(16%)		17	8	(47%)	8	(47%)	1	(6%)	0
DIZZINESS	≤63 Days (All)	238	13	(5%)	0.0515	15	4	(27%)	8	(53%)	3	(20%)	0
	≤49 Days (Group 1)	81	7	(9%)		7	2	(29%)	3	(43%)	2	(29%)	0
	50-56 Days (Group 2)	89	1	(1%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	68	5	(7%)		7	2	(29%)	5	(71%)	0		0
HEADACHE	≤63 Days (All)	238	32	(13%)	0.6228	38	17	(45%)	17	(45%)	4	(11%)	0
	≤49 Days (Group 1)	81	13	(16%)		16	5	(31%)	10	(63%)	1	(6%)	0
	50-56 Days (Group 2)	89	10	(11%)		12	6	(50%)	4	(33%)	2	(17%)	0
	57-63 Days (Group 3)	68	9	(13%)		10	6	(60%)	3	(30%)	1	(10%)	0
HYPERTONIA	≤63 Days (All)	238	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	81	0			0	0		0		0	•	0
	50-56 Days (Group 2)	89	1	(1%)		• 1	1	(100%)	0	,	0		0
	57-63 Days (Group 3)	68	0			0	0		0	ti.	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total	Number	Fisher's					
	Age	Number	of Pts	exact	Number		Severi	•	Unknown
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Ulknowii
CENTR & PERIPH NERVOUS SYSTEM DISC	RDERS (cont.)								
TREMOR	≰63 Days (All)	238	1 (<	1.0000	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (. %)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		. 0	0	0	0	0
HEARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<	1.0000	1	0	0	1 (100%)	0
'	≰49 Days (Group 1)	81	0		. 0	0	0	0	0
	50-56 Days (Group 2)	89	1 (. *)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TINNITUS	≤63 Days (All)	238	1 (<	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (.*)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PECIAL SENSES OTHER, DISORDERS						1			
ANY EVENT	≤63 Days (All)	238	1 (<	1 0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 ((%)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
	•								

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Seve ri	ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p·value	of Events	Mild	Moderate	Severe 0 0 0 0 0 0 1 (25*) 0 0 0 1 (25*) 1 (100*) 0	Unknow
SPECIAL SENSES OTHER, DISORDERS	(cont.)							_	_
TASTE PERVERSION	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	O
SYCHIATRIC DISORDERS						- (2 (201)	0
ANY EVENT	≤63 Days (All)	238	9 (41)	0.2917	10	3 (30%)	4 (40%)		-
	≤49 Days (Group 1)	81	1 (1%)	•	2	0	0		0
	50-56 Days (Group 2)	89	4 (4%)		4	1 (25%)	3 (75%)	•	0
	57-63 Days (Group 3)	68	4 (6%)		4	2 (50%)	1 (25%)	1 (25*)	0
ANXIETY	s63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0		0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
APPETITE INCREASED	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	238	4 (2%)	0.6841	4	1 (25%)	2 (50%)		0
EMOTIONAL DEPTITI	s49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	1 (1%)		. 1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total	Numi		Fisher's	Number				Severi	tv		
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	vent	exact p value	of Events	Mi			rate	•	ere	Unknown
SYCHIATRIC DISORDERS	(cont.)												
HALLUCINATION	≰63 Days (All)	238	1	(<1%)	0.2857	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	0			0	0		0		0		0
	57-63 Days (Group 3)	68	1	(1%)		1	1	(100%)	0		0		0
INSOMNIA	≤63 Days (All)	238	3	(1%)	1.0000	3	0		1	(33%)		(67%)	0
11150.1111	≤49 Days (Group 1)	81	1	(1%)		1	0		0		1	(100%)	0
,	50-56 Days (Group 2)	89	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	68	1	(1%)		1	0		0		1	(100%)	0
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	238	120	(50%)	0.0699	201	77	(38%)	91		33		0
	s49 Days (Group 1)	81	33	(41%)		44	15	(34%)	20	(45%)	9	(20%)	0
· ·	50-56 Days (Group 2)	89	52	(58%)		95	43	(45%)	40		12		0
	57-63 Days (Group 3)	68	35	(51%)		62	19	(31%)	31	(50%)	12	(19%)	0
ABDOMINAL PAIN	≰63 Days (All)	238	4	(2%)	1.0000	4	1	(25%)	2	(50%)		(25%)	0
	≤49 Days (Group 1)	81	1	(1%)		1	0		0			(100%)	0
	50-56 Days (Group 2)	89	2	(21)		2	1	(50%)	1		0		0
	57-63 Days (Group 3)	68	1	(1%)		1	0		1	(100%)	0		0
DIARRHEA	≤63 Days (All)	238	7	(3%)	0.6314	7	3	(43%)	4		0		0
	≰49 Days (Group 1)	81	2	(2%)		2	1	(50%)	1	(50%)	0	•	0
	50-56 Days (Group 2)	89	4	(4%)		4	2	(50%)	2	(50%)	0		0
	57-63 Days (Group 3)	68	1	(1%)		1	0		1	(4004)	0		0

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

Appendix A.1, Table 25

^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	Number	- -			Severi	.ty		
Body System/Event [2]	Group [3]	of Pts	w/Eve		p-value	of Events	Mi	1đ	Mode	rate	Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												
DYSPEPSIA	≰63 Days (All)	238		(3%)	0.6314	9	3	(33%)	5		1	(11%)	0
	≰49 Days (Group 1)	81	2	(2%)		2	1	(50%)	1	•	0		0
	50-56 Days (Group 2)	89		(4%)		6	2	(33%)	3		1	(17%)	0
	57-63 Days (Group 3)	68	1	(1%)		1	0		1	(100%)	0		0
FLATULENCE	≤63 Days (All)	238	3	(1%)	0.6361	3	0		2	(67%)	1	(33%)	0
1	≤49 Days (Group 1)	81	2	(2%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	89	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	68	0			0	0		0		0		0
HAEMATEMESIS	≤63 Days (All)	238	1 ((<1%)	1.0000	1	1	(100%)	0		0		0
India: di locati	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	1	(1%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	68	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	238	99 ((42%)	0.0271	119	49	(41%)	49	(41%)	21	(18%)	0
naoon	≤49 Days (Group 1)	81	24 ((30%)		26	11	(42%)	10	(38%)	5	(19%)	0
	50-56 Days (Group 2)	89	43 ((48%)		55	25	(45%)	22	(40%)	8	(15%)	0
	57-63 Days (Group 3)	68	32 ((47%)		38	13	(34%)	17	(45%)	8	(21%)	0
VOMITING	≤63 Days (All)	238	47 ((20%)	0.0980	58	20	(34%)	29	(50%)	9	(16%)	0
	≤49 Days (Group 1)	81	10 ((12%)		11	2	(18%)	7	(64%)	2	(18%)	0
	50-56 Days (Group 2)	89	20 ((22%)		26	12	(46%)	11	(42%)	3	(12%)	0
	57-63 Days (Group 3)	68	17 ((25%)		. 21	6	(29%)	11	j (52%)	4	(19%)	0

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

Appendix A.1, Table 25

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^[2] NOS - Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severi	t y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ETABOLIC AND NUTRITIONAL DISORDERS						. (000)	. (228)	1 (228)	
ANY EVENT	≤63 Days (All)	238	3 (14)	0.3861	3	1 (33%)	1 (33%)	1 (33%) 1 (50%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	1 (50%)	0		0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
DEHYDRATION	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
DENIDRATION	≰49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
'	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
THIRST	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
Inikai	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
WEIGHT DECREASE	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
WEIGHT DECREASE	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
EART RATE AND RHYTHM DISORDERS									_
ANY EVENT	≰63 Days (All)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	Ο,	0
	50-56 Days (Group 2)	89	0		0	0	0	0 ·	0
	57-63 Days (Group 3)	68	0 .		. 0	0	o i	0	0

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

Appendix A.1, Table 25

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^[2] NOS - Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total	Number	Fisher's	Number		Severi	tv	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	of Events	Mild	Moderate	Severe	Unknown
HEART RATE AND RHYTHM DISORDERS	(cont.)								
TACHYCARDIA	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
••••	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.7790	4	3 (75%)	0	1 (25%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
DYSPNOEA	≰63 Days (All)	238	1 (<1%)	1.0000	2	2 (100%)	0	0	0
2101.NO2.1	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	О	0	0
HAEMOPTYSIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
IMEROT TIDEO	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PULMONARY CONGESTION	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
10M OWNER CONTRACTOR	≰49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	Ο,	0
	50-56 Days (Group 2)	89	0		, 0	0	0	0 .	0
	57-63 Days (Group 3)	68	0		0	0	0 h	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total	Numb		Fisher's	Number		Sever	i + v	
Body System/Event [2]	Age Group (3)	Number of Pts	of I		exact p-value	of Events	Mild	Moderate	Severe	Unknown
LATELET, BLEEDING & CLOTTING DISORDERS										
ANY EVENT	≰63 Days (All)	238	1	(<1%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	81	0			0	0	0	0	0
	50-56 Days (Group 2)	89	1	(1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0			0	0	0	0	0
EPISTAXIS	≤63 Days (All)	238	1	(<1%)	1.0000	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	81	0			0	0	0	0	0
·	50-56 Days (Group 2)	89	1	(1%)	,	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0			0	0	0	0	0
EPRODUCTIVE DISORDERS, PENALE										
ANY EVENT	≤63 Days (All)	238	13	(5%)	0.7221	14	3 (21%)	6 (43%)	5 (36%)	0
	≤49 Days (Group 1)	81	3	(4%)		4	0	2 (50%)	2 (50%)	0
	50-56 Days (Group 2)	89	6	(7%)		6	2 (33%)	2 (33%)	2 (33%)	0
	57-63 Days (Group 3)	68	4	(6%)		4	1 (25%)	2 (50%)	1 (25%)	0
LEUKORRHOEA	≤63 Days (All)	238	2	(<1%)	0.3345	2	2 (100%)	0	0	0
	≰49 Days (Group 1)	81	0			0	0	0	0	0
	50-56 Days (Group 2)	89	2	(2%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	68	0			0	0	0	0	0
MENSTRUAL DISORDER	≤63 Days (All)	238	1	(<1%)	0.2857	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0			0	0	0	Ο,	0
	50-56 Days (Group 2)	89	0			0	0	0 ,	O ·	0
	57-63 Days (Group 3)	68	1	(1%)		1	1 (100%)	o l	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total	Num		Fisher's								
	Age	Number	of	Pts vent	exact p-value	Number of Events	Mile			severi rate	•	ere	Unknown
Body System/Event [2]	Group [3]	of Pts	W/E	venc	p-varde	OI EVENCE	1711	<u>.</u>					
REPRODUCTIVE DISORDERS, FEMALE	(cont.)												
OVARIAN DISORDER	≤63 Days (All)	238	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	68	0			0	0		0		0		0
PREMENSTRUAL TENSION	≤63 Days (All)	238	1	(<1%)	0.2857	1	0		1	(100%)	0		0
ı	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	0			0	0		0		0		0
	57-63 Days (Group 3)	68	1	(1%)		1	0		1	(100%)	0		0
UTERINE HAEMORRHAGE	≤63 Days (All)	238	8	(3%)	1.0000	9	0		4	(44%)	5	(56%)	0
	≤49 Days (Group 1)	81	3	(4%)		4	0		2	(50%)	2	(50%)	0
	50-56 Days (Group 2)	89	3	(3%)		3	0		1	(33%)	2	(67%)	0
	57-63 Days (Group 3)	68	2	(3%)		2	0		1	(50%)	1	(50%)	0
ODY AS A WHOLE - GENERAL DISORDERS							!						
ANY EVENT	≤63 Days (All)	238	164	(69%)	0.0906	255	147	(58%)	82	(32%)	26	(10%)	0
	≤49 Days (Group 1)	81	58	(72%)		97	56	(58%)	29	(30%)	12	(12%)	0
	50-56 Days (Group 2)	89	54	(61%)		74	47	(64%)	21	(28%)	6	(8%)	0
	57-63 Days (Group 3)	68	52	(76%)		84	44	(52%)	32	(38%)	8	(10%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	158	(66%)	0.0910	226	131	(58%)	73	(324)	22	(10%)	0
	≤49 Days (Group 1)	81	55	(68%)		85	47	(55%)	28	(33%)	10	(12%)	0
	50-56 Days (Group 2)	89	52	(58%)		66	43	(65%)	18	(27%)	5	(8%)	0
	57-63 Days (Group 3)	68	51	(75%)		75	41	(55∜)	27	[[] (36¥)	7	(9%)	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total	Number of Pts	Fisher's exact			Sever	itv	
Body System/Event [2]	Age Group [3]	Number of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
ASTHENIA	≤63 Days (All)	238	2 (<1	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	1 (1	;)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1	()	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		О	0	0	0	0
BACK PAIN	≤63 Days (All)	238	6 (3	0.7724	7	4 (57%)	2 (29%)	1 (14%)	0
	≤49 Days (Group 1)	81	3 (4	i)	4	3 (75%)	1 (25%)	0	0
,	50-56 Days (Group 2)	89	2 (2	i)	. 2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	1 (1	1)	1	1 (100%)	0	0	0
CHEST PAIN	≤63 Days (All)	238	1 (<1	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1	k)	1	0	1 (100%)	0	0
FATIGUE	≤63 Days (All)	238	11 (5	0.8614	11	6 (55%)	4 (36%)	1 (9%)	0
	≤49 Days (Group 1)	81	3 (4	b)	3	2 (67%)	0	1 (33%)	0
	50-56 Days (Group 2)	89	4 (4	k)	4	3 (75%)	1 (25%)	0	0
	57-63 Days (Group 3)	68	4 (6	k)	4	1 (25%)	3 (75%)	0	0
FEVER	s63 Days (All)	238	2 (<1	0.5298	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1	k)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	Ο ,	0
	57-63 Days (Group 3)	68	1 (1	k)	1	1 (100%)	٥	0 ·	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severi	.ty	
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.)								
HOT FLUSHES	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
MALAISE	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
•	≰49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		. 0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
PAIN	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
· ·	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
RIGORS	≤63 Days (All)	238	2 (<1%)	0.7444	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (100%)	0
SYNCOPE	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0 '	0
	57-63 Days (Group 3)	68	0		• o	0	ه ا	0 '	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: HASKELL (#2)

	Gestational	Total	Number	Fisher's			8		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	81	0		0	0	0	0	0
·	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: POPPEMA (#3)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severi	ity		- -	
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi			rate	•	ere		nown
ANY EVENT	≤63 Days (All)	164	141	(86%)	0.9576	313	130	(42%)	119	(38%)	63	(20%)	1	(<1
	≤49 Days (Group 1)	65	56	(86%)		113	43		48	(42%)	22	(19%)	0	
	50-56 Days (Group 2)	65	55	(85%)		110	47	(43%)	41	(37%)	22	(20%)	0	
	57-63 Days (Group 3)	34	30	(88%)		90	40	(44%)	30	(33%)	19	(21%)	1	(1%
SKIN AND APPENDAGES DISORDERS														
ANY EVENT	≤63 Days (All)	164	1	(<1%)	1.0000	2	1	(50%)	1	(50%)	0		0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	1	(2%)		2	1	(50%)	1	(50%)	0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	
RASH MACULO-PAPULAR	≤63 Days (All)	164	1	(<1%)	1.0000	2	1	(50%)	1	(50%)	0		0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	1	(2%)		2	1	(50%)	1	(50%)	0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	
MUSCULO-SKELETAL SYSTEM DISORDERS														
ANY EVENT	≰63 Days (All)	164	1	(<1%)	0.2073	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	0			0	0		0		0		0	
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0		0	

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: POPPEMA (#3)

	Gestational	Total	Numb		Fisher's	Number				Severi				
Body System/Event [2]	Age Group [3]	Number of Pts	of F w/Ev		exact p-value	of Events	Mi	1 d	Mode		•	er e	Unk	known
MUSCULO-SERLETAL SYSTEM DISORDERS	(cont.)													
MYALGIA	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	0			0	0		0		0		0	
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0		0	
CENTR & PERIPH NERVOUS SYSTEM DISOR	DERS													
ANY EVENT	≤63 Days (All)	164	27	(16%)	0.2776	31	11	(35%)	13		6	(19%)	1	(3%)
	≤49 Days (Group 1)	65	13	(20%)		13	6	(46%)	6	(46%)	1	(B#)	0	
	50-56 Days (Group 2)	65	7	(11%)		8	3	(38%)	3		2	• ,	0	
	57-63 Days (Group 3)	34	7	(21%)		10	2	(20%)	4	(40%)	3	(30%)	1	(10%)
DIZZINESS	≤63 Days (All)	164	3	(2%)	0.1093	3	0		1	(33%)	2	(67%)	0	
	≤49 Days (Group 1)	65	1	(2%)		1	0		0		1	(100%)	0	
	50-56 Days (Group 2)	65	0			0	0		0		0		0	
	57-63 Days (Group 3)	34	2	(6%)		2	0		1	(50%)	1	(50%)	0	
HEADACHE	≤63 Days (All)	164	25	(15%)	0.4245	28	11	(39%)	12	(43%)	4	(14%)	1	(41)
	≤49 Days (Group 1)	65	12	(18%)		12	6	(50%)	6	(50%)	0		0	
	50-56 Days (Group 2)	65	7	(11%)		8	3	(38%)	3	(38%)	2	(25%)	0	
	57-63 Days (Group 3)	34	6	(18%)		8	2	(25%)	3	(38%)	2	(25%)	1	(13%)
PSYCHIATRIC DISORDERS														
ANY EVENT	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		1	(100%)	0	ı	0	
	≤49 Days (Group 1)	65	0			. 0	0		0		0		0	
	50.56 Days (Group 2)	65	0			0	0		0	ı.	0		0	
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0		0	

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

Appendix A.1, Table 25

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^[2] NOS - Not otherwise specified

^[3] 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: POPPEMA (#3)

	Gestational Age	Total Number	Num of		Fisher's exact	Number				Severi	ty		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	11d	Mode	rate	Sev	ere	Unknown
PSYCHIATRIC DISORDERS	(cont.)												
ANXIETY	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	65	0			0	0		0		0		0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0		0
GASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	164	91	(55%)	0.1284	141	42	(30%)	62	(44%)	37	(26%)	0
	≤49 Days (Group 1)	65	33	(51%)		48	11	(23%)	25	(52%)	12	(25%)	0
	50-56 Days (Group 2)	65	34	(52%)		51	14	(27%)	24	(47%)	13	(25%)	0
	57-63 Days (Group 3)	34	24	(71%)		42	17	(40%)	13	(31%)	12	(29%)	0
ABDOMINAL PAIN	≤63 Days (All)	164	4	(2%)	0.1553	5	3	(60%)	2	(40%)	0		0
	≤49 Days (Group 1)	65	2	(3%)		3	1	(33%)	2	(67%)	0		0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34	2	(6%)		2	2	(100%)	0		0		0
DIARRHEA	≤63 Days (All)	164	8	(5%)	0.7176	8	4	(50%)	3	(38%)	1	(13%)	0
	≤49 Days (Group 1)	65	4	(6%)		4	1	(25%)	2	(50%)	1	(25%)	0
	50-56 Days (Group 2)	65	2	(3%)		2	2	(100%)	0		0		0
	57-63 Days (Group 3)	34	2	(61)		2	1	(50%)	1	(50%)	0		0
DYSPEPSIA	≤63 Days (All)	164	4	(2%)	1.0000	4	2	(50%)	2	(50%)	0		0
	≤49 Days (Group 1)	65	1	(2%)		1	1	(100%)	0		0	ı	0
	50-56 Days (Group 2)	65	2	(3%)		. 2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	34	1	(3%)		1	0	*	1	(100±)	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: POPPEMA (#3)

	Gestational	Total	Num		Fisher's					0			
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	vent	exact p·value	Number of Events		1d		Severi rate	-	ere	Unknowr
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)	·········			·····		-				***************************************		
FLATULENCE	≤63 Days (All)	164	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	65	1	(2%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	164	79	(48%)	0.1305	94	28	(30%)	40	(43%)	26	(28%)	0
à .	≤49 Days (Group 1)	65	26	(40%)		30	8	(27%)	14	(47%)	8	(27%)	0
	50-56 Days (Group 2)	65	32	(49%)		36	10	(28%)	17	(47%)	9	(25%)	0
	57-63 Days (Group 3)	34	21	(62%)		28	10	(36%)	9	(32%)	9	(32%)	0
VOMITING	≤63 Days (All)	164	27	(16%)	0.4649	29	5	(17%)	14	(48%)	10	(34%)	0
	≤49 Days (Group 1)	65	9	(14%)		9	0		6	(67%)	3	(33%)	0
	50-56 Days (Group 2)	65	10	(15%)		11	1	(9%)	6	(55%)	4	(36%)	0
	57-63 Days (Group 3)	34	8	(24%)		9	4	(44%)	2	(22%)	3	(33%)	0
ETABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	164	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	65	0			0	٥		0		0		0
	50-56 Days (Group 2)	65	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	34	0			0	0		0		0		0
THIRST	≤63 Days (All)	164	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	65	0			0	0		0		0	+	0
	50-56 Days (Group 2)	65	1	(2%)		1	0		1	(100%)	0	'	0
	57-63 Days (Group 3)	34	0			0	0		0	lı .	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: POPPEMA (#3)

	Gestational	Total	Num		Fisher's					G			
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	Pts vent	exact p value	Number of Events	Mí	ld	Mode	Severi rate	•	ere	Unknow
RED BLOOD CELL DISORDERS	52 Paul (233)	164	,	(.18)	0.2073	,	0		1	(100%)	0		0
ANY EVENT	≤63 Days (All)	164	1	< 1%)	0.2073	1	0		0	(1004)	0		0
	≰49 Days (Group 1)	65	0			0	0		0		0		0
	50-56 Days (Group 2)	65	0	(20)		1	-		-	(100%)	0		0
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(1004)	U		U
ANAEMIA	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		1	(100%)	0		0
į.	≤49 Days (Group 1)	65	0			0	0		0		0		0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0		0
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	164	104	(63%)	0.0948	135	76	(56%)	39	(29%)	20	(15%)	0
7411 272111	≤49 Days (Group 1)	65	38	(58%)		52	26	(50%)	17	(33%)	9	(17%)	0
	50-56 Days (Group 2)	65	39	(60%)		48	29	(60%)	12	(25%)	7	(15%)	0
	57-63 Days (Group 3)	34	27	(79%)		35	21	(60%)	10	(29%)	4	(11%)	0
ABDOMINAL PAIN	≤63 Days (All)	164	100	(61%)	0.1232	120	72	(60%)	34	(28%)	14	(12%)	0
	≤49 Days (Group 1)	65	37	(57%)		48	25	(52%)	16	(33%)	7	(15%)	0
	50-56 Days (Group 2)	65	37	(57%)		42	27	(64%)	10	(24%)	5	(12%)	0
	57-63 Days (Group 3)	34	26	(76%)		30	20	(67%)	8	(27%)	2	(7%)	0
ASTHENIA	≰63 Days (All)	164	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	65	1	(21)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	65	0	,		; 0	0		0		0	1	0
	57-63 Days (Group 3)	34	0			0	0		0	Į.	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: POPPEMA (#3)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Severi	1 ***	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknowr
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
BACK PAIN	≤63 Days (All)	164	3 (2%	0.4263	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%	ı	2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%	1	1	0	0	1 (100%)	0
FATIGUE	≤63 Days (All)	164 '	5 (3%	1.0000	6	0	2 (33%)	4 (67%)	0
1	≤49 Days (Group 1)	65	2 (3%		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	65	2 (3%	,	2	0	0	2 (100%)	0
	57-63 Days (Group 3)	34	1 (3%	1	2	0	1 (50%)	1 (50%)	0
LEG PAIN	≰63 Days (All)	164	1 (<1%	0.2073	1	0	1 (100%)	0	O
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		o	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%	1	1	0	1 (100%)	0	0
PAIN	≤63 Days (All)	164	1 (<1%	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	1 (2%	1	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
RIGORS	≤63 Days (All)	164	3 (2%	0.4263	3	2 (67%)	1 (33%)	o	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%	l	2	1 (50%)	1 (50%)	0 1	0
	57-63 Days (Group 3)	34	1 (3%	l	1	1 (100%)	٥١	0 '	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: TYSON (#4)

	Gestational Age	Total Number	Num of		Fisher's exact	Number	.			Sever	ity		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknowr
ANY EVENT	≤63 Days (All)	102	82	(80%)	0.5284	169	80	(47%)	67	(40%)	22	(13%)	0
	≤49 Days (Group 1)	68	56	(82%)		120	61	(51%)	41	(34%)	18	(15%)	0
	50-56 Days (Group 2)	25	20	(80%)		42	18	(43%)	20	(48%)	4	(10%)	0
	57-63 Days (Group 3)	9	6	(67%)		7	1	(14%)	6	(86%)	0		0
MUSCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	1	(<1%)	0.3333	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	68	0			0	0		0		0		0
	50-56 Days (Group 2)	25	1	(4%)	,	1	0		1	(100%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
MYALGIA	≤63 Days (All)	102	1	(<1%)	0.3333	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	68	0			0	0		0		0		0
	50-56 Days (Group 2)	25	1	(4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	17	(17%)	0.5277	21	5	(24%)	13		3		0
	≤49 Days (Group 1)	68	13	(19%)		15	3	(20%)	9	(60%)	3	(20%)	0
	50-56 Days (Group 2)	25	4	(16%)		6	2	(33%)	4	(67%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
	•												

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

Appendix A.1, Table 25

^[2] NOS = Not otherwise specified

^[3] 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: TYSON (#4)

	Gestational	Total Number	Numb of I		Fisher's exact	Number -				Severi	tv		
Body System/Event [2]	Age Group [3]	of Pts	w/E		p-value	of Events	Mi		Mode		Sev	ere	Unknow
ENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (cont.)												
DIZZINESS	≤63 Days (All)	102	6	(6%)	0.3885	7	2	(29%)	4	(57%)		(14%)	0
	≤49 Days (Group 1)	68	3	(4%)		3	0		2	(67%)	1	(33%)	0
	50-56 Days (Group 2)	25	3	(12%)		4	2	(50%)	2	(50%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
HEADACHE	≰63 Days (All)	102	13	(13%)	0.4070	13	3	(23%)	8	(62%)	2	(15%)	0
	≤49 Days (Group 1)	68	11	(16%)		11	3	(27%)	6	(55%)	2	(18%)	0
•	50-56 Days (Group 2)	25	2	(8%)		2	0		2	(100%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
TREMOR	≤63 Days (All)	102	1	(<1%)	1.0000	1	0		1	(100%)	0		0
IKEROK	≤49 Days (Group 1)	68	1	(1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
SYCHIATRIC DISORDERS													
ANY EVENT	≤63 Days (All)	102	5	(5%)	0.4397	5	2	(40%)	3	,	0		0
	≤49 Days (Group 1)	68	5	(7%)		5	2	(40%)	3	(60%)	0		0
	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
ANXIETY	≤63 Days (All)	102	1	(<1%)	1.0000	1	0		_	(100%)	0		0
	≤49 Days (Group 1)	68	1	(1%)		1	0		1	(100%)	0 ,		0
	50-56 Days (Group 2)	25	0			. 0	0		0		0	,	0
	57-63 Days (Group 3)	9	0			. 0	0		0	ľ.	0		0

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

Appendix A.1, Table 25

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^[2] NOS - Not otherwise specified

^[3] 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: TYSON (#4)

	Gestational Age	Total Number	Numb of F		Fisher's exact	Number				Severi	tv	
Body System/Event [2]	Group (3)	of Pts	w/E		p-value	of Events	M	ild	Mode	rate	Severe	Unknown
PSYCHIATRIC DISORDERS	(cont.)											
INSOMNIA	£63 Days (All)	102	4	(4%)	0.7052	4	2	(50%)	2	(50%)	0	0
	≤49 Days (Group 1)	68	4	(6%)		4	2	(50%)	2	(50%)	0	0
	50-56 Days (Group 2)	25	0			0	0		0		0	0
	57-63 Days (Group 3)	9	0			0	0		0		0	0
GASTRO-INTESTINAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	102	35	(34%)	0.2754	47	22	(47%)	19	(40%)	6 (13%)	0
	≤49 Days (Group 1)	68	26	(38%)	1	33	18	(55%)	10	(30%)	5 (15%)	0
	50-56 Days (Group 2)	25	8	(32%)		13	4	(31%)	8	(62%)	1 (8%)	0
	57-63 Days (Group 3)	9	1	(11%)		1	0		1	(100%)	0	0
DIARRHEA	≤63 Days (All)	102	3	(3%)	0.6683	3	3	(100%)	0		o	0
	≤49 Days (Group 1)	68	3	(4%)		3	3	(100%)	0		0	0
	50-56 Days (Group 2)	25	0			0	0		0		0	0
	57-63 Days (Group 3)	9	0			0	0		0		0	0
DYSPEPSIA	≤63 Days (All)	102	1	(<1%)	0.3333	1	Ó		0		1 (100%)	0
	≤49 Days (Group 1)	68	0			0	0		0		0	0
	50-56 Days (Group 2)	25	1	(41)		1	0		0		1 (100%)	0
	57-63 Days (Group 3)	9	0			0	0		0		0	0
NAUSEA	≤63 Days (All)	102	31	(30%)	0.0907	31	17	(55%)	10	(32%)	4 (13%)	0
	≤49 Days (Group 1)	68	24	(35%)		24	14	(58%)	6	(25%)	4 (17%)	0
	50-56 Days (Group 2)	25	7	(28%)		. 7	3	(43%)	4	j(57%)	0	0
	57-63 Days (Group 3)	9	0			0	0		0	h .	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: TYSON (#4)

	Gestational	Total Number		nber Pts	Fisher's					Caus :: 1			
Body System/Event [2]	Age Group [3]	of Pts		Event	exact p-value	Number of Events	Mi			Severi erate	-	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												
VOMITING	≤63 Days (All)	102	11	(11%)	0.1755	12	2	(17%)	9	(75%)	1	(8%)	0
	≤49 Days (Group 1)	68	5	(7%)		6	1	(17%)	4	(67%)	1	(17%)	0
	50-56 Days (Group 2)	25	5	(20%)		5	1	(20%)	4	(80%)	0		0
	57-63 Days (Group 3)	9	1	(11%)		1	0		1	(100%)	0		0
METABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	102	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	68	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
DEHYDRATION	s63 Days (All)	102	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	68	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		ο .
REPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	102	2	(2%)	1.0000	2	1	(50%)	0		1	(50%)	0
	≤49 Days (Group 1)	68	2	(3%)		2	1	(50%)	0		1	(50%)	0
	50-56 Days (Group 2)	25	0			0	0		0		0	•	0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
	•												

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: TYSON (#4)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Sever:	i +	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
REPRODUCTIVE DISORDERS, FEMALE	(cont.)								
UTERINE HAEMORRHAGE	≤63 Days (All)	102	1 (<1%	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1%		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
VAGINAL DISCOMFORT	≤63 Days (All)	102	1 (<1%	1.0000	1	1 (100%)	0	0	0
T.	s49 Days (Group 1)	68	1 (1%		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≰63 Days (All)	102	71 (70%	0.7430	92	50 (54%)	31 (34%)	11 (12%)	0
	≤49 Days (Group 1)	68	46 (68%		64	37 (58%)	19 (30%)	8 (13%)	0
	50-56 Days (Group 2)	25	19 (76%		22	12 (55%)	7 (32%)	3 (14%)	0
	57-63 Days (Group 3)	9	6 (67%		6	1 (17%)	5 (83%)	0	0
ABDOMINAL PAIN	≤63 Days (All)	102	71 (70%	0.7430	82	46 (56%)	26 (32%)	10 (12%)	0
	≤49 Days (Group 1)	68	46 (68%		54	33 (61%)	14 (26%)	7 (13%)	0
	50-56 Days (Group 2)	25	19 (76%		22	12 (55%)	7 (32%)	3 (14%)	0
	57-63 Days (Group 3)	9	6 (67%		6	1 (17%)	5 (83%)	0	0
ASTHENIA	≤63 Days (All)	102	2 (2%	1.0000	2	1 (50%)	1 (50%)	0	0
	≰49 Days (Group 1)	68	2 (3%		2	1 (50%)	1 (50%)	O '	0
	50-56 Days (Group 2)	25	0		• 0	0	0 1	0 '	0
	57-63 Days (Group 3)	9	0		0	0	o "	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: TYSON (#4)

	Gestational	Total Number	Number of Pts	Fis exa	her's	Number -		Sever:		
Body System/Event [2]	Age Group [3]	of Pts	w/Even		alue	of Events	Mild	Moderate	Severe	Unknow
OODY AS A WHOLE - GENERAL DISORDERS	(cont.)									
BACK PAIN	≤63 Days (All)	102	2 (2%) 1.0	000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	68	2 (14)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	25	0			0	0	0	0	0
	57-63 Days (Group 3)	9	0			0	0	0	0	0
FATIGUE	≤63 Days (All)	102	2 (21.0	0000	2	0	1 (50%)	1 (50%)	0
1	≤49 Days (Group 1)	68	2 (11)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	25	0			0	0	0	0	0
	57-63 Days (Group 3)	9	0			0	0	0	0	0
LEG PAIN	≤63 Days (All)	102	2 (2%) 1.0	0000	2	2 (100%)	0	0	0
	s49 Days (Group 1)	68	2 (1%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	25	0			0	0	0	0	0
	57-63 Days (Group 3)	9	0			0	0	0	0	0
RIGORS	≤63 Days (All)	102	1 (<	1.0	0000	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	68	1 ((%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0			0	0	0	0	0
	57-63 Days (Group 3)	9	0			0	0	0	0	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	102	1 (<	(1) 1.0	0000	1	1 (100%)	0	o	0
	s49 Days (Group 1)	68	1 (L %)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0			0	0	0	O ·	0
	57-63 Days (Group 3)	9	0			. o	0	۱ ٥	0 0 0 1 (50%) 1 (50%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BLUMENTHAL (#5)

	Gestational	Total		ber	Fisher's	Number				Sever:	itv		
Body System/Event [2]	Age Group [3]	Number of Pts		Pts vent	exact p-value	Number of Events	Mi		Mode		•	ere	Unknown
ANY EVENT	≤63 Days (All)	44	38	(86%)	0.4418	89	33	(37%)	46	(52%)	10	(11%)	0
ANI EVENI	≤49 Days (Group 1)	13	11	(85%)		30	10	(33%)	16	(53%)	4	(13%)	0 ,
	50-56 Days (Group 2)	23	21	(91%)		48	16	(33∜)	27	(56%)	5	(10%)	0
	57-63 Days (Group 3)	8	6	(75%)		11	7	(64%)	3	(27%)	1	(9%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS												(0.5.)	•
ANY EVENT	≤63 Days (All)	44	3	(7%)	1.0000	4	1	(25%)		(50%)	1		0
	≤49 Days (Group 1)	13	1	(8%)		1	0		0			(100%)	0
	50-56 Days (Group 2)	23	2	(9%)		3	1	(33%)	2	(67%)	0		0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
DIZZINESS	≤63 Days (All)	44	2	(5%)	1.0000	2	0		1	(50%)	1		0
D1201.1000	≤49 Days (Group 1)	13	1	(8%)		1	0		0			(100%)	0
	50-56 Days (Group 2)	23	1	(4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
HEADACHE	≤63 Days (All)	44	1	(2%)	1.0000	2	1	(50%)	1	(50%)	0		0
HEADACHE	s49 Days (Group 1)	13	0			0	0		0		0		0
	50-56 Days (Group 2)	23	1	(4%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
GASTRO-INTESTINAL SYSTEM DISORDERS	•												
ANY EVENT	≤63 Days (All)	44	28	(64%)	0.7660	4.8	14	(29%)	28	(58%)		(13%)	0
FMT4 MTMITA	≤49 Days (Group 1)	13	9	(69%)		•17	6	(35%)	9	(53%)		(12%)	0
	50-56 Days (Group 2)	23	15	(65%)		25	4	(16%)	18	(72%)	3		0
	57-63 Days (Group 3)	8	4	(50%)		6	4	(67%)	1	(17%)	1	(17%)	0

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

Appendix A.1, Table 25

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^[2] NOS - Not otherwise specified

^[3] 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: BLUMENTHAL (#5)

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number				Severi	ty	- -	
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)				•								
DIARRHEA	≤63 Days (All)	44	4	(9%)	1.0000	4	1	(25%)	2	(50%)		(25%)	0
	≤49 Days (Group 1)	13	1	(8%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	23	2	(9%)		2	0		2	(100%)	0		0
	57-63 Days (Group 3)	8	1	(13%)		1	1	(100%)	0		0		0
FLATULENCE	≤63 Days (All)	44	1	(2%)	1.0000	1	0		1	(100%)	0		0
ı	≤49 Days (Group 1)	13	0			0	0		0		0		0
	50-56 Days (Group 2)	23	1	(4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	44	22	(50%)	0.5197	27	10	(37%)	15	(56%)	2	(7%)	0
	≰49 Days (Group 1)	13	8	(62%)		12	5	(42%)	6	(50%)	1	(8%)	0
	50-56 Days (Group 2)	23	11	(48%)		12	3	(25%)	8	(67%)	1	(8%)	0
	57-63 Days (Group 3)	8	3	(38%)		3	2	(67%)	1	(33%)	0		0
VOMITING	≤63 Days (All)	44	12	(27%)	0.9042	16	3	(19%)	10	(63%)	3	(19%)	0
	≤49 Days (Group 1)	13	3	(23%)		4	1	(25%)	3	(75%)	0		0
	50-56 Days (Group 2)	23	7	(30%)		10	1	(10%)	7	(70%)	2	(20%)	0
	57-63 Days (Group 3)	8	2	(25%)		2	1	(50%)	0		1	(50%)	0
EPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	44	1	(2%)	1.0000	1	1	(100%)	0		0		0
	≰49 Days (Group 1)	13	0			O	0		0		0		0
	50-56 Days (Group 2)	23	1	(4%)		1	1	(100%)	0	,	0	•	0
	57-63 Days (Group 3)	6	0			. 0	0		0	1.	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BLUMENTHAL (#5)

	Gestational Age	Total Number	Number of Pts	Fisher' exact	s Number				Severi	ity		 -
Body System/Event [2]	Group [3]	of Pts	w/Even	p-value	of Events	Mil	.d	Mode	rate	Sev	ere	Unknow
REPRODUCTIVE DISORDERS, FEMALE	(cont.)								,			
LEUKORRHOEA	≤63 Days (All)	44	1 (1.0000	1	1 (100%)	0		0		0
	≤49 Days (Group 1)	13	0		0	0		0		0		0
	50-56 Days (Group 2)	23	1 (11)	1	1 (100%)	0		0		0
	57-63 Days (Group 3)	8	0		0	0		0		0		0
ODY AS A WHOLE - GENERAL DISORDERS												
ANY EVENT	≤63 Days (All)	44	26 (5	0.9199	36	17	(47%)	16	(44%)	3	(8%)	0
	≤49 Days (Group 1)	13	7 (5	18)	· 12	4	(33%)	7	(58%)	1	(8%)	0
	50-56 Days (Group 2)	23	14 (6	(*)	19	10	(53%)	7	(37%)	2	(11%)	0
	57-63 Days (Group 3)	8	5 (6	(*)	5	3	(60%)	2	(40%)	0		0
ABDOMINAL PAIN	≰63 Days (All)	44	24 (5	o \$) 0.7166	30	15	(50%)	12	(40%)	3	(10%)	0
	≤49 Days (Group 1)	13	6 (4	(1)	8	4	(50%)	3	(38%)	1	(13%)	0
	50-56 Days (Group 2)	23	14 (6	(%)	18	9	(50%)	7	(39%)	2	(11%)	0
	57-63 Days (Group 3)	8	4 (5) *)	4	2	(50%)	2	(50%)	0		0
FATIGUE	s63 Days (All)	44	3 (0.4182	3	1	(33%)	2	(67%)	0		0
	s49 Days (Group 1)	13	2 (1	5%)	2	0		2	(100%)	0		0
	50-56 Days (Group 2)	23	1 (11)	1	1 (100%)	0		0		0
	57-63 Days (Group 3)	8	0 -		0	0		0		0		0
LEG PAIN	≤63 Days (All)	44	1 (2%) 0.1818	1	1 ((100%)	0		0		0
	s49 Days (Group 1)	13	0		0	0		0		0	1	0
	50-56 Days (Group 2)	23	0 .		• 0	0		0	t.	0		0
	57-63 Days (Group 3)	8	1 (1	11)	1	1 (100%)	0	*	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BLUMENTHAL (#5)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number -		Sever	itv	
Body System/Event [2]	Group [3]	of Pts	w/Ev		p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)									
MALAISE	≤63 Days (All)	44	1	(2%)	0.4773	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	13	1	(8%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	23	0			0	0	0	0	0
	57-63 Days (Group 3)	8	0			0	0	0	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BORGATTA (#6)

	Gestational Age	Total Number	Number of Pts	Fisher's exact					Sever	ity		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mi	1 d	Mode	rate	Sev	Severe 25 (19%) 17 (25%) 7 (20%) 1 (3%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Unknown
		-									•	
ANY EVENT	≤63 Days (All)	64	49 (77%)	0.4049	133	50	(38%)	58	(44%)	25	(19%)	0
	≰49 Days (Group 1)	36	27 (75%)		67	23	(34%)	27	(40%)	17	(25%)	0
	50-56 Days (Group 2)	16	11 • (69%)		35	19	(54%)	9	(26%)	7	(20%)	0
	57-63 Days (Group 3)	12	11 (92%)		31	8	(26%)	22	(71%)	1	(3%)	0
SKIN AND APPENDAGES DISORDERS												
ANY EVENT	≰63 Days (All)	64	1 (2%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	36	1 (3%)		. 1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0		0	0		0		0		0
	57-63 Days (Group 3)	12	0		0	0		0		0		0
RASH	≤63 Days (All)	64	1 (2%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	36	1 (3%)		1	0		1	(100%)	0		0
' :	50-56 Days (Group 2)	16	0		0	0		0		0		0
	57-63 Days (Group 3)	12	0		0	0		0		0		0
MUSCULO-SKELETAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	64	2 (3%)	0.4018	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	36	1 (3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0		0	0		0		0		0
	57-63 Days (Group 3)	12	1 (8%)		1	0		1	(100%)	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BORGATTA (#6)

	Gestational	Total	Numb		Fisher's	37				Causei	***		
Body System/Event [2]	Age Group [3]	Number of Pts	of F w/Ev		exact p value	Number of Events	Mi			rate	•	(17%) (17%) (25%) (22%) (20%) (50%) (22%)	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS	(cost.)									,			
ARTHRALGIA	≤63 Days (All)	64	2	(3%)	0.4018	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	36	1	(3%)		1	0		1	(100%)	0		Ó
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	1	(8%)		1	0		1	(100%)	0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDE	RS												
ANY EVENT	≤63 Days (All)	64	14	(22%)	0.0501	18	8	(44%)	7	(39%)	3	(17%)	0
	≤49 Days (Group 1)	36	4	(11%)		4	1	(25%)	2	(50%)	1	(25%)	0
	50-56 Days (Group 2)	16	6	(38%)		9	5	(56%)	2	(22%)	2	(22%)	0
	57-63 Days (Group 3)	12	4	(33%)		5	2	(40%)	3	(60%)	0		0
DIZZINESS	≤63 Days (All)	64	2	(3%)	0.4018	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	36	1	(3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	1	(8%)		1	1	(100%)	0		0		0
HEADACHE	≤63 Days (All)	64	11	(17%)	0.0107	15	6	(40%)	6	(40%)	3	(20%)	0
	≤49 Days (Group 1)	36	2	(6%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	16	6	(38%)		9	5	(56%)	2	(22%)	2	(22%)	0
	57-63 Days (Group 3)	12	3	(25%)		4	1	(25%)	3	(75%)	0		0
TREMOR	≤63 Days (All)	64	1	(2%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	36	1	(3%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	16	0			0	0		0		0	1	0
	57-63 Days (Group 3)	12	0			0	0		0	ľ.	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BORGATTA (#6)

	Gestational	Total	Num		Fisher's					Severi			
Body System/Event [2]	Age Group (3)	Number of Pts	of I	Pts vent	exact p value	Number of Events	Mi			rate	Sev		Unknown
PSYCHIATRIC DISORDERS													
ANY EVENT	s63 Days (All)	64	1	(2%)	1.0000	1	0		1	(100%)	0		0
ANT DVDNI	≤49 Days (Group 1)	36	1	(3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	0			0	0		0		0		0
EMOTIONAL LABILITY	≤63 Days (All)	64	1	(21)	1.0000	1	0		1	(100%)	0		0
Distriction 1	≤49 Days (Group 1)	36	1	(3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	0			0	0		0		0		0
GASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	64	27	(42%)	1.0000	44	12	(27%)	19		13	(30%)	0
	≤49 Days (Group 1)	36	15	(42%)		26	7	(27%)	10	(38%)	9	(35%)	0
	50-56 Days (Group 2)	16	7	(44%)		10	4	(40%)	2		4	(40%)	0
	57-63 Days (Group 3)	12	5	(42%)		8	1	(13%)	7	(88%)	0		0
DIARRHEA	≤63 Days (All)	64	2	(3%)	0.4018	2	0		_	(100%)	0		0
	s49 Days (Group 1)	36	1	(3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	1	(8%)		1	0		1	(100%)	0		0
NAUSEA	s63 Days (All)	64	24	(38%)	1.0000	30	9	(30%)		(40%)		(30%)	0
	≤49 Days (Group 1)	36	14	(39%)		17	5	(29%)	6	(35%)		(35%)	0
	50-56 Days (Group 2)	16	6.	(38%)		• 8	3	(38%)	2	(25%)		(38%)	0
•	57-63 Days (Group 3)	12	4	(33%)		5	1	(20%)	4	"(80%)	0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BORGATTA (#6)

	Gestational Age	Total Number		ber Pta	Fisher's exact					Severi	ty		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												_
VOMITING	≰63 Days (All)	64	12	(19%)	0.8330	12	3	(25%)		(42%)	_		0
	≤49 Days (Group 1)	36	8	(22%)		8	2	(25%)	3	(38%)	-		0
	50-56 Days (Group 2)	16	2	(13%)		2	1	(50%)	0		1	(50%)	0
	57-63 Days (Group 3)	12	2	(17%)		2	0		2	(100%)	0	4 (33%) 3 (38%) 1 (50%)	0
ED BLOOD CELL DISORDERS													_
ANY EVENT	≤63 Days (All)	64	1	(2%)	1.0000	1		(100%)	0		0		0
WAL EAGUI	≤49 Days (Group 1)	36	1	(3%)		. 1	1	(100%)	0		0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	0			0	0		0		0		0
ANAEMIA	≤63 Days (All)	64	1	(2%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	36	1	(3%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	0			0	0		0		0		0
EPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≰63 Days (All)	64	2	(3%)	1.0000	2	1	(50%)	1		0		0
	≤49 Days (Group 1)	36	2	(6%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	0			0	0		0		О		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BORGATTA (#6)

	Gestational Age	Total Number	Number of Pt		Fisher's exact	Number		Sever	i tv	
Body System/Event [2]	Group [3]	of Pts	w/Eve		p-value	of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	(cont.)									
LEUKORRHOEA	≤63 Days (All)	64	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0			. 0	0	0	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0
VAGINAL DISCOMFORT	≤63 Days (All)	64	1	(2%)	1.0000	1	0	1 (100%)	0	0
ı	≤49 Days (Group 1)	36	1	(3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0			0	0	0	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS										
ANY EVENT	≤63 Days (All)	64	40 ((63%)	0.4684	64	28 (44%)	27 (42%)	9 (14%)	0
	≤49 Days (Group 1)	36	20 ((56%)		31	13 (42%)	11 (35%)	7 (23%)	0
	50-56 Days (Group 2)	16	11 ((69%)		16	10 (63%)	5 (31%)	1 (6%)	0
	57-63 Days (Group 3)	12	9 ((75%)		17	5 (29%)	11 (65%)	1 (6%)	0
ABDOMINAL PAIN	≰63 Days (All)	64	35 ((55%)	0.2693	42	22 (52%)	15 (36%)	5 (12%)	0
	≤49 Days (Group 1)	36	17 ((47%)		21	10 (48%)	6 (29%)	5 (24%)	0
	50-56 Days (Group 2)	16	9 ((56%)		9	7 (78%)	2 (22%)	0	0
	57-63 Days (Group 3)	12		(75%)		12	5 (42%)	7 (58%)	0	0
BACK PAIN	≤63 Days (All)	64	3	(5%)	0.4052	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	36	1	(3%)		1	0	1 (100%)	0 .	0
	50-56 Days (Group 2)	16	1	(6%)		, 1	1 (100%)	0 ,	0	0
	57-63 Days (Group 3)	12	1	(8%)		1	0	1 (100%)	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: BORGATTA (#6)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severi	ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe 3 (27%) 1 (20%) 1 (25%) 1 (50%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Unknow
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
FATIGUE	s 63 Days (All)	64	10 (16%)	0.8982	11	1 (9%)	7 (64%)		0
	≰49 Days (Group 1)	36	5 (14%)		5	0	4 (80%)		0
	50-56 Days (Group 2)	16	3 (19%)		4	1 (25%)	2 (50%)	•	0
	57-63 Days (Group 3)	12	2 (17%)		2	0	1 (50%)	1 (50%)	0
FEVER	≤63 Days (All)	64	2 (3%)	0.6875	2	2 (100%)	0	0	0
1	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
HOT FLUSHES	≤63 Days (All)	64	1 (2%)	0.1875	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
MALAISE	≤63 Days (All)	64	3 (5%)	1.0000	3	2 (67%)	1 (33%)	0	0
	s49 Days (Group 1)	36	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
RIGORS	≤63 Days (All)	64	1 (2%)	0.1875	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	O .	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0 .	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

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

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

Center: BORGATTA (#6)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Numb of P w/Ev	ts	Fisher's exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)									
SYNCOPE	≰63 Days (All)	64	1	(2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	1	(3%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	16	0			0	0	0	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: MALLOY (#7)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number			- -	Severi	ty		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	.ld	Mode	rate	Sev	ere	Unknow
ANY EVENT	≤63 Days (All)	52	32	(62%)	0.5361	65	26	(40%)	26	(40%)	13	(20%)	0
	≤49 Days (Group 1)	19	10	(53%)		16	11	(69%)	5	(31%)	0		0
	50-56 Days (Group 2)	11	8	(73%)		14	6	(43%)	6	(43%)	2	(14%)	0
	57-63 Days (Group 3)	22	14	(64%)		35	9	(26%)	15	(43%)	11	(31%)	0
ENTR 4 PERIPH MERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	52	6	(12%)	1.0000	6	2	(33%)	4	(67%)	0		0
	≤49 Days (Group 1)	19	2	(11%)	•	2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	11	1	(9%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	22	3	(14%)		3	0		3	(100%)	0		0
DIZZINESS	≤63 Days (All)	52	3	(6%)	1.0000	3	1	(33%)	2	(67%)	0		0
	≰49 Days (Group 1)	19	1	(5%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	11	1	(9%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	22	1	(5%)		1	0		1	(100%)	0		0
HEADACHE	≤63 Days (All)	52	3	(6%)	0.7919	3	1	(33%)	2	(67%)	0		0
	≤49 Days (Group 1)	19	1	(5%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	11	0			0	0		0		0		0
	57-63 Days (Group 3)	22	2	(9%)		2	0		2	(100%)	0		0
EARING AND VESTIBULAR DISORDERS													
ANY EVENT	≤63 Days (All)	52	1	(2%)	1.0000	. 1	1	(100%)	0		0		0
	≤49 Days (Group 1)	19	0.			• 0	0		0	Į.	0		0
	50-56 Days (Group 2)	11	0			0	0		0	•	0		0
	57-63 Days (Group 3)	22	1	(5%)		1	1	(100%)	0		0		0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: MALLOY (#7)

Age	Total Number	Numb of F		Fisher's exact	Number -		Se	everity	
Group (3)	of Pts	w/E	vent	p-value	of Events	Mild	Moderate	Severe	Unknown
(cont.)									
≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
≤49 Days (Group 1)	19	0			0	0	0	0	0
	11	0			0	0	0	0	0
57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	0	0	0
≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
s49 Days (Group 1)	19	0			0	0	0	0	0
•	11	0		,	0	0	0	0	0
57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	0	0	0
≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
	19	0			0	0	0	0	0
-	11	0			0	0	0	0	0
57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	0	0	0
≤63 Days (All)	52	16	(31%)	0.9263	25	8 (32%)	8 (32)	t) 9 (3	1 6%) 0
≤49 Days (Group 1)	19	6	(32%)		8	6 (75%)	2 (25)	b) 0	0
	11	4	(36%)		6	1 (17%)	4 (67	b) 1 (1	(7%) 0
57-63 Days (Group 3)	22	6	(27%)		11	1 (9%)	2 (18	•) 8 (7	73%) 0
	<pre>(cont.)</pre>	(cont.) s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2) 11 57-63 Days (Group 3) 22 s63 Days (All) 50-56 Days (Group 1) 50-56 Days (Group 2) 11 57-63 Days (Group 3) 22 s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 1) 50-56 Days (Group 2) 11 57-63 Days (Group 3) 22 s63 Days (All) s49 Days (Group 3) 22 s63 Days (Group 1) 57-63 Days (Group 3) 22	(cont.) *63 Days (All) *49 Days (Group 1) 50-56 Days (Group 2) 11 0 57-63 Days (Group 3) 22 1 *63 Days (All) 59-56 Days (Group 1) 50-56 Days (Group 2) 51 0 57-63 Days (Group 3) 22 1 *63 Days (All) 52 1 49 Days (Group 3) 22 1 *63 Days (All) 50-56 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) 21 1 *63 Days (Group 3) 22 1 *63 Days (Group 1) 57-63 Days (Group 3) 21 1 *63 Days (Group 3) 22 1	(cont.) *63 Days (All) *49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) *63 Days (All) *649 Days (Group 1) 50-56 Days (Group 1) 50-56 Days (Group 2) 51 0 57-63 Days (Group 2) *63 Days (Group 3) *63 Days (All) 52 1 (2%) *649 Days (Group 3) 22 1 (5%) *65 Days (Group 1) 50-56 Days (Group 2) 50-56 Days (Group 3) 22 1 (5%) *63 Days (Group 1) 50-56 Days (Group 3) 22 1 (5%) *63 Days (Group 3) 50-56 Days (Group 3) 22 1 (5%)	(cont.) *63 Days (All) *49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) *63 Days (All) *649 Days (Group 3) *65 Days (Group 3) *65 Days (Group 1) 50-56 Days (Group 2) 51 0 57-63 Days (Group 2) 57-63 Days (Group 3) *65 Days (Group 3) *65 Days (Group 3) *65 Days (Group 1) 50-56 Days (Group 1) 50-56 Days (Group 2) 51 0 57-63 Days (Group 3) *65 Days (Group 3) *66 Days (Group 3) *67 Days (Group 3) *68 Days (Group 3) *69 Days (Group 3) *69 Days (Group 3) *60 Days (Group 1) *60 Days (Group 1) *60 Days (Group 2) *61 Days (Group 3) *62 Days (Group 3) *63 Days (Group 1) *64 Days (Group 1) *65 Days (Group 2) *66 Jays (Group 3) *67 Days (Group 3)	(cont.) *63 Days (All) *49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) *63 Days (All) *63 Days (Group 3) 52 1 (2%) 1.0000 1 *63 Days (Group 3) 52 1 (2%) 1.0000 1 *49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) 22 1 (5%) 1 *63 Days (All) *63 Days (Group 3) 52 1 (2%) 1.0000 57-63 Days (Group 3) 52 1 (2%) 1.0000 1 *63 Days (Group 1) 52 1 (2%) 1.0000 1 *63 Days (Group 1) 50 50-56 Days (Group 2) 51 0 57-63 Days (Group 3) 22 1 (5%) 1 *63 Days (Group 3) 50 16 (31%) 0.9263 25 *49 Days (Group 1) 19 6 (32%) 8 50-56 Days (Group 2) 11 4 (36%) 6	(cont.) *63 Days (All)	(cont.) s63 Days (All) s49 Days (Group 1) 19 0 0 0 0 50-56 Days (Group 2) 11 0 57-63 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 5863 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 1) 19 0 0 0 0 57-63 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 57-63 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 1 1 (100%) 0 50-56 Days (Group 3) 22 1 (5%) 3	(cont.) *63 Days (All) *649 Days (Group 1) 19 0 0 0 0 0 0 50-56 Days (Group 2) 11 0 0 0 0 0 57-63 Days (Group 3) *63 Days (All) *649 Days (Group 3) *63 Days (All) *649 Days (Group 1) 19 0 0 0 0 0 *650-56 Days (Group 2) 11 0 0 0 0 0 *649 Days (Group 1) 50-56 Days (Group 2) 11 0 0 0 0 0 57-63 Days (Group 2) 11 0 0 0 0 0 57-63 Days (Group 3) 22 1 (5*) 1 1 (100*) 0 0 0 0 57-63 Days (Group 3) 22 1 (5*) 1 1 (100*) 0 0 0 0 57-63 Days (Group 1) 19 0 0 0 0 0 *63 Days (All) 52 1 (2*) 1.0000 1 1 (100*) 0 0 57-63 Days (Group 1) 19 0 0 0 0 0 57-63 Days (Group 2) 11 0 0 0 0 0 57-63 Days (Group 3) 22 1 (5*) 1 1 (100*) 0 0 0 0 57-63 Days (Group 3) 22 1 (5*) 57-63 Days (Group 3) 22 1 (5*) 1 1 (100*)

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: MALLOY (#7)

	Gestational	Total	Numbe		Fisher's			Carran		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pt w/Eve		exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)									
DIARRHEA	≤63 Days (All)	52	1	(2%)	0.5769	1	1 (100%)	0	0	0
	<pre>s49 Days (Group 1)</pre>	19	1	(5%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	0			0	0	0	0	0
FLATULENCE	≤63 Days (All)	52	1	(2%)	0.2115	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	1	(9%)	•	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	0			0	0	0	0	0
NAUSEA	≤63 Days (All)	52	13	(25%)	0.9204	17	6 (35%)	6 (35%)	5 (29%)	0
	≤49 Days (Group 1)	19	5	(26%)		7	5 (71%)	2 (29%)	0	0
	50-56 Days (Group 2)	11		(18%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	22		(27%)		8	1 (13%)	2 (25%)	5 (63%)	0
VOMITING	≤63 Days (All)	52	4	(8%)	0.1886	6	1 (17%)	1 (17%)	4 (67%)	0
	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	2	(18%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	22	2	(9%)		3	0	0	3 (100%)	0
ENDOCRINE DISORDERS										
ANY EVENT	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0			. 0	0	0	ο '	0
	50-56 Days (Group 2)	11	0.			• 0	0	o į	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	ο "	0	0

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

Appendix A.1, Table 25

FINAL

^[2] NOS - Not otherwise specified

^[3] 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: MALLOY (#7)

	Gestational	Total	Numb		Fisher's					
	Age	Number	of P		exact	Number -		Sever	ity Severe	Unknown
Body System/Event [2]	Group [3]	of Pts	w/Ev	ent	p value	of Events	Mild	Moderate	Severe	Olikilowii
ENDOCRINE DISORDERS	(cont.)									
ENDOCRINE DISORDER NOS	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	0	0	0
HEART RATE AND RHYTHM DISORDERS										
ANY EVENT	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
'	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	0		,	0	0	0	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	0	0	0
TACHYCARDIA	s63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	0			0	0	0	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	0	0	0
URINARY SYSTEM DISORDERS							,			
ANY EVENT	≤63 Days (All)	52	1	(2%)	0.2115	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	1	(9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	0			0	0	0	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: MALLOY (#7)

	Gestational	Total	Num		Fisher's					C			
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	vent	exact p-value	Number of Events	Mi	1d		Severi rate	•	ere	Unknowr
URINARY SYSTEM DISORDERS	(cont.)												
MICTURITION FREQUENCY	≤63 Days (All)	52	1	(2%)	0.2115	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	19	0			0	0		0		0		0
	50.56 Days (Group 2)	11	1	(9%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	22	0			0	0		0		0		0
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	52	24	(46%)	0.2845	29	12	(41%)	13	(45%)	4	(14%)	0
	≤49 Days (Group 1)	19	6	(32%)		6	4	(67%)	2	(33%)	0		0
	50-56 Days (Group 2)	11	6	(55%)		6	4	(67%)	1	(17%)	1	(17%)	0
	57-63 Days (Group 3)	22	12	(55%)		17	4	(24%)	10	(59%)	3	(18%)	0
ABDOMINAL PAIN	≤63 Days (All)	52	23	(44%)	0.4225	24	12	(50%)	9	(38%)	3	(13%)	0
	s49 Days (Group 1)	19	6	(32%)		6	4	(67%)	2	(33%)	0		0
	50-56 Days (Group 2)	11	6	(55%)		6	4	(67%)	1	(17%)	1	(17%)	0
	57 63 Days (Group 3)	22	11	(50%)		12	4	(33%)	6	(50%)	2	(17%)	0
BACK PAIN	≤63 Days (All)	52	1	(2%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	19	0			0	0		0		0		0
	50-56 Days (Group 2)	11	0			0	0		0		0		0
	57-63 Days (Group 3)	22	1	(5%)		1	0		1	(100%)	0		0
FATIGUE	s63 Days (All)	52	2	(4%)	0.5023	2	0		1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	19	0			, 0	0		0		0		0
	50-56 Days (Group 2)	11	0.			• 0	0		0	į.	0		0
	57-63 Days (Group 3)	22	2	(9%)		2	0		1	"(50 %)	1	(50%)	0

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

Appendix A.1, Table 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] 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: MALLOY (#7)

	Gestational	Total	Number	Fisher's			Sever	1640	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)		,						
FEVER	≤63 Days (All)	52	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
LEG PAIN	≤63 Days (All)	52	1 (21)	1.0000	1	0	: '100%)	0	0
ı	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		. 0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: ROTHENBERG (#8)

	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
ANY EVENT	≤63 Days (All)	21	18 (86%)	0.7068	29	14 (48%)	8 (28%)	7 (24%)	o
	≤49 Days (Group 1)	13	10 (77%)		16	9 (56%)	4 (25%)	3 (19%)	0
	50-56 Days (Group 2)	5	5 (100%)		9	3 (33%)	4 (44%)	2 (22%)	0
	57-63 Days (Group 3)	3	3 (100%)		4 .	2 (50%)	0	2 (50%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	2 (10%)	0.6286	2	0	1 (50%)	1 (50%)	0
	s49 Days (Group 1)	13	1 (8%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	21	2 (10%)	0.6286	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	s63 Days (All)	21	9 (43%)	0.0255	14	6 (43%)	3 (21%)	5 (36%)	0
	≤49 Days (Group 1)	13	3 (23%)		4	3 (75%)	0	1 (25%)	0
	50-56 Days (Group 2)	5	3 (60%)		7	2 (29%)	3 (43%)	2 (29%)	0
	57-63 Days (Group 3)	3	3 (100%)		3	1 (33%)	0	2 (67%)	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: ROTHENBERG (#8)

	Gestational	Total	Numb		Fisher's			Severi	*	
Body System/Event [2]	Age Group [3]	Number of Pts	of P		exact p value	Number - of Events	Mild	Moderate	Severe	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)									
DIARRHEA	≤63 Days (All)	21	1	(5%)	0.3810	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0			0	0	0	0	0
	50-56 Days (Group 2)	5	1	(20%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	3	0			0	0	0	0	0
NAUSEA	≰63 Days (All)	21	6	(29%)	0.1910	7	3 (43%)	2 (29%)	2 (29%)	0
	≤49 Days (Group 1)	13	2	(15%)		2	1 (50%)	0	1 (50%)	0
l	50-56 Days (Group 2)	5	3	(60%)		4	1 (25%)	2 (50%)	1 (25%)	0
	57-63 Days (Group 3)	3	1	(33%)	•	1	1 (100%)	0	0	0
VOMITING	≤63 Days (All)	21	4	(19%)	0.0682	6	2 (33%)	1 (17%)	3 (50%)	0
	≤49 Days (Group 1)	13	1	(8%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	5	1	(20%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	3	2	(67%)		2	0	0	2 (100%)	0
ODY AS A WHOLE - GENERAL DISORDERS										
ANY EVENT	≤63 Days (All)	21	10	(48%)	0.3797	13	8 (62%)	4 (31%)	1 (8%)	0
	≤49 Days (Group 1)	13	8	(62%)		11	6 (55%)	4 (36%)	1 (9%)	0
	50 56 Days (Group 2)	5	1	(20%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	3	1	(33%)		1	1 (100%)	0	0	0
ABDOMINAL PAIN	≤63 Days (All)	21	10	(48%)	0.3797	12	8 (67%)	3 (25%)	1 (8%)	0
	≤49 Days (Group 1)	13	8	(62%)		10	6 (60%)	3 (30%)	1 (10%)	0
	50-56 Days (Group 2)	5	1	(20%)		1	1 (100%)	0	0 -	0
	57-63 Days (Group 3)	3	1	(33%)		• 1	1 (100%)	o l	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

^[3] 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: ROTHENBERG (#8)

	Gestational Age	Total Number	Number of Pt		Fisher's exact	Number -		Severi	tv	
Body System/Event (2)	Group [3]	of Pts	w/Eve		p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)									
BACK PAIN	≤63 Days (All)	21	1	(5%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	1	(8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	5	0			0	0	0	0	0
	57-63 Days (Group 3)	3	0			0	0	0	0	0

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

Appendix A.1, Table 25

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^[2] NOS = Not otherwise specified

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

MI# 006859

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

Center: MISHELL (#1)

	Gestational	Total		ber Pts	Fisher's exact	Number				Sever	itv		
Body System/Event	Age Group [2]	Number of Pts		vent	p-value	of Events	Mi	1d	Mode	rate	-	ere	Unknown
ANY EVENT	≤63 Days (All)	204	194	(95%)	0.1456	711	233	(33%)	224	(32%)	254	(36%)	0
ANI EVENI	s49 Days (Group 1)	145	135	(93%)	0.1150	459	166	(36%)	139	(30%)	154	(34%)	0
	50-56 Days (Group 2)	40		(100%)		176	45	(26%)	62	(35%)	69	(39%)	0
	57-63 Days (Group 3)	19		(100%)		76	22	(29%)	23	(30%)	31	(41%)	0
KIN AND APPENDAGES DISORDERS											_		_
ANY EVENT	≤63 Days (All)	204	3		0.1201	3		(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	145	1	(<1%)	,	1		(100%)	0		0		0
	50-56 Days (Group 2)	40	1	(3%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	19	1	(5%)		1	0		1	(100%)	0		0
PRURITUS GENITAL	≤63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	145	1	(<1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
SWEATING INCREASED	≤63 Days (All)	204	2	(<1%)	0.0450	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	145	0			0	0		0		0		0
	50-56 Days (Group 2)	40	1	(3%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	19	1	(5%)		1	0		1	(100%)	0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS	•	1											
ANY EVENT	≤63 Days (All)	204	28	(14%)	0.6366	42	20	(48%)		(26%)		(26%)	0
	≤49 Days (Group 1)	145	18.	(12%)		• 29	15	(52%)		(28%)	6		0
	50-56 Days (Group 2)	40	7	(18%)		9	3	(33%)	2	(22%)	4		0
	57-63 Days (Group 3)	19	3	(16%)		4	2	(50%)	1	(25%)	1	(25%)	0

^[1] 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.

FINAL

^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography. Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

	Gestational	Total	Num		Fisher's					a			
Body System/Event	Age Group (2)	Number of Pts	of w/E	Pts vent	exact p-value	Number of Events		1d	Mode	Severi rate	•	ere	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDER	RS (cont.)												
DIZZINESS	≤63 Days (All)	204	14	(7%)	0.1824	19	9	(47%)	3	(16%)	7	(37%)	0
	≤49 Days (Group 1)	145	8	(6%)		11	6	(55%)	1	(9%)	4	(36%)	0
	50-56 Days (Group 2)	40	3	(8%)		5	2	(40%)	1	(20%)	2	(40%)	0
	57-63 Days (Group 3)	19	3	(16%)		. 3	1	(33%)	1	(33%)	1	(33%)	0
HEADACHE	≤63 Days (All)	204	16	(8%)	0.9098	22	10	(45%)	8	(36%)	4	(18%)	0
	≤49 Days (Group 1)	145	11	(8%)		17	8	(47%)	7	(41%)	2	(12%)	0
,	50-56 Days (Group 2)	40	4	(10%)		4	1	(25%)	1	(25%)	2	(50%)	0
	57-63 Days (Group 3)	19	1	(5%)	·	1	1	(100%)	0		0		0
NEURALGIA	≰63 Day №11)	204	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≤49 Day Froup 1)	145	1	(<1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS							i						
ANY EVENT	≤63 Days (All)	204	116	(57%)	0.2442	196	73	(37%)	41	(21%)	82	(42%)	0
	≤49 Days (Group 1)	145	77	(53%)		123	51	(41%)	21	(17%)	51	(41%)	0
	50-56 Days (Group 2)	40	26	(65%)		47	12	(26%)	13	(28%)	22	(47%)	0
	57.63 Days (Group 3)	19	13	(68%)		26	10	(38%)	7	(27%)	9	(35%)	0
ABDOMINAL PAIN	≰63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	145	1	(<1%)		1	1	(100%)	0		Ο,		0
	50-56 Days (Group 2)	40	0			; O	0		0	1	0		0
	57-63 Days (Group 3)	19	ď			• 0	0		0	L	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: MISHELL (#1)

	Gestational	Total	Num		Fisher's	Number				Severi			
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event		exact p-value	of Events		ld	Moderate		Severe		Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
CONSTIPATION	≤63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	s49 Days (Group 1)	145	1	(<1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0 -		0		0		0
DIARRHEA	≤63 Days (All)	204	26	(13%)	0.0380	28	19	(68%)	6	(21%)	3	(11%)	0
1	s49 Days (Group 1)	145	17	(12%)		18	12	(67%)	3	(17%)	3	(17%)	0
	50-56 Days (Group 2)	40	3	(8%)	•	4	3	(75%)	1	(25%)	0		0
	57-63 Days (Group 3)	19	6	(32%)		6	4	(67%)	2	(33%)	0		0
DYSPEPSIA	≤63 Days (All)	204	3	(1%)	1.0000	4	1	(25%)	2	(50%)	1	(25%)	0
	≤49 Days (Group 1)	145	3	(2%)		4	1	(25%)	2	(50%)	1	(25%)	0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	204	104	(51%)	0.1802	128	41	(32%)	22	(17%)	65	(51%)	0
	≤49 Days (Group 1)	145	68	(47%)		82	31	(38%)	12	(15%)	39	(48%)	0
	50-56 Days (Group 2)	40	25	(63%)		33	7	(21%)	8	(24%)	18	(55%)	0
	57-63 Days (Group 3)	19	11	(58%)		13	3	(23%)	2	(15%)	8	(62%)	0
VOMITING	≤63 Days (All)	204	30	(15%)	0.1325	34	10	(29%)	11	(32%)	13	(38%)	0
	49 Days (Group 1)	145	17	(12%)		17	5	(29%)	4	(24%)	8	(47%)	0
	50-56 Days (Group 2)	40	8	(20%)		. 10	2	(20%)	4	(40%)		(40%)	0
	57-63 Days (Group 3)	19	5.	(26%)		• 7	3	. (43%)	3	(43%)	1	(14%)	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] 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: MISHELL (#1)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number -		Sever:	itv	
Body System/Event	Age Group [2]	of Pts	w/Event	p·value	of Events	Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS									_
ANY EVENT	≤63 Days (All)	204	2 (<1%)	0.4958	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	204	2 (<1%)	0.4958	2	1 (50%)	o	1 (50%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	0
•	50-56 Days (Group 2)	40	0		0	0	0	0	0
!	57-63 Days (Group 3)	19	0		0	0	0	0	0
HYPOTENSION POSTURAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
HITOTEMOTON TOUTONE	≰49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HEART RATE AND RHYTHM DISORDERS	•								
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	145	1 (<1%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	40	0		0	0	o 1	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

^[1] 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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⁽²⁾ Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

	Gestational Age	Total Number	Num of		Fisher's exact	Number -			Severi	ity		
Body System/Event	Group (2)	of Pts		vent	p-value	of Events	Mild	Mode	rate	Sev	ere	Unknowr
HEART RATE AND RHYTHM DISORDERS (cont.)												
TACHYCARDIA	≤63 Days (All)	204	1	(<1%)	1.0000	2	0	1	(50%)	1	(50%)	0
1	≤49 Days (Group 1)	145	1	(<1%)		2	0	1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	40	0			0	0	0		0		0
	57-63 Days (Group 3)	19	0			0	0	0		0		0
RED BLOOD CELL DISORDERS												
ANY EVENT	≤63 Days (All)	204	7	(3%)	0.1476	7	3 (43%)	1			(43%)	0
	≤49 Days (Group 1)	145	3	(2₺)		3	0	1	(33%)	2		0
	50-56 Days (Group 2)	40	3	(8%)		3	2 (67%)	0		1	(33%)	0
	57-63 Days (Group 3)	19	1	(5%)		1	1 (100%)	0		0		0
ANAEMIA	≤63 Days (All)	204	6	(3%)	0.2660	6	2 (33%)	1	(17%)	3	(50%)	0
	≰49 Days (Group 1)	145	3	(2%)		3	0	1	(33%)	2	(67%)	0
	50-56 Days (Group 2)	40	2	(5%)		2	1 (50%)	0		1	(50%)	0
	57-63 Days (Group 3)	19	1	(5%)		1	1 (100%)	0		0		0
ANAEMIA HYPOCHROMIC	≤63 Days (All)	204	1	(<1%)	0.2892	1	1 (100%)	0		0		0
	≤49 Days (Group 1)	145	0			0	0	0		0		0
	50-56 Days (Group 2)	40	1	(3%)		1	1 (100%)	0		0		0
	57-63 Days (Group 3)	19	0			0	0	0		0		0
REPRODUCTIVE DISORDERS, FEMALE	•											
ANY EVENT	≤63 Days (All)	204	14	(7%)	0.0017	14	0	2	(14%)	12		0
	≤49 Days (Group 1)	145	5	(3%)		5	0	1	(20%)	4	(80%)	0
	50-56 Days (Group 2)	40	4	(10%)		4	0	1	"(25%)	3		0
	57-63 Days (Group 3)	19	5	(26%)		5	0	0		5	(100%)	0

^[1] 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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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

	Gestational	Total	Number	Fisher's	Number		e	i basan a sa sa sa sa	
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p.value	Number of Events	Mild	Moderate	Severe	Unknow
EPRODUCTIVE DISORDERS, FEMALE (cont.)									
ENDOMETRITIS	s63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	o	0	0
OVARIAN DISORDER	≤63 Days (All)	204	1 (<1%)	0.2892	1	0	1 (100%)	0	0
1	s49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	204	12 (6%)	0.0015	12	0	0	12 (100%)	0
	≤49 Days (Group 1)	145	4 (3%)		4	0	0	4 (100%)	0
	50-56 Days (Group 2)	40	3 (B%)		3	0	0	3 (100%)	0
	57-63 Days (Group 3)	19	5 (26%)		5	0	0	5 (100%)	0
ODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	204	191 (94%)	0.0744	443	133 (30%)	167 (38%)	143 (32%)	0
	≤49 Days (Group 1)	145	132 (91%)		293	97 (33%)	107 (37%)	89 (30%)	0
	50-56 Days (Group 2)	40	40 (100%)		111	27 (24%)	46 (41%)	38 (34%)	0
	57-63 Days (Group 3)	19	19 (100%)		39	9 (23%)	14 (36%)	16 (41%)	0
ABDOMINAL PAIN	≰63 Days (All)	204	189 (93%)	0.0344	414	123 (30%)	154 (37%)	137 (33%)	0
	s49 Days (Group 1)	145	130 (90%)		271	88 (32%)	97 (36%)	86 (32%)	0
	50-56 Days (Group 2)	40	40 (100%)		105	26 (25%)	43 (41%)	36 (34%)	0
	57-63 Days (Group 3)	19	19 (100%)		38	9 (24%)	14 (37%)	15 (39%)	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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

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

Center: MISHELL (#1)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Sever:	ity	
Body System/Event	Group (2)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ODY AS A WHOLE - GENERAL DISORDERS (con	t.)								
ASTHENIA	≰63 Days (All)	204	2 (<1%)	0.0450	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	0	0	1 (100%)	0
BACK PAIN	≤63 Days (All)	204	11 (5%)	0.8783	14	3 (21%)	7 (50%)	4 (29%)	0
I	s49 Days (Group 1)	145	9 (6%)		12	3 (25%)	6 (50%)	3 (25%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
CHEST PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	o	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FATIGUE	≰63 Days (All)	204	3 (1%)	0.6431	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	145	2 (1%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FEVER	≤63 Days (All)	204	2 (<1%)	0.4958	2	1 (50%)	1 (50%)	0	0
	≰49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	O ·	0
	57-63 Days (Group 3)	19	0		• 0	0	0 ,	o '	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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

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

Center: MISHELL (#1)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi		
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (CO	ont.)								
HOT FLUSHES	≤63 Days (All)	204	1 (<1%)	0.2892	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	19	0		. 0	0	0	0	0
LEG PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
· 1	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RIGORS	≤63 Days (All)	204	3 (1%)	1.0000	3	3 (100%)	0	o	0
	≤49 Days (Group 1)	145	3 (2%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
TEMPERATURE CHANGED SENSATION	s63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	O ,	0
	57-63 Days (Group 3)	19	0		0	0	٥ ا	0.	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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

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

Center: MISHELL (#1)

ody System/Event	Gestational Age	Total Number	Number of Pts	Fisher's exact			Sever	:itv	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ESISTANCE MECHANISM DISORDERS					* * * * * * * * * * * * * * * * * * * *				
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	o o
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
V	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	ō	0	ñ
	50-56 Days (Group 2)	40	0		0	0	Ö	ō	Ď
	57-63 Days (Group 3)	19	0		0	0	0	o	o

^[1] 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.

Appendix A.1, Tables 16 and 25

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

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

Center: HASKELL (#2)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Sever	i + 1/2			
Body System/Event	Group (2)	of Pts		vent	p value	of Events		1d		rate	-	ere	Unkn	10 W N
ANY EVENT	≤63 Days (All)	238	230	(97%)	0.2541	1171	346	(30%)	429	(37%)	395	(34%)	1	(<1
	≤49 Days (Group 1)	81	76	(94%)		354	124	(35%)	134	(38%)	95	(27%)	1	(<1
	50-56 Days (Group 2)	89	87	(98%)		441	127	(29%)	153	(35%)	161	(37%)	0	
	57-63 Days (Group 3)	68	67	(99%)		376	95	(25%)	142	(38%)	139	(37%)	0	
MUSCULO-SKELETAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	238	1	(<1%)	1.0000	1	0		0		1	(100%)	0	
	≤49 Days (Group 1)	81	0			0	0		0		0		0	
	50-56 Days (Group 2)	89	1	(1%)		1	0		0		1	(100%)	0	
	57-63 Days (Group 3)	68	0			0	0		0		0		0	
ARTHRITIS	≤63 Days (All)	238	1	(<1%)	1.0000	1	0		0		1	(100%)	0	
	≤49 Days (Group 1)	81	0			0	0		0		0		0	
•	50-56 Days (Group 2)	89	1	(1%)		1	0		0		1	(100%)	0	
	57-63 Days (Group 3)	68	0			0	0		0		0		0	
CENTR & PERIPH NERVOUS SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	238	48	(20%)	0.3622	74	19	(26%)	46	(62%)	9	(12%)	0	
	≤49 Days (Group 1)	81	13	(16%)		22	7	(32%)	14	(64%)	1	(5%)	0	
	50-56 Days (Group 2)	89	22	(25%)		32	10	(31%)	17	(53%)	5	(16%)	0	
	57-63 Days (Group 3)	68	13	(19%)		20	2	(10%)	15	(75%)	3	(15%)	0	

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: HASKELL (#2)

	Gestational Age	Total Number	Num of		Fisher's exact	Number				Severi	ty	•	·
Body System/Event	Group [2]	of Pts	w/E	vent	p-value	of Events		ild		rate		vere	Unknown
ENTR & PERIPH MERVOUS SYSTEM DI	SORDERS (cont.)												
DIZZINESS	≤63 Days (All)	238	6	(3▮)	0.8780	7	4	(57%)	2	(29%)	1	(14%)	0
	≤49 Days (Group 1)	81	2	(2%)		3	1	(33%)	2	(67%)	0		o o
	50-56 Days (Group 2)	89	3	(3%)		3	2	(67%)	0		1		0
	57-63 Days (Group 3)	68	1	(1%)		1	1	(100%)	0		0		0
HEADACHE	≤63 Days (All)	238	43	(18%)	0.6564	65	15	(23%)	43	(66%)	7	(11%)	0
i	≤49 Days (Group 1)	81	12	(15%)	0.030.	19	6	(32%)	12	(63%)	í		0
	50-56 Days (Group 2)	89	18	(20%)		27	8	(30%)	16	(59%)	3		0
	57-63 Days (Group 3)	68	13	(19%)		19	1	(5%)	15	(79%)	3		0
MIGRAINE	≤63 Days (All)	238	1	(<1%)	1.0000	,	0		0		,	(1005)	•
	≤49 Days (Group 1)	81	0	(<10)	1.0000	0	0		0			(100%)	0
	50-56 Days (Group 2)	89	1	(1%)		1	0		0		0		0
	57-63 Days (Group 3)	68	0	(14)		0	0		0		0	(100%)	0 0
TREMOR	≤63 Days (All)	238	1	(<1%)	1.0000	,	0		,	(1005)	•		•
	s49 Days (Group 1)	81	0	(<1.	1.0000	0	-			(100%)	0		0
	50-56 Days (Group 2)	89	1	(1%)		1	0		0	(1005)	0		0
	57-63 Days (Group 3)	68	0	(14)		0	0		0	(100%)	0		0
SYCHIATRIC DISORDERS													
ANY EVENT	≤63 Days (All)	238	6	(3%)	1.0000	6	1	(17%)	4	(67%)	1	(17%)	0
	≤49 Days (Group 1)	81	2	(2%)		2	0		2	(100%)	0		0
	50-56 Days (Group 2)	89	2	(21)		. 2	0		1	(50%)	1	(50%)	0
	57-63 Days (Group 3)	68	2	(3%)		2	1	(50%)		(50%)	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: HASKELL (#2)

	Gestational	Total	Number	Fisher's					
	Age	Number	of Pts	exact	Number		Sever	ity	·
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
PSYCHIATRIC DISORDERS (cont.)									
ANOREXIA	≤63 Days (All)	238	2 (<1%	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	1 (1%)	1	0	0	1 (100%)	0
,	57-63 Days (Group 3)	68	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	238	1 (<1%	0.2857	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	81	0		0	0	0	0	o
	50-56 Days (Group 2)	89	0		0	0	o o	0	Ô
	57-63 Days (Group 3)	68	1 (1%)	1	0	1 (100%)	0	0
EMOTIONAL LABILITY	≤63 Days (All)	238	1 (<1%	0.6261	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%		1	o o	1 (100%)	Ö	ō
	50-56 Days (Group 2)	89	0 (11	•	n	0	0	Ō	0
	57-63 Days (Group 3)	68	o		ŏ	o	0	ō	ō
INSOMNIA	≤63 Days (All)	238	2 (<1%	0.7444	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	0	• • • • • • • • • • • • • • • • • • • •	0	0	0	0	o o
	50-56 Days (Group 2)	89	1 (1%	1	1	0	1 (100%)	ō	0
	57-63 Days (Group 3)	68	1 (1%		1	1 (100%)	0	o	o
PASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	±63 Days (All)	238	141 (59%	0.1442	284	121 (43%)	92 (32%)	71 (25%)	0
	≰49 Days (Group 1)	81	41 (51%	1	82	43 (52%)	23 (28%)	16 (20%)	0
	50-56 Days (Group 2)	89	58 (65%	1	118	50 (42%)	36 , (31%)	32 (27%)	0
	57-63 Days (Group 3)	68	42 (62%	1	84	28 (33%)	33 (39%)	23 (27%)	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: HASKELL (#2)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Server		
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
LASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	238	1 (<1	0.2857	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1	1)	2	0	2 (100%)	0	0
DIARRHEA	≤63 Days (All)	238	54 (23	0.9422	70	41 (59%)	22 (31%)	7 (10%)	0
ı	≤49 Days (Group 1)	81	19 (23	;)	22	15 (68%)	5 (23%)	2 (9%)	0
	50-56 Days (Group 2)	89	19 (21		28	16 (57%)	11 (39%)	1 (4%)	0
	57-63 Days (Group 3)	68	16 (24	;)	20	10 (50%)	6 (30%)	4 (20%)	0
DYSPEPSIA	≤63 Days (All)	238	2 (<1	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1	:)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1	;)	1	1 (100%)	0	0	О
	57-63 Days (Group 3)	68	0		0	0	0	0	0
FLATULENCE	≤63 Days (All)	238	2 (<1	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	1 (1	1)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	1 (1	;)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HAEMORRHOIDS	s63 Days (All)	238	1 (<1	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1)	. 1	0	1 (100%)	ο '	0
	57-63 Days (Group 3)	68	0.		• 0	0 .	o į	o [']	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: HASKELL (#2)

Gestational	Total		nber	Fisher's					Cauari	F		
Age Group [2]				exact p-value	Number of Events					•		Unknown
							(202)	44	(20%)	46	(315)	0
				0.0679								Ö
≤49 Days (Group 1)												0
50-56 Days (Group 2)												0
57-63 Days (Group 3)	68	34	(50%)		44	14	(32%)	15	(34%)	15	(344)	U
<63 Davs (All)	238	54	(23%)	0.5626	60	21	(35%)	22	(37%)	17	(28%)	0
		15	(19%)		16	9	(56%)	5	(31%)	2	(13%)	0
					26	8	(31%)	7	(27%)	11	(42%)	0
57-63 Days (Group 3)	68				18	4	(22%)	10	(56%)	4	(22%)	0
<63 Davs (All)	238	1	(<1%)	0.2857	1	0		1	(100%)	0		0
		0			0	0		0		0		0
					0	0		0		0		0
57-63 Days (Group 3)	68				1	0		1	(100%)	0		0
-63 Dave (All)	238	1	(<1%)	0.2857	1	0		1	(100%)	0		0
		0			0	0		0		0		0
•					0	0		0		0		0
57-63 Days (Group 3)	68				1	0		1	(100%)	0		0
•												
<63 Davs (All)	238	2	(<1%)	0.3345	2	0		1	(50%)	1 '	(50₹)	0
					. 0	0		0	J	0		0
					2	0		1	¹ (50%)	1	(50%)	0
57-63 Days (Group 3)	68	0			0	0		0		0		0
•	Group [2] 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 2) 57-63 Days (Group 3) s63 Days (All) s49 Days (Group 1) 50-56 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 (Group 3) s63 Days (Group 3) s63 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)	Group [2] of Pts ≤63 Days (All) 238 ≤49 Days (Group 1) 81 50-56 Days (Group 2) 89 57-63 Days (Group 3) 68 ≤63 Days (All) 238 ≤49 Days (Group 1) 81 50-56 Days (Group 2) 89 57-63 Days (Group 3) 68 ≤63 Days (All) 238 ≤49 Days (Group 3) 68 ≤63 Days (All) 238 ≤49 Days (Group 1) 81 50-56 Days (Group 2) 89 57-63 Days (Group 3) 68 ≤63 Days (All) 238 ≤49 Days (Group 1) 81 50-56 Days (Group 1) 81 50-56 Days (Group 3) 68	Group [2] of Pts w/8 s63 Days (All) 238 117 s49 Days (Group 1) 81 32 50-56 Days (Group 2) 89 51 57-63 Days (Group 3) 68 34 s63 Days (All) 238 54 s49 Days (Group 1) 81 15 50-56 Days (Group 2) 89 22 57-63 Days (Group 3) 68 17 s63 Days (All) 238 1 s49 Days (Group 1) 81 0 50-56 Days (Group 2) 89 0 57-63 Days (Group 3) 68 1 s63 Days (All) 238 1 s49 Days (Group 3) 68 1 s63 Days (All) 238 1 s63 Days (All) 238 1 s63 Days (Group 3) 68 1 s64 Days (Group 3) 68 1 s65 Days (Group 3) 68 1	Group [2] of Pts w/Event s63 Days (All) 238 117 (49%) s49 Days (Group 1) 81 32 (40%) 50-56 Days (Group 2) 89 51 (57%) 57-63 Days (Group 3) 68 34 (50%) s63 Days (All) 238 54 (23%) s49 Days (Group 1) 81 15 (19%) 50-56 Days (Group 2) 89 22 (25%) 57-63 Days (Group 3) 68 17 (25%) s63 Days (All) 238 1 (<1%) s49 Days (Group 1) 81 0 50-56 Days (Group 2) 89 0 57-63 Days (Group 3) 68 1 (1%) s63 Days (All) 238 1 (<1%) s63 Days (Group 3) 68 1 (1%) s63 Days (Group 1) 81 0 50-56 Days (Group 2) 89 0 57-63 Days (Group 3) 68 1 (1%) s63 Days (Group 1) 81 0 50-56 Days (Group 3) 68 1 (1%) s63 Days (Group 3) 68 1 (1%) s63 Days (Group 1) 81 0 50-56 Days (Group 3) 68 1 (1%) s63 Days (Group 3) 68 1 (1%)	Group [2] of Pts w/Event p-value s63 Days (All) 238 117 (49%) 0.0679 s49 Days (Group 1) 81 32 (40%) 50-56 Days (Group 2) 89 51 (57%) 57-63 Days (Group 3) 68 34 (50%) s63 Days (All) 238 54 (23%) 0.5626 s49 Days (Group 1) 81 15 (19%) 50-56 Days (Group 2) 89 22 (25%) 57-63 Days (Group 3) 68 17 (25%) s63 Days (All) 238 1 (<1%) 0.2857 s49 Days (Group 1) 81 0 50-56 Days (Group 2) 89 0 57-63 Days (Group 3) 68 1 (1%) s63 Days (Group 3) 68 1 (1%) s63 Days (Group 3) 68 1 (1%) s63 Days (Group 1) 81 0 50-56 Days (Group 2) 89 0 57-63 Days (Group 3) 68 1 (1%) s63 Days (Group 3) 68 1 (1%)	Group [2] of Pts w/Event p-value of Events *63 Days (All) 238 117 (49%) 0.0679 147 *49 Days (Group 1) 81 32 (40%) 42 50-56 Days (Group 2) 89 51 (57%) 61 57-63 Days (Group 3) 68 34 (50%) 44 *63 Days (All) 238 54 (23%) 0.5626 60 *49 Days (Group 1) 81 15 (19%) 16 50-56 Days (Group 2) 89 22 (25%) 26 57-63 Days (Group 3) 68 17 (25%) 18 *63 Days (Group 1) 81 0 0 50-56 Days (Group 2) 89 0 0 57-63 Days (Group 3) 68 1 (1%) 0.2857 1 *49 Days (Group 3) 68 1 (1%) 0.2857 1 *49 Days (Group 3) 68 1 (1%) 0.2857 1 *49 Days (Group 3) 68 1 (1%) 0.2857 1 *49 Days (Group 3) 68 1 (1%) 0.2857 1 *49 Days (Group 3) 68 1 (1%) 0.2857 1 *49 Days (Group 1) 81 0 0 57-63 Days (Group 2) 89 0 0 57-63 Days (Group 3) 68 1 (1%) 1 *63 Days (Group 1) 81 0 0 57-63 Days (Group 3) 68 1 (1%) 1 *63 Days (Group 3) 68 1 (1%) 1 *63 Days (Group 1) 81 0 0 57-63 Days (Group 3) 68 1 (1%) 1	Group [2] of Pts w/Event p-value of Events Mi *63 Days (All) 238 117 (49%) 0.0679 147 57 *49 Days (Group 1) 81 32 (40%) 42 18 50-56 Days (Group 2) 89 51 (57%) 61 25 57-63 Days (Group 3) 68 34 (50%) 44 14 *63 Days (All) 238 54 (23%) 0.5626 60 21 *49 Days (Group 1) 81 15 (19%) 16 9 50-56 Days (Group 2) 89 22 (25%) 26 8 57-63 Days (Group 3) 68 17 (25%) 18 4 *63 Days (All) 238 1 (<1%) 0.2857 1 0 *49 Days (Group 1) 81 0 0 0 50-56 Days (Group 3) 68 1 (1%) 10 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *64 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *66 Days (Group 3) 68 1 (1%) 0.2857 1 0 *67 Days (Group 3) 68 1 (1%) 0.2857 1 0 *68 Days (Group 3) 68 1 (1%) 0.2857 1 0 *69 Days (Group 3) 68 1 (1%) 0.2857 2 0 *69 Days (Group 3) 68 1 (1%) 0.2857 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 68 1 (1%) 0.3345 2 0 *69 Days (Group 3) 89 2 (2%) 2 0	Group [2] of Pts w/Event p-value of Events Mild *63 Days (All) 238 117 (49%) 0.0679 147 57 (39%) *49 Days (Group 1) 81 32 (40%) 42 18 (43%) 50-56 Days (Group 2) 89 51 (57%) 61 25 (41%) 57-63 Days (Group 3) 68 34 (50%) 44 14 (32%) *63 Days (All) 238 54 (23%) 0.5626 60 21 (35%) *49 Days (Group 1) 81 15 (19%) 16 9 (56%) 50-56 Days (Group 2) 89 22 (25%) 26 8 (31%) 57-63 Days (Group 3) 68 17 (25%) 18 4 (22%) *63 Days (All) 238 1 (<1%) 0.2857 1 0 *49 Days (Group 1) 81 0 0 0 50-56 Days (Group 2) 89 0 0 0 57-63 Days (Group 3) 68 1 (1%) 10 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *63 Days (Group 3) 68 1 (1%) 0.2857 1 0 *649 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 1 0 *65 Days (Group 3) 68 1 (1%) 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 1 0 *65 Days (Group 3) 68 1 (1%) 0.2857 2 0 *65 Days (Group 3) 68 1 (1%) 0.2857 2 0 *65 Days (Group 3) 68 1 (1%) 0.2857 2 0 *65 Days (Group 3) 68 1 (1%) 0.2857 2 0 *65 Days (Group 3) 68 1 (1%) 0.2857 2 0 *65 Days (Group 3) 68 1 (1%) 0.3345 2 0 *65 Days (Group 3) 68 1 (1%) 0.3345 2 0 *65 Days (Group 3) 68 1 (1%) 0.3345 2 0 *65 Days (Group 3) 89 0 0 0 0 *65 Days (Group 1) 81 0 0 0 0 *65 Days (Group 1) 81 0 0 0 0 *65 Days (Group 1) 81 0 0 0 0 *65 Days (Group 1) 81 0 0 0 0 *65 Days (Group 2) 89 2 (2%) 0.3345 2 0 0	Group [2] of Pts w/Event p-value of Events Mild Mode *63 Days (All) 238 117 (49%) 0.0679 147 57 (39%) 44 *49 Days (Group 1) 81 32 (40%) 42 18 (43%) 12 50-56 Days (Group 2) 89 51 (57%) 61 25 (41%) 17 57-63 Days (Group 3) 68 34 (50%) 44 14 (32%) 15 *63 Days (All) 238 54 (23%) 0.5626 60 21 (35%) 22 *49 Days (Group 1) 81 15 (19%) 16 9 (56%) 5 50-56 Days (Group 2) 89 22 (25%) 26 8 (31%) 7 57-63 Days (Group 3) 68 17 (25%) 18 4 (22%) 10 *63 Days (All) 238 1 (<1%) 0.2857 1 0 1 *63 Days (Group 1) 81 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 1 *63 Days (Group 3) 68 1 (1%) 1 0 1 *63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 50-56 Days (Group 2) 89 0 0 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-63 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-64 Days (Group 3) 68 1 (1%) 1 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 0 57-65 Days (Group 1) 81 0 0 0 0 0 0 57-65 Days (Group 2) 89 0 0 0 0 0 0 0 0 57-65 Days (Group 3) 68 0 0 0 0 0 0 0 0 0 0 57-65 Days (Group 3) 68 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Group [2] of Pts w/Event p-value of Events Mild Moderate *63 Days (All)	Separation Sep	Severe S

^[1] 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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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

	Gestational	Total	Number	Fisher's	N		Severi	Fw.	
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL (cont.)									
HYPOTENSION	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (21)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.0808	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	81	0	•	0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		3	0	3 (100%)	0	0
PLEURAL PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
SINUSITIS	s63 Days (All)	238	1 (<1%)	0.2857	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		2	0	2 (100%)	0	0
RED BLOOD CELL DISORDERS		1							
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.5061	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	81	0		. 0	0	0 1	0 :	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0

^[1] 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.

FINAL

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

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number -			 .	Severi	ty		
Body System/Event RED BLOOD CELL DISORDERS (cont.) ANAEMIA RIMARY SYSTEM DISORDERS ANY EVENT URINARY TRACT INFECTION REPRODUCTIVE DISORDERS, FEMALE	Group (2)	of Pts	w/E		p value	of Events	Mild	ı	Mode	rate	Sev	ere	Unknown
ED BLOOD CELL DISORDERS (cont.)		·									_		•
ANAEMIA	≤63 Days (All)	238	3	(1%)	0.5061	3	1 (33%)		(67%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	2	(2%)		2	0			(100%)	0		0
	57-63 Days (Group 3)	68	1	(1%)		1	1 (1	00%)	0		0		0
RIMARY SYSTEM DISORDERS									_			(1001)	0
ANY EVENT	≤63 Days (All)	238	1	(<1%)	0.6261	1	0		0			(100%)	0
	≰49 Days (Group 1)	81	1	(1%)	•	1	0		0		_	(100%)	0
	50-56 Days (Group 2)	89	0			0	0		0		0		0
	57-63 Days (Group 3)	68	0			0	0		0		0		0
URINARY TRACT INFECTION	≤63 Days (All)	238	1	(<1%)	0.6261	1	0		0			(100%)	0
	≰49 Days (Group 1)	81	1	(1%)		1	0		0		1	(100%)	0
(50-56 Days (Group 2)	89	0			0	0		0		0		0
1	57-63 Days (Group 3)	68	0			0	0		0		0		0
REPRODUCTIVE DISORDERS, FEMALE												(005)	0
ANY EVENT	≤63 Days (All)	238	50	(21%)	0.6448	57	2	(4%)		(14%)	47		0
	≤49 Days (Group 1)	81	16	(20%)		17	1	(6%)	4	(24%)	12	(71%)	0
	50-56 Days (Group 2)	89	17	(19%)		18	1	(6%)	1	(6%)	16	(89%)	U
	57-63 Days (Group 3)	68	17	(25%)		22	0		3	(14%)	19	(86%)	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: HASKELL (#2)

	Gestational	Total Number	Numi of		Fisher's exact	Number				Sever	itv			
Body System/Event	Age Group [2]	of Pts		vent	p-value	of Events	Mi		Mode		Sev	ere	Unk	nown
EPRODUCTIVE DISORDERS, FEMALE (cont.)														
UTERINE DISORDER NOS	≤63 Days (All)	238	2	(<1%)	0.5298	2	0		_	(100%)	0		0	
	≤49 Days (Group 1)	81	1	(1%)		1	0			(100%)	0		. 0	
	50-56 Days (Group 2)	89	0			0	0		0		0		0	
	57-63 Days (Group 3)	68	1	(1%)		1	0		1	(100%)	0		0	
UTERINE HAEMORRHAGE	≤63 Days (All)	238	48	(20%)	0.7241	54	2	(4%)	5	(9%)	47	(87%)	0	
	≤49 Days (Group 1)	81	15	(19%)		16	1	(6%)	3	(19%)	12	(75%)	0	
'	50-56 Days (Group 2)	89	17	(19%)		18	1	(6%)	1	(6%)	16	(89%)	0	
	57-63 Days (Group 3)	68	16	(24%)		20	0		1	(5%)	19	(95%)	0	
VAGINITIS	≤63 Days (All)	238	1	(<1%)	0.2857	1	0		1	(100%)	0		0	
***************************************	≤49 Days (Group 1)	81	0			0	0		0		0		0	
	50-56 Days (Group 2)	89	0			0	0		0		0		0	
	57-63 Days (Group 3)	68	1	(1%)		1	0		1	(100%)	0		0	
ODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	238	229	(96%)	0.1434	739	202	(27%)	272	(37%)	264	(36%)	1	
	≤49 Days (Group 1)	81	75	(93%)		230	73	(32%)	91	(40%)	65	(28%)	1	(<1%
	50-56 Days (Group 2)	89	87	(98%)		266	66	(25%)	95	(36%)	105	(39%)	0	
	57-63 Days (Group 3)	68	67	(99%)		243	63	(26%)	86	(35%)	94	(39%)	0	
ABDOMINAL PAIN	s63 Days (All)	238	228	(96%)	0.0667	700	189	(27%)	257	(37%)	253		1	
	≤49 Days (Group 1)	81	74	(91%)		215	68	(32%)	83	(39%)	63,		1	(<1%
	50-56 Days (Group 2)	89	87	(98%)		256	62	(24%)	92	(36%)	102	(40%)	0	
	57-63 Days (Group 3)	68	67	(99%)		229	59	(26%)	82 1	(36%)	88	(38%)	0	

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: HASKELL (#2)

	Gestational	Total Number	Number of P		Fisher's exact	Number -			Severi	ty	
Body System/Event	Age Group [2]	of Pts	w/Ev		p-value	of Events	Mild	Mode		Severe	Unknow
DDY AS A WHOLE - GENERAL DISORDERS (cont	.)										
BACK PAIN	≤63 Days (All)	238	12	(5%)	0.6598	14	4 (29%)	7		3 (21%	
	≤49 Days (Group 1)	81	5	(6%)		7	1 (14%)	4	(57%)	2 (29%	
	50-56 Days (Group 2)	89	3	(3%)		3	1 (33%)	2	• • • •	0	0
	57-63 Days (Group 3)	68	4	(6%)		4	2 (50%)	1	(25%)	1 (25%) 0
FATIGUE	≤63 Days (All)	238	7	(3%)	0.3419	7	6 (86%)	1	(14%)	0	0
1	≤49 Days (Group 1)	81	4	(5%)		4	3 (75%)	1	(25%)	0	0
	50-56 Days (Group 2)	89	1	(1%)		1	1 (100%)	0		0	0
	57-63 Days (Group 3)	68	2	(3%)		2	2 (100%)	0		0	0
FEVER	≤63 Days (All)	238	2	(<1%)	0.5298	2	0	1	(50%)	1 (50%) 0
FEVER	≤49 Days (Group 1)	81	1	(1%)		1	0	1	(100%)	0	0
	50-56 Days (Group 2)	89	0	,		0	0	0		0	0
	57-63 Days (Group 3)	68	1	(1%)		1	0	0		1 (100) 0
HOT FLUSHES	≤63 Days (All)	238	2	(<1%)	1.0000	2	2 (100%)	0		0	0
NOT FEOSIES	≤49 Days (Group 1)	81	1	(1%)		1	1 (100%)	0		0	0
	50-56 Days (Group 2)	89	1	(1%)		1	1 (100%)	0		0	0
	57-63 Days (Group 3)	68	0	, ,		0	0	0		0	0
HYPOVOLAEMI A	≤63 Days (All)	238	1	(<1%)	1.0000	1	0	0		1 (100) 0
UILOAOMUMAIN	±49 Days (Group 1)	81	ō			0	0	0		0	0
	50-56 Days (Group 2)	89	1	(1%)		1	0	0		1 - (100)) 0
	57-63 Days (Group 3)	68	Ō,	,		. 0	0	0	L	o '	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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

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

Center: HASKELL (#2)

	Gestational	Total Number	Number of Pts		Fisher's exact	Number -			Severi		
Body System/Event	Age Group (2)	of Pts	w/Even		p-value	of Events	Mi	ld	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDER	RS (cont.)		·								
LEG PAIN	≤63 Days (All)	238	3 (1%)	1.0000	4	1	(25%)	2 (50%)	1 (25%)	0
	≰49 Days (Group 1)	81	1 (14)		1	0		1 (100%)	O	0
	50-56 Days (Group 2)	89	1 (1%)		2	1	(50%)	0	1 (50%)	0
	57-63 Days (Group 3)	68	1 (11)		1	0		1 (100%)	O	0
PAIN	≤63 Days (All)	238	1 (<	11)	0.2857	2	0		0	2 (100%)	0
	≤49 Days (Group 1)	81	0			0	0		0	0	0
'	50-56 Days (Group 2)	89	0			0	0		0	0	0
	57-63 Days (Group 3)	68	1 (11)	,	2	0		0	2 (100%)	0
RIGORS	≰63 Days (All)	238	5 ((2%)	0.3849	5	0		4 (80%)	1 (20%)	0
	≤49 Days (Group 1)	81	1 (11)		1	0		1 (100%)	0	0
	50-56 Days (Group 2)	89	1 (11)		1	0		1 (100%)	0	0
	57-63 Days (Group 3)	68	3 ((4%)		3	0		2 (67%)	1 (33%)	0
SYNCOPE	≤63 Days (All)	238	2 (<	:1%)	0.7444	2	0		0	2 (100%)	0
	≤49 Days (Group 1)	81	0			0	0		0	0	0
	50-56 Days (Group 2)	89	1 ((1%)		1	0		0	1 (100%)	0
	57-63 Days (Group 3)	68	1 ((1%)		1	0		0	1 (100%)	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: POPPEMA (#3)

	Gestational	Total	Num		Fisher's	Number				Sever	itv			
Body System/Event	Age Group [2]	Number of Pts	of w/E	vent	exact p-value	of Events	Mi			rate	•	ere	Unk	nown
ANY EVENT	≤63 Days (All)	164	159	(97%)	0.2754	692	188	(27%)	248	(36%)	252	(36%)	4	(<1%
TALL DADIL	≤49 Days (Group 1)	65	61	(94%)		242	73	(30%)	91	(38%)	76	(31%)	2	(<1%
	50-56 Days (Group 2)	65		(9B%)		297	82	(28%)	101	(34%)	112		2	(<1%
	57-63 Days (Group 3)	34		(100%)		153	33	(22%)	56	(37%)	64	(42%)	0	
SKIN AND APPENDAGES DISORDERS														
ANY EVENT	≰63 Days (All)	164	3	(2%)	0.4263	3	1	(33%)	1	(33%)	1	(33%)	0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	2	(3%)		2	1	(50%)	1	(50%)	0		0	
	57-63 Days (Group 3)	34	1	(3%)		1	0		0		1	(100%)	0	
SWEATING INCREASED	≤63 Days (All)	164	3	(2%)	0.4263	3	1	(33%)	1	(33%)	1	(33%)	0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	2	(3%)		2	1	(50%)	1	(50%)	0		0	
	57-63 Days (Group 3)	34	1	(3*)		1	0		0		1	(100%)	0	
NUSCULO-SKELETAL SYSTEM DISORDERS							·							
ANY EVENT	≤63 Days (All)	164	1	(<1%)	1.0000	3	1	(33%)	1		1	•	0	
	s49 Days (Group 1)	65	1	(2%)		3	1	(33%)	1	(33%)	1	(33%)	0	
	50-56 Days (Group 2)	65	0			0	0		0		0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: POPPEMA (#3)

	Gestational	Total	Numb		Fisher's					6			
Body System/Event	Age Group [2]	Number of Pts	of E		exact p-value	Number of Events		1d		Severi rate	Sev		Unknow
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)													
MYALGIA	s63 Days (All)	164	1	(<1%)	1.0000	3	1	(33%)	1	(33%)	1	(33%)	0
	≤49 Days (Group 1)	65	1	(2%)		3	1	(33%)	1	(33%)	1	(33%)	0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34	0			0	0		0		0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	164	17	(10%)	0.9458	18	6	(33%)	8	(44%)	4	(22%)	0
'	≤49 Days (Group 1)	65	6	(9%)		7	3	(43%)	2	(29%)	2	(29%)	0
	50-56 Days (Group 2)	65	7	(11%)	·	7	3	(43%)	2	(29%)	2	(29%)	0
	57-63 Days (Group 3)	34	4	(12%)		4	0		4	(100%)	0		0
DIZZINESS	≤63 Days (All)	164	9	(5%)	0.5521	9	4	(44%)	3	(33%)	2	(22%)	0
	≤49 Days (Group 1)	65	2	(3%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	65	5	(8%)		5	3	(60%)	0		2	(40%)	0
	57-63 Days (Group 3)	34	2	(61)		2	0		2	(100%)	0		0
HEADACHE	≤63 Days (All)	164	8	(5%)	0.7176	9	2	(22%)	5	(56%)	2	(22%)	0
	s49 Days (Group 1)	65	4	(6%)		5	2	(40%)	1	(20%)	2	(40%)	0
	50-56 Days (Group 2)	65	2	(3%)		2	0		2	(100%)	0		0
	57-63 Days (Group 3)	34	2	(6%)		2	0		2	(100%)	0		0
JASTRO-INTESTINAL SYSTEM DISORDERS		I											
ANY EVENT	≤63 Days (All)	164	103	(63%)	0.0039	195	53	(27%)	74	(38%)	68	(35%)	0
	≤49 Days (Group 1)	65	32	(49%)		58	19	(33%)	26	(45%)	13	(22%)	0
	50-56 Days (Group 2)	65	43	(66%)		85	23	(27%)	29	(34%)	33	(39%)	0
	57-63 Days (Group 3)	34	28	(82%)		52	11	(21%)	19	(37%)	22	(42%)	0

^[1] 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.

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

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

	Gestational Age	Total Number	Num of		Fisher's exact	Number	- -			Severi	ty		.,
Body System/Event	Group [2]	of Pts		vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknow
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													_
ABDOMINAL PAIN	≰63 Days (All)	164	1	(<1%)	0.2073	4	1	(25%)	1	(25%)	2	(50%)	0
	≤49 Days (Group 1)	65	0			0	0		0		0		0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34	1	(3%)		4	1	(25%)	1	(25%)	2	(50%)	0
DIARRHEA	≤63 Days (All)	164	28	(17%)	0.4569	31	11	(35%)	16	(52∜)	4	(13%)	0
1	s49 Days (Group 1)	65	10	(15%)		12	5	(42%)	6	(50%)	1	(8%)	0
	50-56 Days (Group 2)	65	14	(22%)	•	14	5	(36%)	6	(43%)	3	(21%)	0
	57-63 Days (Group 3)	34	4	(12%)		5	1	(20%)	4	(80%)	0		0
NAUSEA	≤63 Days (All)	164	90	(55%)	0.0255	112	37	(33%)	35	(31%)	40	(36%)	0
***************************************	≤49 Days (Group 1)	65	28	(43%)		35	12	(34%)	15	(43%)	8	(23%)	0
	50-56 Days (Group 2)	65	38	(58%)		50	16	(32%)	14	(28%)	20	(40%)	0
	57-63 Days (Group 3)	34	24	(71%)		27	9	(33%)	6	(22%)	12	(44%)	0
VOMITING	≤63 Days (All)	164	43	(26%)	0.0152	48	4	(8%)	22	(46%)	22	(46%)	0
,	≤49 Days (Group 1)	65	10	(15%)		11	2	(18%)	5	(45%)	4	(36%)	0
	50-56 Days (Group 2)	65	19	(29%)		21	2	(10%)	9	(43%)	10	(481)	0
	57-63 Days (Group 3)	34	14	(41%)		16	0		8	(50%)	8	(50%)	0
CARDIOVASCULAR DISORDERS, GENERAL													
ANY EVENT	≤63 Days (All)	164	2	(1%)	0.6839	2	0		2	(100%)	0		0
	\$49 Days (Group 1)	65	0			. 0	0		0		0 '		0
	50-56 Days (Group 2)	65	1	(2%)		• 1	0		1	(100%)	0		0
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: POPPEMA (#3)

	Gestational	Total	Number	Fisher's			0		
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL (cont.)						······································			
HYPOTENSION	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	o	0
HYPOTENSION POSTURAL	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)	,	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	О	0	0
ED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	164	3 (2%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	O	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
ANAEMIA	≤63 Days (All)	164	3 (2%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
EPRODUCTIVE DISORDERS, FEMALE	•								
ANY EVENT	≤63 Days (All)	164	18 (11%)	0.0801	25	6 (24%)	11 (44%)	8 (32%)	0
	≤49 Days (Group 1)	65	3 (5%)		6	2 (33%)	3 (50%)	1 (17%)	0
	50-56 Days (Group 2)	65	9 (14%)		11	3 (27%)	3 (27%)	5 (45%)	0
	57-63 Days (Group 3)	34	6 (18%)		8	1 (13%)	5 (63%)	2 (25%)	0

^[1] 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.

^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography. Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Pi		Fisher's exact	Number -			sev	erity	
Body System/Event	Group [2]	of Pts	w/Eve		p-value	of Events	M	ild	Moderate	Severe	Unkno
EPRODUCTIVE DISORDERS, FEMALE (cont.)			·								
ENDOMETRITIS	≤63 Days (All)	164	7	(4%)	0.8833	7	2		5 (71%)	0	0
	≤49 Days (Group 1)	65	2	(3%)		2	1	(50%)	1 (50%)	0	0
	50-56 Days (Group 2)	65	3	(5%)		3	1	(33%)	2 (67%)	0	0
	57-63 Days (Group 3)	34	2	(6 %)		2	0		2 (100%)	0	0
LEUKORRHOEA	≤63 Days (All)	164	1	(<1%)	1.0000	1	1	(100%)	0	0	0
· ·	≤49 Days (Group 1)	65	0			0	0		0	0	0
	50-56 Days (Group 2)	65	1	(2%)	•	1	1	(100%)	0	0	0
	57-63 Days (Group 3)	34	0			0	0		0	0	0
SALPINGITIS	≤63 Days (All)	164	1	(<1%)	1.0000	1	1	(100%)	0	0	0
	s49 Days (Group 1)	65	1	(2%)		1	1	(100%)	0	0	0
	50-56 Days (Group 2)	65	0			0	0		0	0	0
	57-63 Days (Group 3)	34	0			0	0		0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		1 (100%)	0	0
	≤49 Days (Group 1)	65	0			0	0		0	0	0
	50-56 Days (Group 2)	65	0			0	0		0	0	0
	57-63 Days (Group 3)	34	1	(3%)		1	0		1 (100%)	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	164	14	(9%)	0.2183	14	1	(7%)	5 (36%)		0
	±49 Days (Group 1)	65	3	(5%)		3	0		2 (67%)		0
	50-56 Days (Group 2)	65	6	(9%)		. 6	0		1 (17%)		0
	57-63 Days (Group 3)	34	5	(15%)		• 5	1	(20%)	2 ((40%)	2 (40%)	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: POPPEMA (#3)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number				Sever	itv			
Body System/Event	Group [2]	of Pts		vent	p value	of Events	Mi		Mode		Sev	ere	Unk	known
REPRODUCTIVE DISORDERS, FEMALE (cont.)														
VAGINAL DISCOMFORT	≤63 Days (All)	164	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	1	(21)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	
BODY AS A WHOLE - GENERAL DISORDERS	-													
ANY EVENT	≤63 Days (All)	164	158	(96%)	0.4439	443	120	(27%)	149	(34%)	170	(38%)	4	
,	≤49 Days (Group 1)	65	61	(94%)		167	47	(28%)	59	(35%)	59	(35%)	2	
	50-56 Days (Group 2)	65	64	(98%)		190	52	(27%)	64	(34%)	72	(38%)	2	(1%)
	57-63 Days (Group 3)	34	33	(97%)		86	21	(24%)	26	(30%)	39	(45%)	0	
ABDOMINAL PAIN	≤63 Days (All)	164	158	(96%)	0.4439	420	114	(27%)	138	(33%)	165	(39%)	3	(<1%
	≤49 Days (Group 1)	65	61	(94%)		157	43	(27%)	55	(35%)	58	(37%)	1	(<1%
	50-56 Days (Group 2)	65	64	(98%)		181	50	(28%)	59	(33%)	70	(39%)	2	(1%
	57-63 Days (Group 3)	34	33	(97%)		82	21	(26%)	24	(29%)	37	(45%)	0	
ASTHENI A	≤63 Days (All)	164	3	(2%)	0.8010	3	2	(67%)	1	(33%)	0		0	
	≤49 Days (Group 1)	65	2	(3%)		2	1	(50%)	1	(50%)	0		0	
	50-56 Days (Group 2)	65	1	(2%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	
BACK PAIN	≤63 Days (All)	164	7	(4%)	0.8833	7	1	(14%)	3	(43%)	2	(29%)	1	
	≤49 Days (Group 1)	65	3	(5%)		3	0		1	(33%)	1,	(33%)	1	(33∜
	50-56 Days (Group 2)	65	2	(3%)		; 2	1	(50%)	1	(50%)	0 ·		0	
	57-63 Days (Group 3)	34	2	(6%)		• 2	0		1	(50%)	1	(50%)	0	

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: POPPEMA (#3)

	Gestational	Total	Numb		Fisher's			0		
Body System/Event	Age Group [2]	Number of Pts	of P		exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)			_	(24)	1.0000	,	1 (33%)	1 (33%)	1 (33%)	0
FATIGUE	≤63 Days (All)	164	3	(2%)	1.0000	1	1 (100%)	0	0	n
	≤49 Days (Group 1)	65	1	(2%)		,	0	1 (100%)	0	0
	50 56 Days (Group 2)	65	1	(2%)		1	-		1 (100%)	0
	57-63 Days (Group 3)	34	1	(3%)		1	0	0	1 (1004)	Ü
FEVER	≤63 Days (All)	164	1	(<1%)	1.0000	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	65	1	(2%)		1	1 (100%)	0	0	0
50-56 Days	50-56 Days (Group 2)	65	0	, /		0	0	0	0	0
	57-63 Days (Group 3)	34	0			0	0	0	0	0
OT FLUSHES	≤63 Days (All)	164	1	(<1%)	1.0000	1	0	1 (100%)	o	0
	s49 Days (Group 1)	65	0	,		0	0	0	0	0
	50-56 Days (Group 2)	65	1	(2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0			0	0	0	0	0
LEG PAIN	≤63 Days (All)	164	2	(1%)	0.6839	2	t o	2 (100%)	o	0
	≤49 Days (Group 1)	65	0			0	0	0	0	0
	50-56 Days (Group 2)	65	1	(2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1	(3%)		1	0	1 (100%)	0	0
RIGORS	≰63 Days (All)	164	4	(2%)	0.5346	4	1 (25%)	3 (75%)	0	0
***************************************	≤49 Days (Group 1)	65	3	(5%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	65	1	(2%)		1	0	1 (100%)	0 '	0
	57-63 Days (Group 3)	34	ó	••		• 0	0	٥ ١	0	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: POPPEMA (#3)

,	Gestational Age	Total Number	Number of Pt		Fisher's exact			Sever	itv	
Body System/Event	Group [2]	of Pts	w/Eve		p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISOR	DERS (cont.)									
SYNCOPE	≤63 Days (All)	164	2	(1%)	0.3532	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	65	0			0	0	0	0	0
			•	(3%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	65	2	(30)						

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: TYSON (#4)

	Gestational	Total Number	Number of Pts	Fisher's					Couc			
Body System/Event	Age Group (2)	of Pts	w/Event	exact p-value	Number of Events		1d		Severi	Sev		Unknow
ANY EVENT	≤63 Days (All)	102	98 (96%)	1.0000	403	148	(37%)	156	(39%)	99	(25%)	0
	s49 Days (Group 1)	68	65 (96%)	1.0000	271	101	(37%)	110	(41%)	60	(22%)	ō
	50-56 Days (Group 2)	25	24 (96%)		106	39	(37%)	40		27	(25%)	Ö
	57-63 Days (Group 3)	9	9 (100%)		26	8	(31%)		(23%)	12	(46%)	0
KIN AND APPENDAGES DISORDERS												
ANY EVENT	≤63 Days (All)	102	2 (2%)	0.5578	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	68	1 (1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	25	1 (4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	9	0		0	0		0		0		0
SWEATING INCREASED	≤63 Days (All)	102	2 (2%)	0.5578	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	68	1 (1%)		1	0		1	(100%)	0		0
!	50-56 Days (Group 2)	25	1 (4%)		1	0		1	(100%)	0		0
i	57-63 Days (Group 3)	9	0		0	0		0		0		0
rusculo-skeletal system disorders												
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	25	0		0	0		0		0		0
	57-63 Days (Group 3)	9	0		0	0		0		0		0
										1		

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: TYSON (#4)

	Gestational	Total Number	Number of Pt		Fisher's exact	Number				Severi	+ • • •		
Body System/Event	Age Group [2]	of Pts	w/Eve		p·value	of Events	Mi			rate	•	ere	Unknow
USCULO-SKELETAL SYSTEM DISORDERS (cont.)						# - J.J							
MYALGIA	≤63 Days (All)	102	1 ((<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	68	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	24 ((24%)	0.6176	35	13	(37%)	19	(54%)	3	(9%)	0
,	≤49 Days (Group 1)	68		(26%)		27	10	(37%)	14	(52%)	3	(11%)	0
	50-56 Days (Group 2)	25		(20%)	•	7	3	(43%)	4	(57%)	0		0
	57-63 Days (Group 3)	9		(11%)		1	0		1	(100%)	0		0
DIZZINESS	≤63 Days (All)	102	7	(7%)	0.0493	8	5	(63%)	3	(38%)	0		0
	≤49 Days (Group 1)	68	2	(3%)		2	2	(100%)	0		0		0
	50-56 Days (Group 2)	25	4 ((16%)		5	3	(60%)	2	(40%)	0		0
	57-63 Days (Group 3)	9		(11%)		1	0		1	(100%)	0		0
HEADACHE	≤63 Days (All)	102	16 ((16%)	0.1821	24	6	(25%)	16	(67%)	2	(8%)	0
	\$49 Days (Group 1)	68	14 ((21%)		22	6	(27%)	14	(64%)	2	(9%)	0
	50-56 Days (Group 2)	25	2	(8%)		2	0		2	(100%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
MIGRAINE	≤63 Days (All)	102	1 ((<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	68	1	(1%)		1	0		0		1,	(100%)	0
	50-56 Days (Group 2)	25	0			. 0	0		0		0		0
	57-63 Days (Group 3)	9	0			• 0	0		0	l.	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: TYSON (#4)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	ity	
Body System/Event	Group [2]	of Pts	w/Event	p · value	of Events	Mild	Moderate	Severe	Unknow
CENTR & PERIPH NERVOUS SYSTEM DIS	SORDERS (cont.)								
TREMOR	≤63 Days (All)	102	2 (2	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	68	2 (3	t)	2	2 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
ASTRO-IMTESTIMAL SYSTEM DISORDEI	RS								
ANY EVENT	≤63 Days (All)	102	60 (59	0.9501	104	42 (40%)	34 (33%)	28 (27%)	0
•	s49 Days (Group 1)	68	41 (60	t) .	69	27 (39%)	24 (35%)	18 (26%)	0
	50-56 Days (Group 2)	25	14 (56)	27	12 (44%)	8 (30%)	7 (26%)	0
	57-63 Days (Group 3)	9	5 (56	b)	8	3 (30%)	2 (25%)	3 (38%)	0
CONSTIPATION	s63 Days (All)	102	1 (<1	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1	k)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	102	19 (19	b) 0.7838	22	14 (64%)	4 (18%)	4 (18%)	0
	s49 Days (Group 1)	68	12 (18	k)	14	10 (71%)	2 (14%)	2 (14%)	0
	50-56 Days (Group 2)	25	5 (20	•)	6	3 (50%)	2 (33%)	1 (17%)	0
	57-63 Days (Group 3)	9	2 (22	b)	2	1 (50%)	0	1 (50%)	0
DYSPEPSIA	≰63 Days (All)	102	2 (2	0.5578	3	1 (33%)	0	2 (67%)	0
	s49 Days (Group 1)	68	1 (1	k)	1	1 (100%)	0	0 '	0
	50-56 Days (Group 2)	25	1 (4	b }	2	0	0 1	2 (100%)	0
	57-63 Days (Group 3)	9	0		0	0	o "	0	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: TYSON (#4)

	Gestational	Total		ber	Fisher's	Number				Severi	ítv		
Body System/Event	Age Group [2]	Number of Pts		Pts Vent	exact p·value	Number of Events	Mi	.ld	Mode		•	ere	Unknowr
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
FLATULENCE	≤63 Days (All)	102	1	(<1%)	1.0000	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	68	1	(1%)		2	2	(100%)	0		0		0
	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	102	43	(42%)	1.0000	45	19	(42%)	13	(29%)	13	(29%)	0
1	≤49 Days (Group 1)	68	29	(43%)		31	11	(35%)	10	(32%)	10	(32%)	0
	50-56 Days (Group 2)	25	10	(40%)		10	6	(60%)	2	(20%)	2	(20%)	0
	57-63 Days (Group 3)	9	4	(44%)		4	2	(50%)	1	(25%)	1	(25%)	0
VOMITING	≤63 Days (All)	102	26	(25%)	1.0000	31	6	(19%)	16	(52%)	9	(29%)	0
	≤49 Days (Group 1)	68	18	(26%)		20	3	(15%)	11	(55%)	6	(30%)	0
	50-56 Days (Group 2)	25	6	(24%)		9	3	(33%)	4	(44%)	2	(22%)	0
	57-63 Days (Group 3)	9	2	(22%)		2	0		1	(50%)	1	(50%)	0
RESPIRATORY SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	1	(<1%)	0.3333	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	68	0			0	0		0		0		0
	50-56 Days (Group 2)	25	1	(4%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
DYSPNOEA	≤'63 Days (All)	102	1	(<1%)	0.3333	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	68	0			0	0		0		0	ı	0
	50-56 Days (Group 2)	25	1	(4%)		. 1	1	(100%)	0	ı	0	•	0
	57-63 Days (Group 3)	9	0			0	0		0	ħ.	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] 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: TYSON (#4)

	Gestational	Total	Number	Fisher's	M			Caucr	ity	
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild		lerate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	U									
ANY EVENT	≤63 Days (All)	102	7 (7%)	0.0060	7	0	1	(14%)	6 (86%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0)	1 (100%)	0
	50-56 Days (Group 2)	25	5 (20%)		5	0	1	(20%)	4 (80%)	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	0	1	1 (100%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	102	7 (7%)	0.0060	7	0	1	(14%)	6 (86%)	0
1	s49 Days (Group 1)	68	1 (1%)		1	0	0)	1 (100%)	0
	50-56 Days (Group 2)	25	5. (20%)		5	0	1	(20%)	4 (80%)	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	C)	1 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS										
ANY EVENT	≤63 Days (All)	102	98 (96%)	1.0000	252	91 (36	100	(40%)	61 (24%)	0
	≤49 Days (Group 1)	68	65 (96%)		171	63 (37)) 71	(42%)	37 (22%)	0
	50-56 Days (Group 2)	25	24 (96%)		65	23 (35	:) 26	(40%)	16 (25%)	0
	57-63 Days (Group 3)	9	9 (100%)		16	5 (31	;) 3	(19%)	8 (50%)	0
ABDOMINAL PAIN	≤63 Days (All)	102	98 (96%)	1.0000	226	78 (35	90	(40%)	58 (26%)	0
	≤49 Days (Group 1)	68	65 (96%)		153	54 (35)	:) 65	(42%)	34 (22%)	0
	50-56 Days (Group 2)	25	24 (96%)		57	19 (33	:) 22	(39%)	16 (28%)	0
	57-63 Days (Group 3)	9	9 (100%)		16	5 (31	;) 3	(19%)	8 (50%)	0
ASTHENIA	≤63 Days (All)	102	4 (4%)	0.0828	4	2 (50	;) 1	(25%)	1 (25%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	C)	1 (100%)	0
	50-56 Days (Group 2)	25	3 (12%)		. 3	2 (67)	1)	(33%)	o '	0
	57-63 Days (Group 3)	9	0		0	0	C) 1	0	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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

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

Center: TYSON (#4)

	Gestational	Total Number		ber Pts	Fisher's exact	Number				Severi	tv		
Body System/Event	Age Group [2]	of Pts		vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)													
BACK PAIN	≤63 Days (All)	102	8	(8%)	0.1432	8	3	(38%)	4	(50%)	1	(13%)	0
	≤49 Days (Group 1)	68	8	(12%)		8	3	(38%)	4	(50%)	1	(13%)	0
	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
FATIGUE	≤63 Days (All)	102	3	(3%)	1.0000	4	1	(25%)	2	(50%)	1	(25%)	0
1	s49 Days (Group 1)	68	2	(3%)		3	1	(33%)	1	(33%)	1	(33%)	0
	50-56 Days (Group 2)	25	1	(4%)	,	1	0		1	(100%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
MALAISE	≤63 Days (All)	102	1	(<1%)	0.3333	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	68	0			0	0		0		0		0
	50-56 Days (Group 2)	25	1	(4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
RIGORS	≤63 Days (All)	102	8	(8%)	0.4991	8	6	(75%)	2	(25%)	0		0
	≤49 Days (Group 1)	68	5	(7%)		5	4	(80%)	1	(20%)	0		0
	50-56 Days (Group 2)	25	3	(12%)		3	2	(67%)	1	(33%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
TEMPERATURE CHANGED SENSATION	s63 Days (All)	102	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≰49 Days (Group 1)	68	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	25	0			0	0		0		0 ,		0
	57-63 Days (Group 3)	9	0			. 0	0		0	ł,	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: TYSON (#4)

	Gestational	Total	Number	Fisher's	Number -		Sever	itv	
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	of Events	Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
·	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
ı	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: BLUMENTHAL (#5)

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number				Severi	ty		
Body System/Event	Group [2]	of Pts	w/Ever		p-value	of Events	Mi	1 d	Mode	rate	Sev	ere	Unknow
ANY EVENT	≤63 Days (All)	44	43 (9	98%)	0.1818	166	84	(51%)	60	(36%)	22	(13%)	0
	≤49 Days (Group 1)	13	13 (10			41	21	(51%)	17	(41%)	3	(7%)	0
	50-56 Days (Group 2)	23	23 (10			97	47	(48%)	32	(33%)	18	(19%)	0
	57-63 Days (Group 3)	8		881)		28	16	(57%)	11	(39%)	1	(4%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	44	10 (2	23%)	0.2801	14	1	(7%)	10	(71%)	3	(21%)	0
	≰49 Days (Group 1)	13	4 (3	31%)		5	0		_	(100%)	0		0
	50-56 Days (Group 2)	23	6 (2	26%)		9	1	(11%)	5	(56%)	3	(33%)	0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
DIZZINESS	≤63 Days (All)	44	2	(51)	1.0000	2	1	(50%)	1		0		0
	≤49 Days (Group 1)	13	1	(8%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	23	1	(4%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
HEADACHE	s63 Days (All)	44	8 (1	18%)	0.3926	12	0		9	(75%)	3	(25%)	0
	≤49 Days (Group 1)	13	3 (2	23%)		4	0		4	(100%)	0		0
	50-56 Days (Group 2)	23	5 (2	22%)		8	0		5	(63%)	3	(38¥)	0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS													_
ANY EVENT	≤63 Days (All)	44	28 (6	64%)	0.7071	49	31	(63%)	10	(20%)		(16%)	0
	≤49 Days (Group 1)	13	7 (9	54%)		14	8	(57%)	4	(29%)	_	(14%)	0
	50-56 Days (Group 2)	23	16 (70%)		26	16	(62%)	4	(15%)	6	(23%)	0
	57-63 Days (Group 3)	8	5 (6	63%)		9	7	(78%)	2	(22%)	0		0

^[1] 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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FINAL

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

Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

	Gestational	Total		ber	Fisher's								
Body System/Event	Age Group [2]	Number of Pts		Pts vent	exact p-value	Number of Events		ld		Severi rate	Sev		Unknown
										····			
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)		44	5	(11%)	0.6850	6	2	(33%)	2	(33%)	2	(33%)	o
DIARRHEA	≤63 Days (All)		_		0.6650	2	1	(50%)	1	(50%)	ō	(334)	ō
	≤49 Days (Group 1)	13	2	(15%)		2	1	(25%)	•	(25%)	2	(50%)	ō
	50-56 Days (Group 2)	23	3	(13%)		4	_	(254)	0	(254)	ō	(304)	ő
	57-63 Days (Group 3)	8	0			0	0		U		U		U
FLATULENCE	≤63 Days (All)	44	1	(2%)	1.0000	2	0		1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	13	0			0	0		0		0		0
	50-56 Days (Group 2)	23	1	(4%)		2	0		1	(50%)	1	(50%)	0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	44	28	(64%)	0.7071	32	24	(75%)	4	(13%)	4	(13%)	0
NAUSEA	≤49 Days (Group 1)	13	7	(54%)	0.7071	8	5	(63%)	2	(25%)	1	(13%)	0
	50-56 Days (Group 2)	23	16	(70%)		19	14	(74%)	2	(11%)	3	(16%)	0
	57-63 Days (Group 3)	8	5	(63%)		5		(100%)	0	(220)	0	, ,	0
VOMITING	s63 Days (All)	44	7	(16%)	0.0601	9	5	(56%)	3	(33%)	1	(11%)	0
VONITING	≤49 Days (Group 1)	13	4	(31%)	0.0001	4	2		1	(25%)	1	(25%)	0
	50-56 Days (Group 2)	23	,	(4%)		1	-	(100%)	0	,,,,	0		0
	57-63 Days (Group 3)	8	2	(25%)		4	2	(50%)	2	(50%)	0		0
REPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	44	1	(2%)	1.0000	3	0		3	(100%)	0		0
tare promi	\$49 Days (Group 1)	13	0	,,		0	0		0		0 -		0
	50-56 Days (Group 2)	23	1	(4%)		. 3	0			(100%)	0		0
	57-63 Days (Group 3)	8	•	(10)		. 0	0	1	0	£	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: BLUMENTHAL (#5)

	Gestational	Total	Number	Fisher's	ht				Severi			
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p·value	Number of Events	Mi			rate	Sev		Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)					<u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>		-					,
BREAST ENGORGEMENT	≤63 Days (All)	44	1 (2%)	1.0000	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	13	0		0	0		0		0		0
	50-56 Days (Group 2)	23	1 (4%)		2	0		2	(100%)	0		0
	57-63 Days (Group 3)	8	0		0	0		0		0		0
BREAST PAIN FEMALE	≤63 Days (All)	44	1 (2%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	13	0		0	0		0		0		0
,	50-56 Days (Group 2)	23	1 (4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	8	0		0	0		0		0		0
BODY AS A WHOLE - GENERAL DISORDERS												
ANY EVENT	≤63 Days (All)	44	43 (98%)	0.1818	100	52	(52%)	37	(37%)	11	(11%)	0
	≤49 Days (Group 1)	13	13 (100%)		22	13	(59%)	8	(36%)	1	(5%)	0
	50-56 Days (Group 2)	23	23 (100%)		59	30	(51%)	20	(34%)	9	(15%)	0
	57-63 Days (Group 3)	8	7 (88%)		19	9	(47%)	9	(47%)	1	(5%)	0
ABDOMINAL PAIN	≤63 Days (All)	44	43 (98%)	0.1818	95	52	(55%)	33	(35%)	10	(11%)	0
	≤49 Days (Group 1)	13	13 (100%)		21	13	(62%)	7	(33%)	1	(5♦)	0
	50-56 Days (Group 2)	23	23 (100%)		56	30	(54%)	18	(32%)	8	(14%)	0
	57-63 Days (Group 3)	8	7 (88%)		18	9	(50%)	8	(44%)	1	(6%)	0
FEVER	≤63 Days (All)	44	1 (2%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	13	0		0	0		0		0,		0
	50-56 Days (Group 2)	23	1 (4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	8	0.		• 0	0		0	L	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: BLUMENTHAL (#5)

Body System/Event	Gestational	Total Number	Number of Pts		Fisher's exact	Number	Severity						
	Age Group [2]	of Pts	w/E		p value	of Events	Mild	Moderate	Severe	Unknown			
ODY AS A WHOLE - GENERAL DISORDERS (cont.)												
LEG PAIN	≤63 Days (All)	4 4	2	(5%)	0.2220	2	0	2 (100%)	0	0			
	≰49 Days (Group 1)	13	1	(8%)		1	0	1 (100%)	0	0			
	50-56 Days (Group 2)	23	0			0	0	0	0	0			
	57-63 Days (Group 3)	8	1	(13%)		1	0	1 (100%)	0	0			
OEDEMA	≤63 Days (All)	44	1	(2%)	1.0000	1	0	0	1 (100%)	0			
	s49 Days (Group 1)	13	0			0	0	0	0	0			
·	50-56 Days (Group 2)	23	1	(4%)		1	0	0	1 (100%)	0			
	57-63 Days (Group 3)	8	0			0	0	0	0	0			
PAIN	≤63 Days (All)	44	1	(2%)	1.0000	1	0	1 (100%)	0	0			
	s49 Days (Group 1)	13	0			O	0	0	0	0			
	50-56 Days (Group 2)	23	1	(4%)		1	0	1 (100%)	0	0			
	57-63 Days (Group 3)	8	0			0	0	0	0	0			

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: BORGATTA (#6)

	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			Moderate		Severe		Unknown
ANY EVENT	≤63 Days (All)	64	59 (92)	92%) 0.8202	255	109	(43%)	92	(36%)	54	(21%)	o
	s49 Days (Group 1)	36	32 (89))	149	69	(46%)	49	(33%)	31	(21%)	0
	50-56 Days (Group 2)	16	15 (94))	62	22	(35%)	25	(40%)	15	(24%)	0
	57-63 Days (Group 3)	12	12 (1001)	44	18	(41%)	18	(41%)	8	(18%)	0
CENTR & PERIPH NERVOUS SYSTEM DIS	ORDERS											
ANY EVENT	≤63 Days (All)	64	12 (19	0.2844	21	8	(38%)	9	(43%)	4	(19%)	0
	≤49 Days (Group 1)	36	6 (171) .	9	3	(33%)	5	(56%)	1	(11%)	0
	50-56 Days (Group 2)	16	5 (31)	10	4	(40%)	3	(30%)	3	(30%)	0
	57-63 Days (Group 3)	12	1 (81)	2	1	(50%)	1	(50%)	0		0
DIZZINESS	≤63 Days (All)	64	3 (51) 1.0000	3	3	(100%)	0		0		0
	≤49 Days (Group 1)	36	2 (61)	2	2	(100%)	0		0		0
	50-56 Days (Group 2)	16	1 (61)	1	1	(100%)	0		0		0
	57-63 Days (Group 3)	12	0		0	0		0		0		0
HEADACHE	≤63 Days (All)	64	9 (14)	0.3812	17	5	(29%)	8	(47%)	4	(24%)	0
	≤49 Days (Group 1)	36	4 (11))	6	1	(17%)	4	(67%)	1	(17%)	0
	50-56 Days (Group 2)	16	4 (251)	9	3	(33%)	3	(33%)	3	(33%)	0
	57-63 Days (Group 3)	12	1 (81)	2	1	(50%)	1	(50%)	0		0
PARAESTHESIA	≰63 Days (All)	64	1 (2) 1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	36	1 (31)	1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0		. 0	0		0	1	0		0
	57-63 Days (Group 3)	12	o ·		0	0		0	v	0		0

^[1] 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.

Appendix A.1, Tables 16 and 25

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^[2] 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: BORGATTA (#6)

Body System/Event	Gestational Age Group [2]	Total Number	Number of Pts	Fisher's exact	Number		Severity					
		of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown			
PSYCHIATRIC DISORDERS												
ANY EVENT	s63 Days (All)	64	4 (6%)	0.3760	4	2 (50%)	2 (50%)	0	0			
	≤49 Days (Group 1)	36	4 (11%)		4	2 (50%)	2 (50%)	0	0			
	50-56 Days (Group 2)	16	0		0	0	0	0	0			
	57-63 Days (Group 3)	12	0		, 0	0	0	0	0			
ANOREXIA	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0			
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0			
	50-56 Days (Group 2)	16	0		0	0	0	0	0			
	57-63 Days (Group 3)	12	0	•	0	0	0	0	0			
ANXIETY	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0			
	≰49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0			
	50-56 Days (Group 2)	16	0		0	0	0	0	0			
	57-63 Days (Group 3)	12	0		0	0	0	0	0			
DEPRESSION	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0			
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0			
	50-56 Days (Group 2)	16	0		0	0	0	0	0			
	57-63 Days (Group 3)	12	0		0	0	0	0	0			
EMOTIONAL LABILITY	≰63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0			
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0			
	50-56 Days (Group 2)	16	0		0	0	0	Ο,	0			
	57-63 Days (Group 3)	12	0		• 0	0	o l	0 .	0			

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Appendix A.1, Tables 16 and 25

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^[2] 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: BORGATTA (#6)

Body System/Event	Gestational Age Group [2]	Total Number	Number of Pts w/Event		Fisher's exact	Number				Severi	erity						
		of Pts			p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknowi				
ASTRO-INTESTINAL SYSTEM DISORDERS		-															
ANY EVENT	≤63 Days (All)	64	40	(63%)	0.3372	78	35	(45%)	25	(32%)	18	(23%)	0				
	s49 Days (Group 1)	36	25	(69%)		51	21	(41%)	16	(31%)	14	(27%)	0				
	50-56 Days (Group 2)	16	8	(50%)		15	8	(53%)	5	(33%)	2	(13%)	0				
	57-63 Days (Group 3)	12	7	(58%)		12	6	(50%)	4	(33%)	2	(17%)	0				
DIARRHEA	s63 Days (All)	64	13	(20%)	0.5833	13	7	(54%)	4	(31%)	2		0				
•	≤49 Days (Group 1)	36	8	(22%)		8	4	(50%)	2	(25%)	2	(25%)	0				
	50-56 Days (Group 2)	16	4	(25%)		4	2	(50%)	2	(50%)	0		0				
	57-63 Days (Group 3)	12	1	(8%)		1	1	(100%)	0		0		0				
DYSPEPSIA	≤63 Days (All)	64	2	(3%)	0.4018	2	0		2	(100%)	0		0				
	≤49 Days (Group 1)	36	1	(3%)		1	0		1	(100%)	0		0				
	50-56 Days (Group 2)	16	0			U	0		0		0		0				
	57-63 Days (Group 3)	12	1	(8%)		1	0		1	(100%)	0		0				
FLATULENCE	≤63 Days (All)	64	1	(2%)	0.1875	1	0		0		1	(100%)	0				
	≤49 Days (Group 1)	36	0			0	0		0		0		0				
	50-56 Days (Group 2)	16	0			0	0		0		0		0				
	57-63 Days (Group 3)	12	1	(8%)		1	0		0		1	(100%)	0				
NAUSEA	≤63 Days (All)	64	35	(55%)	0.8347	46	22	(48%)		(30%)	10		0				
	≰49 Days (Group 1)	36	21	(58%)		29	12	(41%)	9	(31%)	8	(28%)	0				
	50-56 Days (Group 2)	16	8	(50%)		9	5	(56%)	3	(33%)		(11%)	0				
	57-63 Days (Group 3)	12	6	(50%)		. 8	5	(63%)	2	(25%)	1	(13%)	0				

^[1] 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.

Appendix A.1, Tables 16 and 25

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