Page 6 of 52

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	Fisher's	355							
Body System/Event [2]	_	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mi	1d	Mode	Sever: erate	•	ere	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)											
ABDOMINAL PAIN	s63 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		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		2	(20%)	0
ASTHENIA	s63 Days (All)	204	1 (<1%)	1.0000	1	0		1	(100%)	0		0
1	, s49 Days (Group 1)	145	1 (<1%		1	0	1	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		0		0		0
BACK PAIN	≤63 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	s63 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		1	(25%)	0
 , , , , , , , , , , , , , , , , , ,	50-56 Days (Group 2)	40	0		0	0	•	. 0	* !	0		0
r r 🔥 .	57-63 Days (Group 3)	19	0		• 0	0	j		•	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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FINAL

^[2] NOS = Not otherwise specified

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

Page 7 of 52

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				ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)		· · · · · · · · · · · · · · · · · · ·		The state of the s				
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		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
	s49 Days (Group 1)	145	0		0	0	0	0	0
1	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
<u> </u>	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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FINAL

^[2] NOS = Not otherwise specified

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

Page 8 of 52

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	Num	ber Pts	Fisher's exact	Number				Sever	itv		
Body System/Event [2]	Group [3]	of Pts		vent	p value	of Events		1d		erate	Sev		Unknown
•													
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		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
SKIN AND APPENDAGES DISORDERS	ı												
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		1		0
	50-96 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%)	Ō
SWEATING INCREASED	≤63 Days (All)	238	4	(21)	0.8345	4 1	0		2	(50%)	2	(50%)	0
	s49 Days (Group 1)	81	2	(21)		2	0		1	(50%)	1		Ö
	50-56 Days (Group 2)	89	1	(1%)		1	0		ī	(100%)	0	(300)	Ö
	57-63 Days (Group 3)	68	1	(1%)		1	0		ō	(1000)	-	(100%)	o
USCULO-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	ō	, , , ,	Ô	(200)	ň		ň
	50-56 Days (Group 2)	89	ō			o	Ô		0		ň		Ď
	57-63 Days (Group 3)	68	2	(3%)		2	1	(50%)	1	(50%)	0		0
2							•		-		•		•

^[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.

Page 9 of 52

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		ber Pts	Fisher's exact	Number				Severi	i tv -		
Body System/Event [2]	Group [3]	of Pts w/Event			p value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknown
Musculo-skelėtal system disorders	(cont.)				P			·· ·		· · · · · · · · · · · · · · · · · · ·			
ARTHRALGIA	≤63 Days (All)	238	2	(<1%)	0.0808	2	1	(50%)	1	(50%)	0		o
	≤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 DISORDI	ers												
ANY EVENT	. ≤63 Days (All)	238	41	(17%)	0.3182	55	22	(40%)	26	(47%)	7	(13%)	0
	s49 Days (Group 1)	81	18	(221)		23	7	(30%)	13	(571)		(13%)	0
	50-56 Days (Group 2)	89	12	(134)		15	7	(47%)	5	(33%)	3	(20%)	0
	57-63 Days (Group 3)	68	11	(16%)		17	8	(47%)	8		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	(291)	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	,,	Ō
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	(601)	3		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	• 1	0		0
3 (4	50-56 Days (Group 2)	89	1	(11)		• 1	1	(100%)	. 0	9 !	0		0
	57-63 Days (Group 3)	68	0			, o	0	e e	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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FINAL

^[2] NOS = Not otherwise specified

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

Page 10 of 52

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					
	λge	Number	of Pts	e xact	Number -	- -	Sever:	ity	
Body System/Event (2)	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDER	S(cont.)								
TREMOR	≤63 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%)	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%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		ó	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
TINNITUS	≤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
SPECIAL 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	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		
2	•								

^[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.

Page 11 of 52

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					
Body System/Event [2]	3	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknown
SPECIAL SENSÉS OTHER, DISORDERS	(cont.)								
TASTE PERVERSION	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	l 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
PSYCHIATRIC DISORDERS									
ANY EVENT	. s63 Days (All)	238	9 (4%)	0.2917	10	3 (30%)	4 (40%)	3 (30%)	0
	≤49 Days (Group 1)	81	1 (1%)		2	. 0	0	2 (100%)	0
	50-56 Days (Group 2)	89	4 (4%)		4	1 (25%)	3 (75%)	0	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	0
	57-63 Days (Group 3)	68	0		0	o ,	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
r · · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	Ó	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	238	4 (2%)	0.6841	4	1 (25%)	2 (50%)	1 (25%)	0
Ť.	≤49 Days (Group 1)	81	1 (1%)		1	0	, 0	1 (100%)	0
v (• • • • • • • • • • • • • • • • • •	50-56 Days (Group 2)	89	1 (1%)	į	. 1	0 i .	1 (1001)	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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FINAL

^[2] NOS - Not otherwise specified

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

Page 12 of 52

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								
Bady Custom/Frant (2)	Age	Number	of		exact p value	Number of Events	Mil			Severi erate	•		Unknown
Body System/Event [2]	Group [3]	of Pts		vent	p varue	or Events	mı.		MOG	erate	Sev	ere	URKNOWN
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	s63 Days (All)	238	3	(1%)	1.0000	3	0		1	(33%)	2	(67%)	0
1	≰49 Days (Group 1)	81	1	(1*)		1	0		0	. 1	1	(100%)	a
	50-56 Days (Group 2)	89	1	(1%)		1	0		1	(100%)	ď		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	(45%)	33	(16%)	0
	<pre>s49 Days (Group 1)</pre>	01	33	(41%)		44	15	(34%)	20	(45%)	9	(20%)	0
	50-56 Days (Group 2)	89	52	(58%)		95	43	(45%)	40	(42%)	12	(13%)	0
	57-63 Days (Group 3)	58	35	(51%)		62	19	(31%)	31	(50%)	12	(19%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	4	(21)	1.0000	4	1	(25%)	2	(50%)	1	(25%)	0
	≰49 Days (Group 1)	81	1	(1%)		1	0		0		1	(100%)	0
t e e e e e e e e e e e e e e e e e e e	50-56 Days (Group 2)	89	2	(21)		2	1	(50%)	- 1	(50%)	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	(57%)	0		0
r ·	<pre>s49 Days (Group 1)</pre>	91	2	(2%)		2	1	(50%)	1	, (50 %)	0		0
**************************************	50-56 Days (Group 2)	89	4	(4%)		. 4	2	(50 ∜)"	' 2	*(50%)	0		0
1 1 • • • · · · · · · · · · · · · · · ·	57 63 Days (Group 3)	68	1	(11)		1	0	,! **	1	(1001)	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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FINAL

^[2] NOS - Not otherwise specified

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

Page 13 of 52

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					Seve	ity	·	
Body System/Event [2]	Group [3]	of Pts	w/Even	t	p·value	of Events	Mi	1 d	Mode	rate	Sev	/ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)						,						
DYSPEPSIA	≤63 Days (All)	238	7 (3%)	0.6314	9	' 3	(33%)	5	(56%)	1	(11%)	0
	s49 Days (Group 1)	81	2 (2%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	89	4 (4%)		6	2	(33%)	3	(50%)	1	(17%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	0		1	(100%)	0		0
FLATULENCE	≤63 Days (All)	238	3 (14)	0.6361	3	0		2	(67%)	1	(33%)	0
ı	≤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
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	1 (14)		1	1	(100%)	0		0		0
!	57-63 Days (Group 3)	68	0			0	0		0		0		0
NAUSEA .	≤63 Days (All)	238	99 (4	2%)	0.0271	119	49	(41%)	49	(41%)	21	(18%)	0
	≤49 Days (Group 1)	81	24 (3	04)		26	11	(42%)	10	(38%)	5	(19%)	0
	50-56 Days (Group 2)	89	43 (4	81)		55	25	(45%)	22	(40%)	8	(15%)	0
· ·	57-63 Days (Group 3)	68	32 (4	7%)		38	13	(34%)	17	(45%)	8	(21%)	0
VOMITING	≤63 Days (All)	238	47 (2	0%)	0.0980	58	20	(34%)	29	(50%)	9	(16%)	0
	≰49 Days (Group 1)	81	10 (1	2%)		11	2	(18%)	7	(64%)	2	(18%)	0
-	50-56 Days (Group 2)	89	20 (2	21)		.26	12	(46%).*	11	(42%)	•	(12%)	0
	57-63 Days (Group 3)	68	17 (2	51)		21	6	(29 \ i)	11	(521)	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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FINAL

^[2] NOS = Not otherwise specified

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

Page 14 of 52

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		Sever:	it v	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
SETABOLIC AND MUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.3861	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	1 (50%)	0	1 (50%)	Ō
	50-56 Days (Group 2)	89	0		0	0	0	0	o
	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
1	≤49 Days (Group 1)	61	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
	≤49 Days (Group 1)	81	1 (1%)		1:	1 (100%)	0	0	ō
	50-56 Days (Group 2)	89	0		0	0	0	0	ō
	57-63 Days (Group 3)	68	0		o i	0	0	0	0
WEIGHT DECREASE	≤63 Days (All)	238	1 (<1%)	0.2857	1	o	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
to the second se	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
4 .	≤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	o .'	j • · ·	0	0
						Tr.			

^[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.

Page 15 of 52

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					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number - 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	. s63 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 (24)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
DYSPNOEA	s63 Days (All)	238	1 (<1%)	1.0000	2	2 (100%)	0	0	0
	≰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	0	0	0
HAEMOPTYSIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	O	0	0
r '	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	o	0
→ .	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%),	0 1	0	0
e e 🐞 🖟	50-56 Days (Group 2)	89	0		• 0	0 "	0	0	0
	57-63 Days (Group 3)	68	0		o	0 1	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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FINAL

^[2] NOS - Not otherwise specified

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

Sec. 4 60

The Population Council Protocol 166A

Page 16 of 52

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 Ptr	8	Fisher's exact	Number		Severit	y	· · · · · · · · · · · · · · · · · · ·
Body System/Event [2]	Group [3]	of Pts	w/Ever	nt	p-value	of Events	Mild	Moderate	Severe	Unknown
PLATELET, 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
	≤49 Days (Group 1)	81	0			,0	0	0	0	0
•	50-56 Days (Group 2)	89	1	(1%)		'n	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
	s49 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%)	ō
	57-63 Days (Group 3)	68		(61)		4	1 (25%)	2 (50%)	1 (25%)	0
LEUKORRHOEA	≤63 Days (All)	238	2 (<	<11)	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 (-	<14)	0.2857	1	1 (100%)	σ ,	0	0
2	≤49 Days (Group 1)	81	0			0	0	0.,	0	0
7.	50-56 Days (Group 2)	89	0			; 0	0	9 O 11	0	0
P P No. 2 P N	57-63 Days (Group 3)	68	1	(1%)		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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FINAL

^[2] NOS - Not otherwise specified

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

Page 17 of 52

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		sher's act	Number							
Body System/Event [2]	Group [3]	of Pts	w/Ever		value	of Events		ld		rate	•		Unknow
SPRODUCTIVE DISORDERS, FEMALE	(cont.)												
OVARIAN DISORDER	≰63 Days (All)	238	1 (14) 1.0	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	11)		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
ļ	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	(56%) (50%) (67%) (50%) (10%) (12%) (10%) (10%) (10%) (12%) (8%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	238	8 (3%) 1.0	0000	9	0		4	(44%)	5	(56 1)	0
	≰49 Days (Group 1)	81	3 (41)		4	0		2	(50%)	2	(50%)	0
	50-56 Days (Group 2)	89	3 (31)		3	0		1	(33%)	2	(67%)	0
	57-63 Days (Group 3)	68	2 (34)		2	0		1	(50%)	1	(50%)	0
DDY AS A WHOLE - GENERAL DISORDERS							,						
ANY EVENT	≤63 Days (All)	238	164 (6	91) 0.0	0906	255	147	(58%)	82	(32%)	26	(10%)	0
	≤49 Days (Group 1)	81	58 (7	21)		97	56	(58%)	. 29	(30%)	12	(12%)	0
t '	50-56 Days (Group 2)	89	54 (6	14)		74	47	(64%)	21	(28%)	6	(8%)	0
	57-63 Days (Group 3)	68	52 (7	61)		84	44	(52%)	32	(384)	8	(10%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	158 (6	6%) 0.6	0910	226	131	(58%)	73	(32%)	22	(10%)	0
-	≤49 Days (Group 1)	81	55 (6	81)	ĺ	.85	47	(55%)	1 28	(33%)	10	(12%)	0
r e 📦 🖟 - A	50-56 Days (Group 2)	89	52 (5	81)	,	' 66	43	(65%)	18	(27%)	5	(8%)	0
	57-63 Days (Group 3)	68	51 (7	51)		75	41	(55%)	27	1(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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FINAL

^[2] NOS = Not otherwise specified

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

Page 18 of 52

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		Sever	ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)				,			4	
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		0	0	0	0	0
BACK PAIN	≤63 Days (All)	238	6 (3%)	0.7724	7	4 (57%)	2 (29%)	1 (14%)	0
1	≤49 Days (Group 1)	81	3 (4%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	ó	0
CHEST PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	s49 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
FATIGUE	≤63 Days (All)	238	11 (5%)	0.8614	11	6 (55%)	4 (36%)	1 (9%)	0
•	≤49 Days (Group 1)	81	3 (4%)		3	2 (67%)	0	1 (33%)	0
	50-56 Days (Group 2)	89	4 (4%)		4	3 (75%)	1 (25%)	0	0
1	57-63 Days (Group 3)	68	4 (6%)		4	1 (25%)	3 (75%)	0	0
FEVER	≤63 Days (All)	238	2 (<1%)	0.5298	2	2 (100%)	0	o	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
No. of the second	57-63 Days (Group 3)	68	1 (1%)		. 1	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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FINAL

^[2] NOS = Not otherwise specified

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

Page 19 of 52

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

Center: HASKELL (#2)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Sever Moderate	ity Severe	Unknow
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)								,
HOT FLUSHES	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	•	
	s49 Days (Group 1)	81	1 (1%)	0.0201	1	1 (100%)	Ö	0	Ů
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	ő	0
MALAISE	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (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 (1%)		. 1	0	1 (100%)	ő	0
PAIN	≴63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	n	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	Ö	n	ň
i ,	50-56 Days (Group 2)	89	0		0	0	Ö	Ô	ň
:	57-63 Days (Group 3)	68	0		0	0	ō	Ö	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	ů
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	Ö	Ō	ő
•	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%)	o
Ť.,	50-56 Days (Group 2)	89	0		0	0 .	0 1	6 (2001)	ō
e e 🐞 🖟	57-63 Days (Group 3)	68	0		• 0	0	0	f	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.

Page 20 of 52

The Population Council Protocol 166A

Appendix D, Table Sb (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 -		Sever	itv	· • • • • • • •
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	s49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (14)		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 - 5	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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FINAL

^[2] NOS - Not otherwise specified

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

Page 21 of 52

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

Center: POPPEMA (#3)

	Gestational	Total		ber	Fisher's					_				
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event		exact p-value	Number of Events		1 d		rate	Sev		Unk	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	(38%)	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	(19)
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	İ		0	0		0		0	,	0	
	50-56 Days (Group 2)	65	1	(2 ¹ %)		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		Ō	
	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 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.

Sout 50

The Population Council Protocol 166A

Page 22 of 52

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									
Body System/Event [2]	Age Group (3)	Number of Pts	of w/E	Pt s vent	exact p-value	Number of Events	Mi	ld	Mode	Severi erate	•	ere	Unk	nown
MUSCULO-SKELĒTAL SYSTEM DISORDERS	(cont.)				1.1.4									
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 DIS	ORDERS													
ANY EVENT	≤63 Days (A11)	164	27	(16%)	0.2776	31	11	(35%)	13	(42%)	6	(19%)	1	(3%
	≰49 Days (Group 1)	65	13	(20%)		13	6	(46%)	6	(464)	1	(8%)	0	
	50-56 Days (Group 2)	65	7	(111)		8	3	(38%)	3	(38%)	2	(25%)	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	(21)		1	0		0		1	(100%)	0	
	50-56 Days (Group 2)	65	0			0	0		1 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	(4%
	s49 Days (Group 1)	65	12	(1B%)		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		0	
v v • 3	≤49 Days (Group 1)	65	0			O	0	;	0	4	0		0	
• • • •	50-56 Days (Group 2)	65	0			0	0	•	0	_	0		0	
	57-63 Days (Group 3)	34	. 1	(3€)		1	0	ŗ	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.

Page 23 of 52

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

Center: POPPEMA (#3)

				Fisher's					_			
Age Group [3]	of Pts			exact p value	Number of Events					•		Unknown
(cont.)												
-	164	1	(<1%)	0.2073	1	0		1.1	(100%)	O		0
· · · · · · · · · · · · · · · · · · ·		0			0	0		1 -		0		0
	65	0			0	0		0		ō		Ö
57-63 Days (Group 3)	34 -	1	(3%)		ì	0		1	(100%)	0		0
. ≤63 Days (All)	164	91	(55%)	0.1284	141	42	(30%)	62	(44%)	37	(26%)	0
s49 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	(314)	12	(29%)	0
≤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
≤63 Days (All)	164	8	(51)	0.7176	8	4	(50 %)	3	(38%)	1	(13%)	0
s49 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%)	1 0		0		0
57-63 Days (Group 3)	34	2	(61)		2	1	(50%)	1	(50%)	0		0
≰63 Days (All)	164	4	(2%)	1.0000	4	2	(50%)	2	(501)	0		0
s49 Days (Group 1)	65	1	(21)		1	1	(100%).*	. 0	4. 1	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	°r	1	(100%)	0		0
	Age Group [3] (cont.) s63 Days (All) s49 Days (Group 1) 50 56 Days (Group 2) 57-63 Days (Group 3) 49 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 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 1) 50-56 Days (Group 1) 50-56 Days (Group 2)	Age Group [3] Number of Pts (cont.) s63 Days (All) 164 s49 Days (Group 1) 65 50 56 Days (Group 2) 65 57-63 Days (Group 1) 65 50-56 Days (Group 1) 65 57-63 Days (Group 2) 65 57-63 Days (Group 2) 65 57-63 Days (Group 3) 34 s63 Days (All) 164 s49 Days (Group 1) 65 50-56 Days (Group 2) 65 57-63 Days (Group 3) 34 s63 Days (Group 1) 65 50-56 Days (Group 3) 34 s63 Days (All) 164 s49 Days (Group 1) 65 50-56 Days (Group 2) 65 57-63 Days (Group 3) 34 s63 Days (Group 3) 34 s63 Days (Group 3) 34	Age Group [3] of Pts w/E (cont.) s63 Days (All) 164 1 s49 Days (Group 1) 65 0 50 56 Days (Group 2) 65 0 57-63 Days (Group 3) 34 1 s63 Days (All) 164 91 s49 Days (Group 1) 65 33 50-56 Days (Group 2) 65 34 57-63 Days (Group 3) 34 24 s63 Days (All) 164 4 s49 Days (Group 1) 65 2 50-56 Days (Group 1) 65 2 50-56 Days (Group 2) 65 0 57-63 Days (Group 3) 34 2 s63 Days (All) 164 8 s49 Days (Group 1) 65 4 50-56 Days (Group 2) 65 4 50-56 Days (Group 3) 34 2 s63 Days (All) 164 8 s49 Days (Group 3) 34 2 s63 Days (Group 3) 34 2 s63 Days (Group 3) 34 2	Age Group [3] cont.) s63 Days (All) s49 Days (Group 1) 50 56 Days (Group 2) 57-63 Days (Group 3) s63 Days (All) s49 Days (Group 3) s63 Days (All) s65 Days (Group 3) s63 Days (All) s65 Days (Group 1) s65 Days (Group 1) s65 Days (Group 2) s65 Days (Group 2) s65 Days (Group 3) s63 Days (All) s63 Days (Group 3) s63 Days (All) s63 Days (Group 1) s65 Days (Group 1) s65 Days (Group 2) s65 Days (Group 3) s63 Days (Group 3) s63 Days (Group 3) s63 Days (Group 3) s64 Days (Group 3) s65 Days (Group 3) s66 Days (Group 3) s67 Days (Group 3) s68 Days (Group 3) s69 Days (Group 1) s69 Days (Group 1) s69 Days (Group 1) s69 Days (Group 1) s69 Days (Group 2)	Age Group [3] Sof Pts W/Event P value	Number of Pts exact p value of Events	Age Group [3]	Number of Pts Pts	Age Group [3] Number of Pts exact Number of Events Mild Mod	Age Group [3] Number of Pts exact Number of Events Mild Moderate	Age Group [3] Of Pts W/Event P value Of Events Mild Moderate Severity	Age Group [3]

^[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.

Page 24 of 52

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	Number of Pts	Fisher's exact	Number			Severity	
Body System/Event [2]	•	of Pts	w/Event	p value	of Events	Mild	Moderat	•	Unknown
HASTRO-INTESCINAL SYSTEM DISORDERS	(cont.)			.,					
FLATULENCE	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (10	0%) 0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (10	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
NAUSEA	≤63 Days (All)	164	79 (48%)	0.1305	94	28 (30	40 (4	3%) 26 (289) 0
	≤49 Days (Group 1)	65	26 (40%)		30	8 (27)	b) 14 (4	74) 8 (271) 0
	50-56 Days (Group 2)	65	32 (49%)		36	10 (28	17 (4	74) 9 (251) 0
	57 63 Days (Group 3)	34	21 (62%)		28	10 (36	9 (3	24) 9 (321) 0
VOMITING	s63 Days (All)	164	27 (16%)	0.4649	29	5 (17	14 (4	8%) 10 (349) 0
	≰49 Days (Group 1)	65	9 (14%)		9	0	6 (6	7%) 3 (33%) 0
	50-56 Days (Group 2)	65	10 (15%)		11	1 (9	6 (5	50) 4 (369) . 0
	57-63 Days (Group 3)	34	8 (24%)		9	4 (44)	2 (2	24) 3 (33)) 0
ETABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (10	0%) 0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
i ·	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (10	0%) 0	0
	57-63 Days (Group 3)	34	0		0	0	0	O	0
THIRST	≴63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (10	0%) 0	0
÷.	≰49 Days (Group 1)	` 6 5	0		0	0	0 .	0	0
	50-56 Days (Group 2)	65	1 (2%)		. 1	0	1 (16	0%) 0	0
A Company of the Com	57-63 Days (Group 3)	34	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.

Page 25 of 52

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								
Body System/Event [2]	Age	Number	of F		exact	Number				Sever	•		
BODY SYNCEMIA EVENT [2]	Group [3]	of Pts	w/Ev	/ent	p value	of Events	Mi	.1d	Mode	erate	Sev	/ere	Unknown
RED BLOOD CELL 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
ANAEMIA	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		1	(100%)	0		0
1	≤49 Days (Group 1)	65	0			0	0		0	(1000)	0		ŏ
	50-56 Days (Group 2)	65	0			o	o		Ö	•	ō		Ô
	57-63 Days (Group 3)	34	1	(3%)		1	ō		•	(100%)	ō		0
BODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	164	104	(63%)	0.0948	135	76	(56%)	39	(29%)	20	(15%)	0
1	≤49 Days (Group 1)	65		(58%)		52	26	(50%)	17	(33%)	9	(178)	0
	50-56 Days (Group 2)	65		(60%)		48	29	(60%)	12		7		Ö
}	57-63 Days (Group 3)	34		(79%)		35	21	(60%)	10			(11%)	0
ABDOMINAL PAIN	s63 Days (All)	164	100	(61%)	0.1232	120	72	(60%)	34	(28%)	14	(12%)	0
	s49 Days: (Group 1)	65		(57%)		48	25	(52%)	16	(33%)	7		0
(50-56 Days (Group 2)	65		(57%)		42	27	(64%)	10	(24%)	. 5	(12%)	0
	57-63 Days (Group 3)	34		(76%)	;	30	20	(67%)	8		2		0
ASTHENIA	≤63 Days (All)	164	1	(<1%)	1.0000	1	0		0		1	(100%)	0
4 .	≤49 Days (Group 1)	65	1	(2%)		1	0		_	. 1		(100%)	Ö
	50-56 Days (Group 2)	65	ō			. 0	o		` ,	4. !	a	. 2004/	0
· / • · ·	57-63 Days (Group 3)	34	ō			0	Ö	,*	0	•	ő		0
	,							' r '		•			-

^[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.

Page 26 of 52

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	Fisher's					
Body System/Event [2]	Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Severi Moderate	Severe	Unknown
BODY AS A WHÔLE - 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	o o
	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
FATIGUE	≤63 Days (Äll)	164	5 (3%)	1.0000	6	0	2 (33%)	4 (67%)	0
i	≤49 Days (Group 1)	65	2 (3%)		2	0	1 (50%)	1 (50%)	o
	50-\$6 Days (Group 2)	65	2 (3%)		2	0	0	2 (100%)	ō
	57-63 Days (Group 3)	34	1 (3%)		2	0	1 (50%)	1 (50%)	0
LEG PAIN	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	<pre>s49 Days (Group 1)</pre>	65	0		O :	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
PAIN	≰63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 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
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%)		2	1 (50%)	1 (501)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	1 (100%)	' r 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.

Page 27 of 52

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		ber Pts	Fisher's exact	Number				·Severi	tv		
Body System/Event [2]	Group [3]	of Pts	w/Event		p-value	of Events	Mi	1d	Mode	erate	Sev		Unknown
•													
ANY EVENT	≤63 Days (All)	102	82	(80%)	0.5284	169	80	(47%)	67	(40%)	22	(13%)	0
	<pre>s49 Days (Group 1)</pre>	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	j		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 MERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	17	(17%)	0.5277	21	5	(24%)	13	(62%)	3	(14%)	0
,	\$49 Days (Group 1)	68	13	(19%)		15	3	(20%)	9	(60%)	3		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

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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.

Page 28 of 52

The Population Council Protocol 166A

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	Number of Pts	Fisher's exact	Number		Severi	i tv	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
TENTR & PERION NERVOUS SYSTEM DISC	ORDERS (cont.)								
DIZZINESS	≤63 Days (All)	102	6 (6\$	0.3885	7	2 (29%)	4 (57%)	1 (14%)	0
	≤49 Days (Group 1)	68	3 (4%)	3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	25	3 (12%	1	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
1	≤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	s63 Days (All)	102	1 (<1%	1.0000	1	0	1 (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	0	0
SYCHIATRIC DISORDERS		ļ							
ANY EVENT	≤63 Day# (All)	102	5 (5%		5	2 (40%)	3 (60%)	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	0	1 (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 4	0	0
e e • e · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	9	0		0	0 .1	0	0	0
						°r.	•		

^[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.

Page 29 of 52

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

Center: TYSON (#4)

	Gestational Age		Numbe:		Fisher's					_	•.	
Body System/Event [2]	_	Number of Pts			exact p-value	Number of Events		ild		Sever: erate	Severe	Unknown
PSYCHIATRIC DISORDERS	(cont.)											
INSOMNIA	s63 Days (All)	102	4	(4%)	0.7052	4	2	(50%)	2	(50%)	0	0
	s49 Days (Group 1)	68	4	(6%)		4	2	(50%)	2	(50%)	0	Ō
	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%)		33	18	(55%)	10	(30%)	5 (151)	Ō
	50-56 Days (Group 2)	25	8 (:	32%)		13	4	(31%)	8	•	1 (8%)	o
	57-63 Days (Group 3)	9	1 (111)		1	0		1	(100%)	0	0
DIARRHEA	≤63 Days (All)	102	3	(3%)	0.6683	3	3	(i00%)	0		ď	0
	s49 Days (Group 1)	68	3	(4%)		3		(100%)	o		0	0
	50-56 Days (Group 2)	25	0			0	0	•	0		0	Ô
	57-63 Days (Group 3)	9	0			0	0		o		0	0
DYSPEPSIA	≤63 Days (All)	102	1 (<1%)	0.3333	1	,		0		1 (100%)	0
	≤49 Days (Group 1)	68	0	,	0.3333	0	ň		ň		0	0
	50-56 Days (Group 2)	25	•	(4%)		1	Ô		1 0		1 (100%)	Ö
	57-63 Days (Group 3)	9	0	,		0	ļ		o		0	ō
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%).		(25%)	4 (17%)	0
s i s	50-56 Days (Group 2)	25		28%)	ļ	, 7	3	(43%)		(571)	0	0
	57-63 Days (Group 3)	9	0			0	0	Ţ	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.

Page 30 of 52

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						
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Even			Mild	Moderat	•	Unknown
DASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)							·	
VOMITING	≤63 Days (All)	102	11 (1	11) 0.175	5 12	2 (1	78) 9 (7	5%) 1 (8%)	0
	s49 Days (Group 1)	68		78)	6	1 (1		78) 1 (178)	ō
	50-56 Days (Group 2)	25		0%)	5	1 (2)		01) 0	Ô
	57-63 Days (Group 3)	9 .	-	1%)	1	0	1 (10		0
METABOLIC AND NUTRITIONAL DISORDERS								i	
ANY EVENT	≤63 Days (All)	102	1 (<	1%) 1.000	0 1	ο '	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1 🕻)	1	0	0	1 (100%)	o
	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	≤63 Days (All)	102	1 (<	11) 1.000	0 1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (14)	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
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	102	2 (2%) 1.000	0 2	1 (50) %) 0	1 (50%)	0
r e e	≤49 Days (Group 1)	68		3%)	2	1 (50		1 (50%)	ō
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	o	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.

Page 31 of 52

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	Number of Pts	Fisher's exact	Number				Sever	ity		
Body System/Event [2]	Group [3]	of Pts	w/Event	p·value	of Events	Mi	1d	Mode	rate	-	ere	Unknown
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
1	≤49 Days (Group 1)	68	1 (1%)		1	1	(100%)	0	4	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
į ,	≰49 Days (Group 1)	68	46 (68%)		64	37	(58%)	19	(30%)	8	(13%)	0
<u> </u>	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%)	i i	6	1	(17%)	5	(83%)	0		0
ASTHENIA	≤63 Days (All)	102	2 (2%)		2	1	(50%)		(50%)	q		0
. , , , , , , , , , , , , , , , , , , ,	≰49 Days (Group 1)	68	2 (3%)		2	1	(50%)	, 1	(50%)	•		0
n de la companya de l	50-56 Days (Group 2)	25	0		• 0	0	ì	∜ 0	* 1	ø		0
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	9	0		0	0	r	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.

Page 32 of 52

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	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)				***************************************	······································			,
BACK PAIN	≤63 Days (All)	102	2 (2%)	1.0000	2	0	2 (100%)	0	0
	s49 Days (Group 1)	68	2 (3%)		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 (2%)	1.0000	2	0	1 (50%)	1 (50%)	0
1	≰49 Days (Group 1)	68	2 (3%)		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%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	68	2 (3%)		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		o ¹	0	0	0	0
RIGORS	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (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	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
r.	50-56 Days (Group 2)	25	0		0	0	0.,	0	0
	57-63 Days (Group 3)	9	0		, o	0	0 1	0	0

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

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 Milepristone [1] By Center
[Safety Evaluable Patients]

Center: BLUMENTHAL (#5)

	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	1d	Mode	rate	Sev	ere	Unknow
ANY EVENT	≰63 Days (All)	44	38	(86%)	0.4418	. 89	33	(37%)	46	(52%)	10	(11%)	0
	≤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
ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≰63 Days (All)	44	3	(7)	1.0000	4	1	(25%)	2	(50%)		(25%)	0
	≰49 Days (Group 1)	13	1	(B)		1	0		0		1	(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%)		(50%)	0
	≤49 Days (Group 1)	13	1	(8%)		1	0		0		1	(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
,	≰49 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
ASTRO-INTESTINAL SYSTEM DISORDERS	•												
ANY EVENT	≰63 Days (All)	44	28	(64%)	0.7660	48	14	(29%).		(581)	6	•	0
•	≰49 Days (Group 1)	13	9	(69%)		• 17	6	(35)		(531)	2		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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Page 33 of 52

^[2] NOS = Not otherwise specified

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

Page 34 of 52

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

Center: BLUMENTHAL (#5)

	Gestational	Total	Numb		Fisher's	**-							
Body System/Event [2]	Age Group [3]	Number of Pts	of I	vent	exact p-value	Number of Events	Mi	1d	Moi	Severi derate	-	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)					····							
DIARRHEA	≤63 Days (All)	44	4	(9%)	1.0000	4	1	(25%)	:	2 (50%)	1	(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	ı	(2%)	1.0000	1	0			1 (100%)	0		0
· ·	s49 Days (Group 1)	13	0			þ	0		1	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%)	1	5 (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%)		B (67%)	1	(8%)	0
	57-63 Days (Group 3)	8	3	(38%)		3	2	(67%)	1	1 (33%)	0		0
VOMITING	≤63 Days (All)	44	12	(27%)	0.9042	16	3	(19%)	1	0 (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
REPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≰63 Days (All)	44	1	(21)	1.0000	1	1	(100%)		0 -	0		0
$\vec{\sigma}_c$	≰49 Days (Group 1)	13	0			0	0			0	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

^[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.

Page 35 of 52

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

Center: BLUMENTHAL (#5)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	(cont.)								
LEUKORRHOEA	≤63 Days (All)	44	1 (2	1.0000	1	1 (100%)	0	0	D
	s49 Days (Group 1)	13	0		0	0	0	0	o
	50-56 Days (Group 2)	23	1 (49)	1	1 (100%)	0	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	26 (59	0.9199	36	17 (47%)	16 (44%)	3 (8%)	o
	≤49 Days (Group 1)	13	7 (54)		12	4 (33%)	7 (581)	1 (8%)	Ö
	50 56 Days (Group 2)	23	14 (61)		19	10 (53%)	7 (37%)	2 (11%)	o
	57-63 Days (Group 3)	8	5 (63)		5	3 (60%)	2 (40%)	0	ō
ABDOMINAL PAIN	≤63 Days (All)	44	24 (55)) 0.7166	30	15 (50%)	12 (40%)	3 (10%)	0
	≤49 Days (Group 1)	13	6 (46)		8	4 (50%)	3 (38%)	1 (13%)	Ô
	50-56 Days (Group 2)	23	14 (61)		18	9 (50%)	7 (39%)	2 (11%)	0
	57-63 Days (Group 3)	8	4 (50)	•	4	2 (50%)	2 (50%)	0	0
FATIGUE	≤63 Days (All)	44	3 (71) 0.4182	1	1 (33%)	2 (67%)	0	•
	≰49 Days (Group 1)	13	2 (15		2	0	2 (100%)	Ŏ	0
4	50-56 Days (Group 2)	23	1 (41		- 1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	ō	•	ō	0	0	ő	0
LEG PAIN	≤63 Days (All)	44	1 (21) 0.1818 (1	1 (100%)	0	0	0
4 .	≤49 Days (Group 1)	13	0		ō	0 .	0 1	Ö	o
	50-56 Days (Group 2)	23	ō	į	, 0	o i	G .	Ö	n
• • •	57-63 Days (Group 3)	8	1 (13))	i	1 (100%)	ı ŏ ,	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.

Page 36 of 52

Appendix D, Table Sb (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's exact	Number -		Se veri	itv	
Body System/Event (2)	Group [3]	of Pts	w/Even		p value	of Events	Mild	Moderate	Severe	Unknown
BODY 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.

Page 37 of 52

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		nber Pts	Fisher's exact	Number				Sever	itv		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	1d	Mode	erate	-	vere	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		13		Ö
	50-56 Days (Group 2)	16	11	(69%)		35	19	(54%)	9	, ,		(20%)	ň
	57-63 Days (Group 3)	12	11	(921)		31	8	(26%)	22			(3%)	0
IN AND APPENDAGES DISORDERS													
ANY EVENT	- ≤63 Days (All)	64	1	(2%)	1.0000	1	0			(100%))	0
	≰49 Days (Group 1)	36	1	(3%)		1	o			(100%)			Ŏ
	50-56 Days (Group 2)	16	0			0	0		ō	(1000)	í		0
	57-63 Days (Group 3)	12	0			0	0		ō		Ò		0
RASH	≤63 Days (All)	64	1	(2%)	1.0000	1	0		,	(100%)		•	•
	≤49 Days (Group 1)	36	1	(3%)	2,0200	i	Ô			(100%)	·		0
1	50 56 Days (Group 2)	16	0	,,		0	0		0	(1004)	,		0
	57-63 Days (Group 3)	12	0			0	ō		0		Č	, }	0
SCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	64	2	(3%)	0.4018	2	0		,	(100%)			_
*	≤49 Days (Group 1)	36	1	(3%)	5.4516	1	n				(U
	50-56 Days (Group 2)	16	Ô	(30)			^			(100%)			Ü
	57-63 Days (Group 3)	12	1	(8%)		1	0		0	(100%)			0
	j- (aroup 5)	••	-	(00)		•	J		1	(1004)	1 0		U

^[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.

Page 38 of 52

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	l man	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknow
USCULO-SKELETAL SYSTEM DISORDERS	(cont.)							······································	
ARTHRALGIA	≰63 Days (All)	64	2 (3	0.4018	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3	t).	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0	1	0	0	0	0	0
	57-63 Days (Group 3)	12 .	1 (8	1)	1	0	1 (100%)	0	0
ENTR & PERIPH NERVOUS SYSTEM DISORDER	5								
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	1)	4	1 (25%)	2 (50%)	1 (25%)	ō
	50-56 Days (Group 2)	16	6 (38)		9	5 (56%)	2 (22%)	2 (22%)	o
	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	i)	1	0 .	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		o [!]	0	0	0	0
	57-63 Days (Group 3)	12	1 (8	1)	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
<i>i</i>	50-56 Days (Group 2)	16	6 (38	i)	9	5 (56%)	2 (221)	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
4 .	s49 Days (Group 1)	36	1 (3)	:)	1	1 (100%).	0	0	0
	50-56 Days (Group 2)	16	0		, o	0 ;	` o *.!	0	0
•	57-63 Days (Group 3)	12	0		Ō	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.

Page 39 of 52

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

Center: BORGATTA (#6)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Sever	itv		
Body System/Event (2)	Group [3]	of Pts	w/E	vent	p value	of Events	Mi	1d	Mod	erate	•	ere	Unknown
PSYCHIATRIC 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			(100%)	Ō		0
	50-56 Days (Group 2)	16	0			0	0		0		ň		0
	57-63 Days (Group 3)	12	0			0	o		ō		Ŏ		0
EMOTIONAL LABILITY	≤63 Days (All)	64	1	(2%)	1.0000	1	0		1	(100%)	0		0
•	≤49 Days (Group 1)	36	1	(34)		1	ō			(100%)	0		Ŏ
	50 56 Days (Group 2)	16	0			0	0		0		0		Ö
	57-63 Days (Group 3)	12	0	. !		0	Ō		0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	64	27	(42%)	1.0000	44	12	(27%)	19	(43%)	13	(30%)	0
	≰49 Days (Group 1)	36	15	(42%)		26	7	(27%)	10		9	(35%)	ŏ
	50-56 Days (Group 2)	16	7			10	4	(40%)	2	- ,	4	(40%)	Ö
•	57-63 Days (Group 3)	12		(42%)		8	1	(13%)	7		Ö	(400)	0
DIARRHEA	≰63 Days (All)	64	2	(3%)	0.4018	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	36	1	(3%)		1	ō			(100%)	ŏ		0
	50-56 Days (Group 2)	16	0	,,		0	Ö		ō		0		0
	57-63 Days (Group 3)	12	1	(8%)		1	ō		•	(100%)	ő		0
NAUSEA .:	≤63 Days (All)	64	24	(38%)	1.0000	30		(208)			_	(_
* !	≤49 Days (Group 1)	36	14	(39%)	1.0000	. 17	9	(30%)		(40%)	9	,	0
v v •	50-56 Days (Group 2)	16	6	(38%)		8	5	(291)	i.	(35%)	6	(35%)	0
	57-63 Days (Group 3)	16				=	3	(384)		(25%)	3	(381)	0
•	21-03 pays (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.

Page 40 of 52

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

Center: BORGATTA (#6)

	Gestational	Total	Number	Fisher's					
	Age	Number	of Pts	exact	Number		Sever	ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)								
VOMITING	≤63 Days (All)	64	12 (19%)	0.8330	12	3 (25%)	5 (42%)	4 (33%)	0
	≰49 Days (Group 1)	36	8 (22%)		8	2 (25%)	3 (38%)	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	0
RED BLOOD CELL DISORDERS									
ANY EVENT	. ≤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
ANAEMIA	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	s49 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
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	64	2 (3%)	1.0000	2	1 (50%)	1 (50%)	0	0
r '	s49 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	Ö	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.

Page 41 of 52

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

Center: BORGATTA (#6)

	Gestational	Total	Number	Fisher's					
Body System/Event (2)	Age Group {3}	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknow
EPRODUCTIVE DISORDERS, FEMALE	(cont.)								
LEUKORRHOEA	≤63 Days (All)	64	1 (21) 1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (31)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	D	0	0	0
	57-63 Days (Group 3)	12 .	0		0	0	0	0	0
VAGINAL DISCOMFORT	≤63 Days (All)	64	1 (25) 1.0000	1	o	1 (100%)	0	0
4	s49 Days (Group 1)	36	1 (3))	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	о :	0 '	0
	57-63 Days (Group 3)	12	0		. 0	0	0	o '	0
ODY 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 (569)	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
	s49 Days (Group 1)	36	17 (47)		21	10 (48%)	6 (29%)	5 (24%)	Ö
Company of the Compan	50-56 Days (Group 2)	16	9 (56		9	7 (78%)	2 (221)	0	o
	57-63 Days (Group 3)	12	9 (751		12	5 (42%)	7 (58%)	0	ō
BACK PAIN	≰63 Days (All)	64	3 (51) 0.4052	3	1 (33%)	2 (671)	0	0
-i .	£49 Days (Group 1)	36	1 (31)	1	0 .	1 (1001)	0	0
v v 🔥 🔭 🕹	50-56 Days (Group 2)	16	1 (69)	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.

Page 42 of 52

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

Center: BORGATTA (#6)

	Gestational	Total Number	Number of Pts	Fisher's			•		
Body System/Event [2]	Age Group [3]	of Pts	w/Event	exact p·value	Number of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
FATIGUE	≤63 Days (All)	64	10 (16%)	0.8982	11	1 (9%)	7 (64%)	3 (27%)	0
	≤49 Days (Group 1)	36	5 (14%)		5	0	4 (80%)	1 (20%)	0
	50-56 Days (Group 2)	16	3 (19%)		4	1 (25%)	2 (50%)	1 (25%)	0
	57-63 Days (Group 3)	12 .	2 (17%)		2	0	1 (50%)	1 (50%)	0
FEVER	≤63 Days (All)	64	2 (31)	0.6875	2	2 (100%)	0	0	0
1	. s49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0 , '	jo	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	o ·	0
	57-63 Days (Group 3)	12	0		. 0	0	0	0	0
HOT FLUSHES	s63 Days (All)	64	1 (2%)	0.1875	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	O	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
	≤49 Days (Group 1)	36	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	1 (100%)	Ð	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
\vec{r} , \vec{r}	50-56 Days (Group 2)	16	0		0	0 . ,	0	0	0
A series of the	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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FINAL

^[2] NOS = Not otherwise specified

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

Page 43 of 52

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		Seve r	:itv	
Body System/Event [2]	Group [3]	of Pts	w/Even		p value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)			_						
SYNCOPE	≤63 Days (All)	64	1 (2%)	1.0000	ı	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.

Page 44 of 52

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			
Body System/Event [2]	Group [3]	of Pts		vent	p value	of Events		ld		rate	•	ere	Unknown
•													· · · · · · · · · · · · · · · · · · ·
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	(641)		35	9	(26%)	15	(43%)	11	(31%)	0
ENTR & PERIPH MERVOUS SYSTEM DISORDERS	1												
ANY EVENT	s63 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	31	1	(33%)	2	(67%)	0		0
	≤49 Days (Group 1)	19	1	(5%)		1	0			(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	(61)	0.7919	3	1	(33%)	2	(67%)	0		0
	s49 Days (Group 1)	19	1	(5%)		1	1	(100%)	0		0		0
r · · · · · · · ·	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
BARING AND VESTIBULAR DISORDERS	•												
ANY EVENT	≤63 Days (All)	52	1	(2%)	1.0000	1	1	(100%).	, о	4. 1	0		0
	≤49 Days (Group 1)	19	0			, o	0		. 0	4. !	0		ō
• • •	50-56 Days (Group 2)	11	0			. 0	0	•	1 0		ō		Ö
	57-63 Days (Group 3)	22	1	(5%)		1	1	(100€)	0	1	Ö		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.

Page 45 of 52

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		ber	Fisher's					
Body System/Event [2]	Group [3]	of Pts		Pts vent	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
HEARING AND VESTIBULAR DISORDERS	(cont.)						· · · · · · · · · · · · · · · · · · ·			
TINNITUS	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	•
	<pre>s49 Days (Group 1)</pre>	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	0			o o	n	0	0	0
	57-63 Days (Group 3)	22 .	1	(5%)		1	1 (100%)	ō	0	0
PSYCHIATRIC DISORDERS										
ANY EVENT	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	•	•
	≤49 Days (Group 1)	19	0			Ō	0	o '	0	0
	50-56 Days (Group 2)	11	0			0	Ō	0	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	Ö	Ö	0
INSOMNIA	≤63 Days (All)	52	,	(21)	1.0000	,	1 (1001)	•	_	
	≤49 Days (Group 1)	19	ō	(24)	1.0000	1	1 (100%)	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
GASTRO-INTESTINAL SYSTEM DISORDERS										•
ANY EVENT	≤63 Days (All)	52	1.0	(218)	0.0063					
e · · · · · · · · · · · · · · · · · · ·	≤49 Days (Group 1)		16	(31%)	0.9263	25	8 (32%)	8 (32%)	9 (36%)	0
	50-56 Days (Group 2)	19				8	6 (75%)	2 (25%)	0	0
		11	4	(36%)		6	1 (17%)	4 (67%)	1 (17%)	0
•	57-63 Days (Group 3)	22	6	(27%)		11	1 (9%)	2 (18%)	8 (73%)	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.

Page 46 of 52

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

Center: MALLOY (#7)

	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	Number -		Severi	l tv	
Body System/Event [2]	Group [3]	of Pts	w/Eve	ent	p value	of Events	Mild	Moderate	Severe	Unknown
JASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)									
DIARRHEA	≤63 Days (All)	52	1	(2%)	0.5769	1	1 (100%)	0	0	0
	s49 Days (Group 1)	19		(5%)		1	1 (100%)	0	Ô	n
	50-56 Days (Group 2)	11	0			0	0	Ō	0	ň
	57-63 Days (Group 3)	22 .	0			0	0	o	ō	0
FLATULENCE	≤63 Days (All)	52	1	(2%)	0.2115	1	0	1 (100%)	0	•
i.	≤49 Days (Group 1)	19	0	,		Ĭ.	Ô	0	0	0
	50-56 Days (Group 2)	11	-	(9%)		i	n	1 (100%)	0	0
	57 63 Days (Group 3)	22	0	(20)		ō	ō	0	0	0
NAUSEA	≤63 Days (All)	52	13 ((25%)	0.9204	17	6 (35%)	6 (35%)	5 (201)	_
	≤49 Days (Group 1)	19		26%)	0.7204	7	5 (71%)		5 (29%)	0
	50-56 Days (Group 2)	: 11		18%)		2	0	2 (29%)	0	0
	57-63 Days (Group 3)	22		27%)		8	1 (13%)	2 (100%) 2 (25%)	0 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	o
	50-56 Days (Group 2)	11	2 (18%)		3	1 (33%)	1 (33%)	1 (33%)	ō
· '	57-63 Days (Group 3)	22	2	(9%)		3	0	0	3 (100%)	ō
INDOCRINE DISORDERS										
ANY EVENT	s63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
÷.	≤49 Days (Group 1)	19	0			0	0	0 1	Ö	0
A TO A STATE OF THE STATE OF TH	50-56 Days (Group 2)	11	0			, 0	0	9 9 1	Ö	Õ
· ,	57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	0.	ō	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.

Page 47 of 52

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	Number of P		Fisher's exact	Number -		Sever	itv	
Body System/Event [2]	Group [3]	of Pts	s w/Event		p value	of Events	Mild	Moderate	Severe	Unknown
INDOCRINE DISORDERS	(cont.)									· · · · · · · · · · · · · · · · · · ·
ENDOCRINE DISORDER NOS	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	O	•	•
	≤49 Days (Group 1)	19	0	,,	2.0000	'n	0	0	0	0
	50-56 Days (Group 2)	11	0			n	n	• •	0	0
	57-63 Days (Group 3)	22 .	1	(5%)		1	1 (100%)	ō	0	0
EART RATE AND RHYTHM DISORDERS										
ANY EVENT	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0		•
	s49 Days (Group 1)	19	0		-	0	0	o ·	0 .	0
	50-56 Days (Group 2)	11	0			o	0	0 .	0	0
	57-63 Days (Group 3)	22	1	(5%)		1	1 (100%)	Ö	0	0
TACHYCARDIA	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	_		_
	s49 Days (Group 1)	19	Ô	124/	1.0000	^	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
RIMARY SYSTEM DISORDERS							•			
ANY EVENT	≤63 Days (All)	52	1	(2%)	0.2115	1	0	1 (1001)	•	_
* ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '	s49 Days (Group 1)	19	ō	, ,	0.2113	•	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	1	(91)		1	0	0	0	0
	57-63 Days (Group 3)	22	Ô	12.07		, ,	•	1 (100%)	0	0
,			•			v	U	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.

Page 48 of 52

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								
Age Group [3]	of Pts			Number of Events	Mi	ld	Mode		•	ere	Unknown
(cont.)								<u> </u>	• • • • • • • • • • • • • • • • • • • •		
•	52	1 (2) 0.2115	1	0		1	(100%)	0		0
-		0		0	0		0		0		0
		1 (9	L)	1	0		1	(100%)	0		0
57-63 Days (Group 3)	22	0		0	0		0		0		0
						t		1			
. ≤63 Days (All)	52	24 (46	0.2845	29	12	(41%)	13	(45%)	4	(14%)	0
	19			6	4	(67%)			Ö		0
- ·	11	6 (55	t)	- 6	4	(67%)	1		1	(17%)	0
57-63 Days (Group 3)	22			17	4	(24%)	10		3		0
≤63 Days (All)	52	23 (44	b) 0.4225	24	12	(50%)	9	(38%)	3	(13%)	0
	19	6 (32	b)	6	4	(67%)			0		0
	11			6	4	(67%)	1		1	(17%)	0
57-63 Days (Group 3)	22			12	4	(33%)	6		2		0
≤63 Days (All)	52	1 (2	1.0000	1	0		1	(100%)	0		0
≤49 Days (Group 1)	19	0		0	0		Q		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
sål Dave (All)	52	2 (4	L) 0.5023	2	0		1	(50%)	1	(50%)	0
		-	.,		-					,	ō
		Ō		• 0	0		0	* •	n		ő
57-63 Days (Group 3)	22	2 (9	*)	2	ō	r	1	(50%)	1	(50%)	o
	(cont.) #63 Days (All) #49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) #63 Days (Group 1) 50-56 Days (Group 1) 50-56 Days (Group 3) #63 Days (All) #49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) #63 Days (All) #49 Days (Group 3) #63 Days (Group 3) #64 Days (Group 3)	(cont.) #63 Days (All) #63 Days (Group 1) #63 Days (Group 1) #65 Days (Group 2) #63 Days (Group 3) #63 Days (Group 3) #63 Days (Group 3) #63 Days (Group 1) #64 Days (Group 1) #65 Days (Group 3) #65 Days (Group 3) #66 Days (Group 1) #67 Days (Group 1) #68 Days (Group 1) #68 Days (Group 3) #68 Days (Group 3) #68 Days (Group 3) #69 Days (Group 1) #69 Days (Group 3) #65 Days (Group 3) #66 Days (Group 3) #67 Days (Group 3) #68 Days (Group 3) #68 Days (Group 3) #69 Days (Group 3) #69 Days (Group 3) #69 Days (Group 1) #69 Days (Group 2)	Group {3} of Pts w/Event	(cont.) #63 Days (All) #63 Days (Group 1) #65 Days (Group 2) #65 Days (Group 3) #65 Days (Group 3) #65 Days (Group 1) #65 Days (Group 1) #65 Days (Group 1) #65 Days (Group 1) #65 Days (Group 2) #65 Days (Group 2) #66 Days (Group 3) #66 Days (Group 3) #67 Days (Group 3) #68 Days (All) #69 Days (Group 1) #69 Days (Group 1) #69 Days (Group 2) #65 Days (Group 3) #65 Days (Group 1) #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 2) #60 Days (Group 3)	Group {3} of Pts w/Event p value of Events (cont.) #63 Days (All) 52 1 (2%) 0.2115 1 #49 Days (Group 1) 19 0 0 0 50-56 Days (Group 2) 11 1 (9%) 1 1 57-63 Days (Group 3) 22 0 0 0 **63 Days (All) 52 24 (46%) 0.2845 29 **49 Days (Group 1) 19 6 (32%) 6 6 50-56 Days (Group 2) 11 6 (55%) 6 6 50-56 Days (Group 1) 19 6 (32%) 6 6 50-56 Days (Group 1) 19 6 (32%) 6 6 50-56 Days (Group 3) 22 11 (50%) 12 12 *63 Days (All) 52 2 (2%) 1.0000 1 1 49 Days (Group 1) 19 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 <td>Group [3] of Pts w/Event p value of Events Min (cont.) \$63 Days (All) \$52 1 (2%) 0.2115 1 0 \$49 Days (Group 1) 19 0 0 0 0 0 0 \$50.56 Days (Group 2) 11 1 (9%) 1 0 0 0 \$63 Days (Group 3) 22 0 0 0 0 0 \$63 Days (Group 1) 19 6 (32%) 6 4 4 50.56 Days (Group 2) 11 6 (55%) 6 4 4 57.63 Days (Group 3) 22 12 (55%) 17 4 \$63 Days (Group 1) 19 6 (32%) 6 4 4 57.63 Days (Group 1) 19 6 (32%) 6 4 4 57.63 Days (Group 2) 11 6 (55%) 6 4 4 57.63 Days (Group 3) 22 11 (50%) 12 4 4 57.63 Days (Group 1) 19 0 0 0 0 0 0 0<</td> <td> Group [3] Of Pts W/Event p value Of Events Mild </td> <td>Group {3} of Pts w/Event p value of Events Mild Mode (cont.) *63 Days (All) 52 1 (2%) 0.2115 1 0 1 *49 Days (Group 1) 19 0 0 0 0 0 50 56 Days (Group 3) 22 0 0 0 0 0 *63 Days (All) 52 24 (46%) 0.2845 29 12 (41%) 13 *49 Days (Group 1) 19 6 (32%) 6 4 (67%) 2 50 56 Days (Group 2) 11 6 (55%) 6 4 (67%) 1 57 63 Days (Group 3) 22 12 (55%) 17 4 (24%) 10 *63 Days (All) 52 23 (44%) 0.4225 24 12 (50%) 9 *49 Days (Group 1) 19 6 (32%) 6 4 (67%) 2 50 -56 Days (Group 3) 22 11 (50%) 12 4 (33%) 6 *63 Days (All) 52 1 (2%) 1.0000</td> <td>Group [3] of Pts w/Event p value of Events Mild Moderate (cont.) #63 Days (All) 52 1 (2%) 0.2115 1 0 1 (100%) 349 Days (Group 1) 19 0 <t< td=""><td>Group [3] of Pts w/Event p value of Events Mild Moderate Sevents (cont.) #63 Days (All) 52 1 (2%) 0.2115 1 0 1 (100%) 0</td><td> Group [3] Of Pts W/Event P value Of Events Mild Moderate Severe </td></t<></td>	Group [3] of Pts w/Event p value of Events Min (cont.) \$63 Days (All) \$52 1 (2%) 0.2115 1 0 \$49 Days (Group 1) 19 0 0 0 0 0 0 \$50.56 Days (Group 2) 11 1 (9%) 1 0 0 0 \$63 Days (Group 3) 22 0 0 0 0 0 \$63 Days (Group 1) 19 6 (32%) 6 4 4 50.56 Days (Group 2) 11 6 (55%) 6 4 4 57.63 Days (Group 3) 22 12 (55%) 17 4 \$63 Days (Group 1) 19 6 (32%) 6 4 4 57.63 Days (Group 1) 19 6 (32%) 6 4 4 57.63 Days (Group 2) 11 6 (55%) 6 4 4 57.63 Days (Group 3) 22 11 (50%) 12 4 4 57.63 Days (Group 1) 19 0 0 0 0 0 0 0<	Group [3] Of Pts W/Event p value Of Events Mild	Group {3} of Pts w/Event p value of Events Mild Mode (cont.) *63 Days (All) 52 1 (2%) 0.2115 1 0 1 *49 Days (Group 1) 19 0 0 0 0 0 50 56 Days (Group 3) 22 0 0 0 0 0 *63 Days (All) 52 24 (46%) 0.2845 29 12 (41%) 13 *49 Days (Group 1) 19 6 (32%) 6 4 (67%) 2 50 56 Days (Group 2) 11 6 (55%) 6 4 (67%) 1 57 63 Days (Group 3) 22 12 (55%) 17 4 (24%) 10 *63 Days (All) 52 23 (44%) 0.4225 24 12 (50%) 9 *49 Days (Group 1) 19 6 (32%) 6 4 (67%) 2 50 -56 Days (Group 3) 22 11 (50%) 12 4 (33%) 6 *63 Days (All) 52 1 (2%) 1.0000	Group [3] of Pts w/Event p value of Events Mild Moderate (cont.) #63 Days (All) 52 1 (2%) 0.2115 1 0 1 (100%) 349 Days (Group 1) 19 0 <t< td=""><td>Group [3] of Pts w/Event p value of Events Mild Moderate Sevents (cont.) #63 Days (All) 52 1 (2%) 0.2115 1 0 1 (100%) 0</td><td> Group [3] Of Pts W/Event P value Of Events Mild Moderate Severe </td></t<>	Group [3] of Pts w/Event p value of Events Mild Moderate Sevents (cont.) #63 Days (All) 52 1 (2%) 0.2115 1 0 1 (100%) 0	Group [3] Of Pts W/Event P value Of Events Mild Moderate Severe

^[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	Numbe of Pt		Fisher's exact	Number -		Severi	i ty -	
Body System/Event [2]	Group (3)	of Pts	w/Eve	nt	p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cost.)									
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	(2%)	1.0000	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	19	0			0	0	0	0	0
,	50-56 Days (Group 2)	11	0			0	0	0	O .	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.

Page 50 of 52

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 Pts	Fisher's exact	Number				Sever:			
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	of Events		.1 d		erate	-	ere	Unknow
•												
ANY EVENT	≤63 Days (All)	21	18 (86%)	0.7068	29	14	(48%)	8	(28%)	7	(24%)	0
	<pre>\$49 Days (Group 1)</pre>	13	10 (77%)		16	9	(56%)	4		3		0
	50-56 Days (Group 2)	5	5 (100%)		9	3	(33%)	4		2		0
	57 63 Days (Group 3)	3	3 (100%)		4	2	(50%)	0		_	(50%)	0
NTR & PERIPH NERVOUS SYSTEM DISORDERS	ř											
ANY EVENT	≤63 Days (All)	21	2 (10%)	0.6286	2	0		1	(50%)		(50%)	
	≤49 Days (Group 1)	13	1 (8%)		1	ñ		ō	•		(100%)	0
	50 56 Days (Group 2)	5	1 (20%)		,	0			(100%)	0	(1004)	
	57-63 Days (Group 3)	3	0		ō	ō		ō		0		0
HEADACHE	≤63 Days (All)	21	2 (10%)	0.6286	2.1	•		_	(===)			
:	≤49 Days (Group 1)	13	1 (8%)	0.0200	2	0		1	(50%)		(50%)	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	•	0			(100%)	0
i	57-63 Days (Group 3)	3	0		0	0			(100%)	0		0
	ov os bayb (droup sy	,	Ū		U	U		0		0		0
STRO-INTESTINAL SYSTEM DISORDERS												
ANY EVENT	≤63 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		2	1	0
	57-63 Days (Group 3)	3	3 (100%)		3	1	(33%)	ó			(67%)	0
					-	•	,,,,,	·	,	-	(0/1)	U

^[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		Mild	Sever: Moderate	Severe	Unknown
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	MIIU	Moderate	Severe	Ulikilowii
DASTRO-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
1	≤49 Days (Group 1)	13	2 (15%)	2	1 (50%)	0 ,	1 (50%)	0
	50-56 Days (Group 2)	5	3 (6d%)	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
OODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≰63 Days (All)	21	10 (48%	0.3797	13	B (62%)	4 (31%)	1 (8%)	0
	≤49 Days (Group 1)	13	8 (621)	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
4 . , , , , , , , , , , , , , , , , , , ,	≰49 Days (Group 1)	13	8 (62%)	10	6 (60%).	3 (30%)	1 (10%)	0
s e 🔥 🕹	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

^[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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Page 52 of 52

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	Numb of P		Fisher's exact			Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Ev	ent	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.

Page 1 of 53

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

Center: MISHELL (#1)

	Gestational Age	Total Number		nber Pts	Fisher's exact	Number				Sever	itv	• • • • • • •	
Body System/Event	Group [2]	of Pts	w/E	vent	p value	of Events		ld		erate	-	ere	Unknown
1											····		
ANY EVENT	≤63 Days (All)	204	194	(95%)	0.1456	711	233	(33%)	224	(32%)	254	(36%)	_
	≤49 Days (Group 1)	145	135	(93%)	0.2130	459	166	(36%)	139	(30%)	154		0
	50-56 Days (Group 2)	40		(100%)		176	45	(26%)	62	(35%)	69	(34%) (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	(1%)	0.1201	3	2	(67%)	1	(33)	0:		•
	s49 Days (Group 1)	145	1			1		(100%)	0	(33))	71		0
	50-56 Days (Group 2)	40	1	(3%)		1		(100%)	0		0		0
	57-63 Days (Group 3)	19	1	(5%)		1	0	(1004)	_	(100%)	0		0
PRURITUS GENITAL	≤63 Days (All)	204	1	(<1%)	1.0000			(100%)					_
	≤49 Days (Group 1)	145	ì	(<1%)	1.0000	•		(100%)	0		0		0
	50-56 Days (Group 2)	40	0	(<1*)		1		(1004)	0		0		0
	57-63 Days (Group 3)	19	ő			0	0		0		0		0
SWEATING INCREASED	≤63 Days (All)	204	2	(<1 %)	0.0450	•	•	(50)	_	4			
	≤49 Days (Group 1)	145	0	(<14)	0.0430	2	1	(50%)	1	(50%)	0		0
, ,	50-56 Days (Group 2)	40	1	(3%)		0	0	(1000)	. 0		0		0
	57-63 Days (Group 3)	19	1	(5%)		1	0	(100%)	1	(100%)	0		0
INTR & PERIPH NERVOUS SYSTEM DISORDERS	•												·
ANY EVENT	≤63 Days (All)	204	28	(14%)	0.6366	42	20	(48%)	11	Jacas		(268)	_
1 1 6 ° °	≤49 Days (Group 1)	145	18	(12%)	0500	.29	15	(52%)	, 11	(26%) (28%)	11	(26%)	0
	50-56 Days (Group 2)	40	7	(18%)		9	3	(33%)	1 -		6	(21%)	0
	57-63 Days (Group 3)	19	3	(16%)		4	2	(33 ₹)		(22%)		(44%)	0
	or or boys (Group s)	1,		(100)		•	2	(504)	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.

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

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Page 2 of 53

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

Center: MISHELL (#1)

	Gestational	Total		nber	Fisher's								
Body System/Event	Age	Number		Pts	exact	Number		• • • • • • • • • • • • • • • • • • •			•		
Body System/Event	Group [2]	of Pts	w/E	Event	p value	of Events	М	ild	Mode	erate	Sev	ere	Unknown
ENTR & PERÎPH NERVOUS SYSTEM DISORDER	S (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	(91)	4	(36%)	0
	50-56 Days (Group 2)	40	3	(8%)		5	2	(40%)	1	(20%)	2	(40%)	Ō
	57-63 Days (Group 3)	19 .	3	(16%)		3	1	(33%)	1		1		o
HEADACHE	≤63 Days (All)	204	16	(8%)	0.9098	22	10	(45%)	8	(36%)	4	(18%)	0
I .	≤49 Days (Group 1)	145	11	(8%)		17	8	(47%)	7		2	(12%)	Ö
	50 56 Days (Group 2)	40	4	(10%)		4	1	(25%)	1		2	(50%)	0
	57 63 Days (Group 3)	19	1.	(5%)		1	1	(100%)	ō	(20)	ō	(300)	ō
NEURALGIA	≤63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		o		0
	≤49 Days (Group 1)	145	1			1		(100%)	ŏ		0		Ô
	50-56 Days (Group 2)	40	0	,		ō	0	(2001)	ő		0		0
	57 63 Days (Group 3)	19	0			0	0		ō		ō		Ö
ASTRO-INTESTINAL SYSTEM DISORDERS													
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		21	(17%)	51	(41%)	0
t ' '	50 56 Days (Group 2)	40	26	(65%)		47	12	(26%)	13	(28%)	22	(47%)	0
	57 63 Days (Group 3)	19	13			26	10		7	(27%)	9	(35%)	ō
ABDOMINAL PAIN	≤63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		, o		0
	≰49 Days (Group 1)	145	1	(<1 %)		. 1	1	(100%)	0.		0		0
e e 📢 🦂	50-56 Days (Group 2)	40	0			• 0	0			4. !	o		0
	57-63 Days (Group 3)	19	0			0	0		0	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 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.

Page 3 of 53

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

Center: MISHELL (#1)

	Gestational Age	Total Number	Number of P		Fisher's exact	Number			 -		-Severit	v - · · ·		
Body System/Event	Group (2)	of Pts	w/Eve		p value	of Events		1đ		odera	-	•	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Unknow
STRO-INTESTINAL SYSTEM DISORDERS (cont.)									,					
CONSTIPATION	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	26	(13%)	0.0380	28	19	(68%)		6 (21%)	3	(11%)	0
	≰49 Days (Group 1)	145	17	(12%)		18	12	(67%)		3 (171)	3		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 (334)	0		0
DYSPEPSIA	s63 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 (501)	1	(25%)	0
j .	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 Day8 (All)	204	104	(51%)	0.1802	129	41	(32%)	:	22 (178)	65	(51%)	0
	≰49 Days (Group 1)	145	68	(47%)		82	31	(38%)	1	12 (151)	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	(581)		13	3	(23%)		2 (15%)	8	(62%)	0
VOMITING	≤63 Days (All)	204	30	(15%)	0.1325	34	10	(29%)	1	11 (321)	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%)	4	(40%)	0
v v • °	57-63 Days (Group 3)	19	5	(26%)		• 7	3	(434)	i.	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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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Page 4 of 53

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			_		
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Sever Moderate	ity 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	O		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	204	2 (<1%)	0.4958	2	1 (50%)	0	1 (50%)	0
1	. ≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	Ō	0	o
	50-56 Days (Group 2)	40	1 (3%)		1	0	o '	1 (100%)	Ô
	57-63 Days (Group 3)	19	0		. 0	0	0	0	o
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	ň	1 (100%)	0
	50-56 Days (Group 2)	40	0		0	0	n	0	0
	57-63 Days (Group 3)	19	0		0	Ŏ	o	ō	Ö
HYPOTENSION POSTURAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	1 (<1%)	1.000	i	Ô	Ů	1 (100%)	0
1	50-56 Days (Group 2)	40	0		0	0		0	ŏ
	57-63 Days (Group 3)	19	0		0	ō	0	ő	0
HEART RATE AND RHYTHN 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%)	2.2300	. 2	0 ;	1 (50%)	1 (50%)	0
•	50 56 Days (Group 2)	40	0		0	o ,		0	0
	57-63 Days (Group 3)	19	Ö		ň	0 '	0,	0	0
•	2: 22 22/0 (0100p 3)	• • •	ŭ		J	•	1	U	U

^[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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Page 5 of 53

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				1.	
Body System/Event	Age Group [2]	of Pts	w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
HEART RATE AND RHYTHM DISORDERS (CODt.)		·			· · · · · · · · · · · · · · · · · · ·	*			
TACHYCARDIA	≤63 Days (All)	204	1 (<1%	1.0000	2	0	1 (50%)	1 (50%)	0
	s49 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
ED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	204	7 (3%	0.1476	7	3 (43%)	1 (14%)	3 (43%)	0
:	≤49 Days (Group 1)	145	3 (2%)	3	0	1 (33%)	2 (67%)	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
	s49 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
1	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
EPRODUCTIVE DISORDERS, FEMALE	•								
ANY EVENT	≤63 Days (All)	204	14 (7%	0.0017	14	0	2 (14%)	12 (86%)	0
	≤49 Days (Group 1)	145	5 (3))	• 5	o , i	1 (201)	4 (80%)	0
	50-56 Days (Group 2)	40	4 (10%)	4	0	1 (25%)	3 (75%)	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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39

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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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Page 6 of 53

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			_		
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Sever: Moderate	Severe	Unknown
EPRODUCTIVE DISORDERS, FEMALE (cont.)				***				1	
ENDOMETRITIS	≤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
OVARIAN DISORDER	≰63 Days (All)	204	1 (<1%)	0.2892	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	0		0	0	o .	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 (8%)		3	0	0	3 (100%)	0
	57-63 Days (Group 3)	19	5 (26%)		5	0	0	5 (100%)	0
DDY AS A WHOLE - GENERAL DISORDERS			i						
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
*	≤49 Days (Group 1)	145	130 (90%)	į.	271	88 (32	97 (36%)	86 (32%)	0
· · · · ·	50-56 Days (Group 2)	40	40 (100%)	,	105	26 (25	1) 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.

Page 7 of 53

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					
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknow
DDY AS A WHOLE - GENERAL DISORDERS	G (cont.)								
ASTHENIA	s63 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
1	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	Ö	0
CHEST PAIN	≤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
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%)	0	0
A Company	57-63 Days (Group 3)	19	0		• 0	0 ,	0 11	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.

Page 8 of 53

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		Panani.		
Body System/Event	Group (2)	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknow
DDY AS A WHOLE - GENERAL DISORDERS (cont.))								
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	Ö
	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
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	ο .	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	s63 Days (All)	204	3 (1%)	1.0000	3	3 (100%)	0	0	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	o	0	0
SYNCOPE	≤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
TEMPERATURE CHANGED SENSATION	≤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	o
<i>•</i> ,	50-56 Days (Group 2)	40	0		. 0	0	0	0	Ō
	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.

Page 10 of 53

Appendix D, Table Sc (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	itv		
Body System/Event	Group [2]	of Pts		vent	p value	of Events		ld		rate	•	(27%) (37%) (37%) (100%) (100%) (100%) (100%) (12%) (5%)	Unknown
ANY EVENT	≤63 Days (All)	238	230	(97%)	0.2541	1171	346	(205)	420	(274)	100	40.01	
	≤49 Days (Group 1)	81	76	(94%)	0.2341	354	124	(30%)	429	(37%)	395		1 (<1%)
	50-56 Days (Group 2)	89	87	(98%)		441	127	(35%) (29%)	134	(38%)	95		1 (<1%)
	57-63 Days (Group 3)	68	67	(991)		376	95	(25%) (25%)	153 142	(35%) (38%)	161 139		0
NUSCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	230	1	(<1%)	1.0000	1	0		0		1	(1008)	0
	≰49 Days (Group 1)	81	0			ō	0		o		0	11004)	0
	50-56 Days (Group 2)	89	1	(1%)		1	ō		ō		1	(100%)	0
	57-63 Days (Group 3)	68	0			0	0		0		ō	(1000)	Ŏ
ARTHRITIS	≤63 Days (All)	238	1	(<1%)	1.0000	1	0		0		,	(100%)	0
	≤49 Days (Group 1)	81	0			0	0		0		•	(1000)	0
	50-56 Days (Group 2)	89	1	(1%)		1	0		Ö		1	(100%)	0
1	57-63 Days (Group 3)	68	0			0	0		o		ō	(1004)	o
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	238	48	(20%)	0.3622	74	19	(26%)	46	(62%)	۰	(12%)	0
	≤49 Days (Group 1)	81	13	(16%)		22	7	(32%)	14	(64%)	,		0
	50-56 Days (Group 2)	89	22	(25%)		32	10	(31%)	17	(53%)	5		Ö
	57-63 Days (Group 3)	68	13	(19%)		20	2	(10%)	15				0
$oldsymbol{oldsymbol{\epsilon}}$, which is a second constant of $oldsymbol{\epsilon}$	•						_				•	.2347	v

^[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.

Page 9 of 53

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			Sever	it v	
Body System/Event	Group (2)	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
RESISTANCE RECHANISH DISORDERS									
ANY EVENT	x63 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
INFECTION VIRAL	≤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 ^L 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 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.

Page 11 of 53

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 P		Fisher's exact	Number	- -	• • • • • • • • • • •		Severi	tv		
Body System/Event	Group [2]	of Pts	w/Ev		p-value	of Events		ild		erate	•	ere	Unknown
ENTR & PERÎPH MERVOUS SYSTEM DISOR	DERS (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		0	, ,	Ô
	50-56 Days (Group 2)	89	3	(3%)		3	2	(67%)	0		ì	(33%)	Ö
	57 63 Days (Group 3)	68 .	1	(1%)		1	1	(100%)	ō		0	(330)	ő
HEADACHE	≤63 Days (All)	238	43	(18%)	0.6564	65	15	(23%)	43	(66%)	7	(11%)	0
	≤49 Days (Group 1)	81		(15%)		1/9	6	(321)	12		í	(5%)	0
	50-56 Days (Group 2)	89		(20%)		27	8	(30%)	16		3		0
	57 63 Days (Group 3)	68		(19%)		19	1	(5%)	15		_	(16%)	0
MIGRAINE	≤63 Days (All)	238	1	(<1%)	1.0000	1	0		0			(1001)	
	s49 Days (Group 1)	81	ō	(~10)	1.0000	0	0					(100%)	0
	50-56 Days (Group 2)	89	1	(1%)		,	0		U		0	(4.5.5)	0
	57-63 Days (Group 3)	68	Ô	(10)		0	0	1	0		0	(100%)	0
		İ											-
TREMOR .	≤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
SYCHIATRIC DISORDERS													
ANY EVENT	≰63 Days (All)	238	6	(31)	1.0000	6	1	(17%)	4	(67%)	1	(17%)	0
♣ , , , , , , , , , , , , , , , , , , ,	≰49 Days (Group 1)	81	2	(2%)		2	0	٠,		(100%)	0	•	ō
e e 📢 - A	50-56 Days (Group 2)	89	2	(21)		. 2	0			(50%)	1	(50%)	o
•	57-63 Days (Group 3)	68	2	(3%)		2	1	(50 %)		(50%)	0	,	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 misopostol or 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.

Page 12 of 53

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 Pts	Fisher's exact	Number		·Sever:	i bar	:
Body System/Event	Age Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
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
ı	≤49 Days (Group 1)	81	0		0	0	ο .	0	0
	50-56 Days (Group 2)	89	0		0	0	0	o ·	0
	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	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
INSOMNIA	≤63 Days (All)	238	2 (<11)	0.7444	2	1 (50%)	1 (50%)	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
1	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	O	0	0
ASTRO-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%)	į	. 82	43 (52%)	23 (28%)	16 (20%)	0
* * * * * · * · · · · · · · · · · · · ·	50-56 Days (Group 2)	89	58 (65%)	,	118	50 (42%)	36 (31%)	32 (27%)	0
	57-63 Days (Group 3)	68	42 (62%)		84	28 (33Å)	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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FINAL

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

Page 13 of 53

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

Center: HASKELL (#2)

	Gestational Age	Total Number	Numb of F		Fisher's exact	Number		. 		Severi	tv		
Body System/Event	Group [2]	of Pts	w/Ev		p·value	of Events	M	ild	Mod	lerate	•	rere	Unknown
ASTRO-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	(11)		2	0		2	(100%)	0		0
DIARRHEA	≤63 Days (All)	238	54	(23%)	0.9422	70	41	(59%)	22	(31%)	7	(10%)	0
	≤49 Days (Group 1)	81	19	(23%)		22	15		5	i	2	(9%)	0
	50-56 Days (Group 2)	89	19	(21%)		28	16	(57%)	11		1	(4%)	0
	57-63 Days (Group 3)	68	16	(24%)		20	10	(50%)	6	(30%)	4	(201)	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	1	0
	57-63 Days (Group 3)	68	0			0	0		0	1	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	0		1	(100%)	0		0
	50-56 Days (Group 2)	89	1	(1%)		1	0		. 0	١	1	(100%)	0
•	57-63 Days (Group 3)	68	0			0	0		0)	0		O
HAEMORRHOIDS	≤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
4 .	50-56 Days (Group 2)	89	1	(1%)		1	0		' , 1	(1001)	0		0
	57-63 Days (Group 3)	68	0			• 0	0	ji V	ì	•	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.

Page 14 of 53

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				Severi	tv		
Body System/Event	Group [2]	of Pts	w/E	vent	p value	of Events		.1d		rate		ere	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)				····	_								
NAUSEA	≤63 Days (All)	238	117	(49%)	0.0679	147	57	(39%)	44	(30%)	46	(31%)	0
	≤49 Days (Group 1)	81	32	(40%)		42	18	(43%)	12	(29%)	12	(29%)	0
	50-56 Days (Group 2)	89	51			61	25	(41%)	17	(28%)	19	(31%)	ň
	57-63 Days (Group 3)	68 -	34			44	14	(32%)	15		15	(34%)	0
VOMITING	≤63 Days (All)	238	54	(23%)	0.5626	60	21	(35%)	22	(37%)	17	(28%)	0
	≤49 Days (Group 1)	81	15	(19%)		16	9	(56%)	5		2	(13%)	0
	50-56 Days (Group 2)	89	22	(25%)		26	8	(31%)	7		11	(42%)	0
	57 63 Days (Group 3)	68	17	(25%)		18	4	(22%)	10		4	(22%)	ō
ETABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	238	1	(<1%)	0.2857	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	81	0			0	0		0	(1000)	0		Ö
	50-56 Days (Group 2)	89	0			0	0		0		ŏ		n
	57-63 Days (Group 3)	68	1	(1%)		1	0		1	(100%)	ō		0
WEIGHT DECREASE	s63 Days (All)	238	1	(<1 %)	0.2857	1	0		1	(100%)	0		•
	≤49 Days (Group 1)	81	0			0	ō			(1000)	ň		0
1	50 56 Days (Group 2)	89	0			0	ō		n				0
	57-63 Days (Group 3)	68	1	(14)		1	ō		1	(100%)	Ö		0
ARDIOVASCULAR DISORDERS, GENERAL	•	1											
ANY EVENT	≤63 Days (All)	238	2	(<1%)	0.3345	2	0		1	(50%)	1	(50%)	0
A G A A	s49 Days (Group 1)	81	ō	,	-,33.3	• 0	0	i.		1.(504)	1,6	(304)	0
•	50-56 Days (Group 2)	89	2	(2%)		2	0		1	(50%)	1	(50%)	0
•	57-63 Days (Group 3)	68	0	,,		ō	0	· · · · · · · · · · · · · · · · · · ·	ô	(304)	0	(304)	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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Page 15 of 53

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		Severi	i tv	
Body System/Event	Group (2)	of Pts	w/Event	p value	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 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68 .	0		0	0	0	0	0
ESPIRATORY SYSTEM DISORDERS	1								
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.0808	3	O	3 (100%)	^	0
	≤49 Days (Group 1)	81	0	0.0000	'n	Ô	0	•	0
	50 56 Days (Group 2)	89	Ô		Ô	0	0	•	0
	57-63 Days (Group 3)	68	2 (3%)		3	o	3 (100%)	0	0
PLEURAL PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	11	0	1 (100%)	•	
	≤49 Days (Group 1)	81	0	0.2037	o	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	o	1 (100%)	0	0
SINUSITIS	-63 Davis (811)	220		0 2057	_				
51115	≰63 Days (All)	238	1 (<1%)	0.2857	2	0	2 (100%)	0	0
r	s49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2) 57-63 Days (Group 3)	89 68	0 1 (1%)		0	0	0	0	0
	37-63 Days (Group 3)	0.0	1 (1%)		2	U	2 (100%)	0	0
ED BLOOD CELL DISORDERS	•								
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.5061	3	1 (33%) ,	2 (671)	0	0
and the second s	s49 Days (Group 1)	81	0		• 0	0	0	o o	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'	Ö	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 misoprostone 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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Page 16 of 53

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

Center: HASKELL (#2)

	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	N 1		_		
Body System/Event	Group [2]	of Pts	w/Eve		p value	Number of Events	Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS (cont.)										
ANAEMIA	≤63 Days (All)	238	3	(1%)	0.5061	3	1 (33%)	2 (67%)	0	•
	≤49 Days (Group 1)	81	Ō	(0.7)		ó	0	0	0	0
	50.56 Days (Group 2)	89		(2%)		2	0	2 (100%)	0	0
	57 63 Days (Group 3)	68		(11)		1	1 (100%)	0	0	0
RINARY SYSTEM DISORDERS										
ANY EVENT	. ≤63 Days (All)	238	1 (<18)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81		(18)		1	o o	0	1 (100%)	0
	50 56 Days (Group 2)	89	0	.) .		Ō	0	0	0	0
	57 63 Days (Group 3)	68	0			0	ō	o	Ö	0
URINARY TRACT INFECTION	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	•
	≤49 Days (Group 1)	81		(1%)	0.0201	,	ő	o o		0
	50-56 Days (Group 2)	89	'n	,		0	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0			0	0	0	0	0
EPRODUCTIVE DISORDERS, PENALE										
ANY EVENT	≤63 Days (All)	238	50 (21%)	0.6448	57	2 (4%)	8 (14%)	47 (82%)	•
•	≤49 Days (Group 1)	81		20%)	0.0110	17	1 (6%)	4 (24%)		0
	50-56 Days (Group 2)	89		19%)		18	1 (6%)	1 (6%)	12 (71%)	0
	57-63 Days (Group 3)	68		25%)		22	0	3 (14%)	16 (89%) 19 (86%)	0
4 .	•						•	, (200,	15 (004)	v

^[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 misepristone 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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Page 17 of 53

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		ber Pts	Fisher's exact	M								
Body System/Event	Age Group [2]	of Pts		vent	p-value	Number of Events	Mi			Sever erate	Sev	ere	Unk	nown
REPRODUCTIVE DISORDERS, FEMALE (cont.)										***				
UTERINE DISORDER NOS	≤63 Days (All)	238	2	(<1%)	0.5298	2	0		2	(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 .	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	
ı	≤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	(64)	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	(<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	≰63 Days (All)	238	228	(96%)	0.0667	700	189	(27%)	257	(37%)	253	(36%)	1	(<1%)
→	≰49 Days (Group 1)	81	74	(91%)		215	68	(32%)		(39%)	63	(29%)	1	(<1%)
e e e e e e e e e e e e e e e e e e e	50-56 Days (Group 2)	89	87	(98%)		256	62	(24.8)		(364)	102	(40%)	0	
	57-63 Days (Group 3)	68	67	(99%)		229	59	(26%)	82	(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.

Page 18 of 53

Appendix D, Table Sc (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	ity		·
Body System/Event	Group [2]	of Pts	w/E	vent	p·value	of Events	Mi	114	Mode	erate	-	ere	Unknow
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)												
BACK PAIN	≤63 Days (All)	238	12	(5%)	0.6598	14	4	(29%)	7	(50%)	3	(21%)	0
	≤49 Days (Group 1)	81	5	(6%)		7	1	(14%)	4	(57%)	2	(29%)	0
	50-56 Days (Group 2)	89	3	(3%)		3	1	(33%)	2	(67%)	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
ı	≤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	s63 Days (All)	238	2	(<1%)	0.5298	2	0		1	(50%)	1	(50¥)	0
	≰49 Days (Group 1)	81	1	(1%)		1	0		1	(100%)	ø		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	ż	(<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		0
• '	57-63 Days (Group 3)	68	0			0	0		0		0		0
HYPOVOLAEMIA	≤63 Days (All)	238	1	(<1%)	1.0000	1	O		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	1	(100%)	0
A A A A	57-63 Days (Group 3)	68	0		,	• 0	0	j.	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.

Page 19 of 53

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 P		Fisher's exact	Number -				Severi	tv		
Body System/Event	Group [2]	of Pts	w/Ev		p-value	of Events	Mi	1đ	Mode	rate	Seve	ere	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (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	(1%)		1	ō			(100%)	ō	(450)	ñ
	50 56 Days (Group 2)	89	1	(1%)		2	1	(50%)	0	(2227)	1	(50%)	n
	57-63 Days (Group 3)	68 .	1	(1%)		1	0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	_	(100%)	0	(300)	ō
PAIN	≤63 Days (All)	238	1	(<1%)	0.2857	2	0		0	ı	2	(100%)	0
l .	≤49 Days (Group 1)	81	0			0	0	'	0	ļ	0		0
	50-56 Days (Group 2)	89	0			0	0		0	1	6		Ó
	57-63 Days (Group 3)	68	1	(1%)		. 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	(1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	89	1	(1%)		1	0		1	(100%)	0	1	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			(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

J:\USA\166A\SASPGMS\apdxd\final\ade3.SAS 24NOV98:16:20

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

Page 20 of 53

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		nber Pts	Fisher's exact	Number				Sever	itv			
Body System/Event	Group [2]	of Pts	w/E	ent	p value	of Events		1d		rate		vere	Uni	known
ANY EVENT	≤63 Days (All)	164	159	(971)	0.2754	692	188	(27%)	248	(36%)	252	(36%)	4	(<1%
	s49 Days (Group 1)	65	61	(94%)		242	73	(30%)	91	(38%)	76			(<1%
	50 56 Days (Group 2)	65	64			297	82	(28%)	101		112	•		(<1%
	57-63 Days (Group 3)	34		(100%)		153	. 33	(22%)	56		64		ō	(
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	. ,,	Ö	
	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	(331)	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 Daya (All)	164	1	(<1%)	1.0000	3	1	(33%)	1	(33%)	1	(33%)	0	
•	s49 Days (Group 1)	65	1	(2%)		3	1	(33%)	1		· 1	(33%)	ŏ	
	50-56 Days (Group 2)	65	0			0	0		0		. 0	,	ŏ	
•	57-63 Days (Group 3)	34	0			0	0		ō		0		ō	
4 ,		'								,	1			

^[1] Includes hausea, 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.

Page 21 of 53

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 P		Fisher's exact	Number				Severi	tv		
Body System/Event	Group [2]	of Pts	w/Ev		p-value	of Events	Mi	.1 d		erate	Sev		Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)					•								
MYALGIA	≤63 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 4 PERIPE NERVOUS SYSTEM DISORDERS	1												
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%)		(291)	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
i.	50-56 Days (Group 2)	65	5	(8%)		5 ¹	3	(60%)	0		2	(40%)	0
	57-63 Days (Group 3)	34	2	(6%)		2	0		2	(100%)	0		0
HEADACHE	≤63 Days (All)	164	8	(5%)	0.7176	9	2	(22%)	5	(56%)	2	(22%)	0
	≰49 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	(61)		2	0		2	(100%)	0		0
GASTRO-INTESTINAL SYSTEM DISORDERS	•												
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	1 (45%)	13	(22%)	0
•	50-56 Days (Group 2)	65	43	(66%)		85	23	(278)		(34%)	33	(39%)	0
i je	57-63 Days (Group 3)	34 .	28	(82%)		52	11	(241)	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.

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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Page 22 of 53

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

Center: POPPEMA (#3)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number							
Body System/Event	Group [2]	of Pts		Event	p value	of Events	Mi	1 d	Mode	Sever:	-	ere	Unknown
LASTRO-INTEŠTINAL 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		ō	(230)	0	(300)	ő
	50-56 Days (Group 2)	65	0			0	0		0		0		ň
	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
, ·	≤49 Days (Group 1)	65	10	(15%)		12	5	(42%)	6	(50%)	1	(8%)	Ŏ
	50-56 Days (Group 2)	65	14	(22%)		14	5	(36%)	6	(43%)	3	(21%)	Ŏ
	57-63 Days (Group 3)	34	4,	1		5	1	(20%)	4		ō	(224)	ŏ
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%)	A	(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%)	o
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%)	Ö
	50-56 Days (Group 2)	65	19	(29%)		21	2	(10%)	9	(43%)	10	(48%)	Ö
•	57-63 Days (Group 3)	34	14	(41%)		16	0	,,,,	8		8	(50%)	ō
ARDIOVASCULAR DISORDERS, GENERAL													
ANY EVENT	≤63 Days (All)	164	2	(1%)	0.6839	2	0		2	(100%)	0		0
$m{\phi}_{i,j}$, $m{\phi}_{i,j}$	≤49 Days (Group 1)	65	0			0	0			! g. i	Ö		0
K. H. William B.	50-56 Days (Group 2)	65	1	(2%)		1	0	i .	ı 1	(100%)	0		Õ
	57-63 Days (Group 3)	34	1	(3%)		1	0	*		(100%)	0		ő

^[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.

Page 23 of 53

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

Center: POPPEMA (#3)

Age										
Group (2)	Number of Pts	of Pts w/Even	exact p-val			Mild		Sever: Moderate	ity Severe	Unknow
		*								Oliknowi
•			•) 0.207	3 1		0		1 (100%)	0	0
- •		0		0		0		0	0	0
	65	0		0		0		0	0	0
57-63 Days (Group 3)	34	1 (:	*)	1		0		1 (100%)	0	0
≰63 Days (All)	164	1 (<	3) 1.000	0 1		0		1 (100%)	•	
			-,			-			-	0
		_	t)	1				- :	- .	0
57-63 Days (Group 3)	34	0 (• ,	. 0		0		0	0	0
463 Dave (811)	164		• • • • • • • • • • • • • • • • • • •							
		· ·		0 3					0	0
			-	1				0	0	0
	!			1			į.		0	0
57-63 Days (Group 3)	34	1 (3	r)	1		0		1 (100%)	0	0
-63 Davis (811)	1		• • • • • • • • • • • • • • • • • • • •	_						
				0 3					0	0
				1		1 (100%)		0	0	0
		-		1		0		1 (100%)	0	0
57-63 Days (Group 3)	34	1 (3	t)	1		0		1 (100%)	0	0
1										
≰63 Days (All)	164	18 (11	0.080	1 25		6 (24%)	•	11 (44%)	8 (32%)	0
≰49 Days (Group 1)	65	3 (5	i)	. 6			1.			Ö
50-56 Days (Group 2)	65						l			0
57 63 Days (Group 3)	34						!	•		0
	<pre>s49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 3) s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) s63 Days (Group 3) s63 Days (All) s49 Days (Group 3)</pre>	#49 Days (Group 1) 65 50-56 Days (Group 2) 65 57-63 Days (Group 3) 34 #63 Days (All) 164 #49 Days (Group 1) 65 50-56 Days (Group 2) 65 57-63 Days (Group 3) 34 #63 Days (All) 164 #49 Days (Group 1) 65 50-56 Days (Group 3) 34 #63 Days (All) 164 #49 Days (Group 3) 34 #63 Days (All) 164 #49 Days (Group 1) 65 57-63 Days (Group 3) 34 #63 Days (All) 164 #49 Days (Group 3) 34 #63 Days (All) 165 50-56 Days (Group 3) 34	#49 Days (Group 1) 65 0 50-56 Days (Group 2) 65 0 57-63 Days (Group 3) 34 1 (3 #63 Days (All) 164 1 (<1 #49 Days (Group 1) 65 0 50-56 Days (Group 2) 65 1 (2 57-63 Days (Group 3) 34 0 #63 Days (All) 164 3 (2 #49 Days (Group 1) 65 1 (2 50-56 Days (Group 2) 65 1 (2 57-63 Days (Group 3) 34 1 (3 #63 Days (All) 164 3 (2 #63 Days (Group 3) 34 1 (3 #63 Days (Group 3) 34 1 (3 #63 Days (Group 1) 65 1 (2 57-63 Days (Group 1) 65 1 (2 57-63 Days (Group 3) 34 1 (3 #63 Days (Group 3) 36 5 1 (2 #65 Days (Group 3) 36 5 9 (14 #65 Days (Group 1) 65 3 (5) #65 Days (Group 1) 65 3 (5) #65 Days (Group 1) 65 3 (5) #65 Days (Group 2) 65 9 (14 #65 Days (Group 3) 65 9 (14 #65 Days (#49 Days (Group 1) 65 0 50-56 Days (Group 2) 65 0 57-63 Days (Group 3) 34 1 (3%) #63 Days (All) 164 1 (<1%) 1.000 #49 Days (Group 1) 65 0 50-56 Days (Group 2) 65 1 (2%) 57-63 Days (Group 3) 34 0 #63 Days (All) 164 3 (2%) 1.000 #49 Days (Group 1) 65 1 (2%) 50-56 Days (Group 2) 65 1 (2%) 57-63 Days (Group 3) 34 1 (3%) #63 Days (All) 164 3 (2%) 1.000 #49 Days (Group 1) 65 1 (2%) 50-56 Days (Group 2) 65 1 (2%) 50-56 Days (Group 3) 34 1 (3%) #63 Days (Group 1) 65 1 (2%) 57-63 Days (Group 3) 34 1 (3%) #63 Days (Group 3) 34 1 (3%) #63 Days (All) 164 18 (11%) 0.080 #649 Days (Group 1) 65 3 (5%) 50-56 Days (Group 2) 65 9 (14%)	x49 Days (Group 1) 65 0 0 50 - 56 Days (Group 2) 65 0 0 57 - 63 Days (Group 3) 34 1 (3%) 1 x63 Days (All) 164 1 (<1%)	#49 Days (Group 1)	x49 Days (Group 1) 65 0 0 0 50 56 Days (Group 2) 65 0 0 0 57 63 Days (Group 3) 34 1 (3%) 1 0 x63 Days (All) 164 1 (<1%)	x49 Days (Group 1) .65 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	#49 Days (Group 1)	#49 Days (Group 1) 65 0 0 0 0 0 0 0 0 0 0 0 0 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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Page 24 of 53

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	Numbe of Pt		Fisher's								
Body System/Event	Group (2)	of Pts	w/Eve		exact p value	Number of Events		ild		Severi oderate	-	/ere	Unknow
EPRODUCTIVE DISORDERS, PENALE (cont.)												·	
ENDOMETRITIS	≤63 Days (All)	164	7	(4%)	0.8833	7	2	(29%)	ŧ	5 (71%)	0		•
	s49 Days (Group 1)	65		(3%)		,	ī	(50%)	- 1	1 (50%)	0		0
	50 56 Days (Group 2)	65		(5%)		3	i	(33%)	1.	2 (67%)	0		0
	57 63 Days (Group 3)	34 -		(6%)		2	ō	(334)		2 (100%)	0		0
LEUKORRHOEA	≤63 Days (All)	164	1 ((<1%)	1.000d	,		(1006)			_		
	≤49 Days (Group 1)	65	0 '	(. 1 .)	1.0000	1	0	(100%)		0	0		0
	50-56 Days (Group 2)	65	•	(2%)		1	•	(1001)		0 .	0		0
	57-63 Days (Group 3)	34	0	(28)		1		(100 %)		0	0		0
	3, 03 Days (Group 3)		U			· U	0			0	0		0
SALPINGITIS	≤63 Days (All)	164	1 (<1%)	1.0000	1	1	(100%)		0	0		0
	≰49 Days (Group 1)	65	1	(2%)		1	1	(100%)		0	0		n
	50-56 Days (Group 2)	65	0			0	0			0	Ô		n
	57-63 Days (Group 3)	34	0			0	0			0	0		ŏ
JTERINE DISORDER NOS	≤63 Days (All)	164	·1 (<11)	0.2073	1	0			1 (100%)	0		•
	≤49 Days (Group 1)	65	0			0	ň			0	0		•
	50-56 Days (Group 2)	65	Ō			Ô	ñ			0	,		0
	57 63 Days (Group 3)	34	1	(3%)		1	ō		1	1 (100%)	0		0
UTERINE HAEMORRHAGE	≤63 Days (All)	164	14	(91)	0.2183	14		/261	1	F (248)			
	\$49 Days (Group 1)	65		(5%)	0.2163	14	1	(7%)		5 (36%)	8		0
. ,	50-56 Days (Group 2)	65		(9\$)		,	0			2 (67%)	1	(33%)	0
	57-63 Days (Group 3)	34		15%)	ĺ			(nde)		,	5	(83%)	0
	2. 02 pala (group 3)	34) (134)	,	• 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.

Page 25 of 53

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	ber Pts	Fisher's exact	Number				· · · Sever	:ity			
Body System/Event	Group {2}	of Pts	w/E	vent	p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unk	nown
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	(2%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	34 ·	0			0	0		0		0		0	
BODY AS A WHOLE - GENERAL DISORDERS								1		1				
ANY EVENT	≤63 Days (All)	164	158	(96%)	0.4439	443	120	(27%)	149	(34%)	170	(38%)	4	(<1%)
	≰49 Days (Group 1)	65	61	(94%)		167	47	(28%)	59	(35%)	59	(35%)	2	(1%)
	50-56 Days (Group 2)	65	64	(981)		190	52	(271)	64	(34%)	72	(38%)	2	(11)
	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	(<11)
	50-56 Days (Group 2)	65	64	(98%)		181	50	(28%)	59	(33%)	70	(39%)	2	(11)
	57-63 Days (Group 3)	34	33	(97%)		82	21	(26%)	24	(29%)	37	(45%)	0	•
ASTHENIA	≤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	(14%)
$oldsymbol{arphi}_{i,j}$	≤49 Days (Group 1)	65	3	(5%)		3	0	.*		·(334)	1	(33%)	1	(33%)
K. O. 🐞 🛴 🕹	50-56 Days (Group 2)	65	2	(3%)		. 2	1	(50Å)		(50%)	0		0	
•	57-63 Days (Group 3)	34	2	(6%)		2	0	,	l.	t (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.

Page 26 of 53

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

Center: POPPEMA (#3)

Body Cress and / Process	Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	(Fv	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
DY AS A WHOLE - GENERAL DISORDERS (cont.)								
FATIGUE	≤63 Days (All)	164	3 (2%)	1.0000	,	. (224)			
	≤49 Days (Group 1)	65	1 (2%)	1.0000	,	1 (33%)	1 (334)	1 (33%)	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
		34	1 (38)		1	0	0	1 (100%)	0
FEVER	≤63 Days (All)	164	1 (.15)		_				
	≤49 Days (Group 1)	65	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	50-56 Days (Group 2)		1 (2%)		1	1 (100%)	O .	0	O
	57 63 Days (Group 3)	65	0		0	0	0	0	0
	37 63 Days (Group 3)	34	0		. 0	0	0	0	0
HOT FLUSHES	-63 Davis (811)								
	≤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	n
	57-63 Days (Group 3)	34	0		0	0	0	o	ň
LEG PAIN								*	·
DEG FRIN	≤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%)	ň	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	. 0	0
n. cone			+			-	1 (1001)	. •	U
RIGORS	≤63 Days (All)	164	4 (2%)	0.5346	4	1 (25%)	3 (75%)	0	_
\$	≰49 Days (Group 1)	65	3 (5%)		1	1 (33%)	2 (67%)	-	0
*	50-56 Days (Group 2)	65	1 (2%)		1	1 (234)		0	0
A A A A	57-63 Days (Group 3)	34	0		. 0	0 . ,	1 (1001)	0	0
·	• • • • • • • • • • • • • • • • • • • •		-			,	0	ło	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 misopristone and misoprostol or 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.

Page 27 of 53

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 Pts	Fisher's exact	Number		Sever	itv	
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
SYNCOPE	≰63 Days (All)	164	2 (1%)	0.3532	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	65	О,		0	0	0	0	o
	50-56 Days (Group 2)	65	2 (3%		2	0	0	2 (100%)	0
	57-63 Days (Group 3)	34	0		n	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.

[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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Page 28 of 53

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

Center: TYSON (N4)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number							
Body System/Event	Group (2)	of Pts	w/Event	p-value	of Events		1d		Sever: erate	Sev		Unknown
•										·		
ANY EVENT	≤63 Days (All)	102	98 (96%)	1.0000	403	148	(37%)	156	(39%)	99	(25%)	0
	≤49 Days (Group 1)	68	65 (96%)		271	101	(37%)	110		60	(22%)	ō
	50-56 Days (Group 2)	25	24 (96%)		106	39	(37%)	40		27	(251)	Ō
	57-63 Days (Group 3)	9	9 (100%)		26	8	(31%)	6		12	(46%)	0
SKIN 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			(100%)	ō		Ö
	50-56 Days (Group 2)	25	1 (4%)		. 1	0			(100%)	Ŏ		o
	57-63 Days (Group 3)	9	0		0	0		0	, ,	Ō		ō
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			(100%)	0		0
	50 56 Days (Group 2)	25	1 (4%)		1	0			(100%)	Ö		0
	57 63 Days (Group 3)	9	0		o	ō		ō	(1000)	ō		Ö
USCULO-SKELETAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	0		0			(100%)	0
1	≤49 Days (Group 1)	68	1 (1%)	2.2000	i	n		n			(100%)	0
	50-56 Days (Group 2)	25	0 (10)		Ô	n		ň			11004)	0
	57 63 Days (Group 3)	9	0		ŏ	0		0		0		0
,	, , , , , , , , , , , , , , , , , , , ,	-	-		•	·		·		·		v

^[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 misepristone 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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Page 29 of 53

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	~~~ ~~~~	····Sever:	1 tv	
Body System/Event	Group [2]	of Pts	w/Event		of Events	Mild	Moderate	Severe	Unknown
MUSCULO-SERUETAL SYSTEM DISORDERS (cont.)									
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					1				
ANY EVENT	≤63 Days (All)	102	24 (24	1) 0.6176	3 ¹ 5	13 (37%)	19 (54%)	3 (9%)	0
:	≰49 Days (Group 1)	68	18 (26	%)	27	10 (37%)	14 (52%)	3 (11%)	0
	50-56 Days (Group 2)	25	5 (20	b)	. 7	3 (43%)	4 (57%)	0	0
	57-63 Days (Group 3)	. 9	1 (11	•)	1	0	1 (100%)	0	0
DIZZINESS	≤63 Days (All)	102	7 (7	1) 0.0493	8	5 (63%)	3 (38%)	0	0
	s49 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	1 (11	•)	1	0	1 (1001)	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
t · · · · ·	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	o .	1 (100%)	0
$artheta_i = artheta_i$	≤49 Days (Group 1)	68	1 (1	₹)	1	0 .	0	1 (100%)	0
A A B	50-56 Days (Group 2)	25	0		. 0	0 ,	0	0	0
•	57-63 Days (Group 3)	9	0		0	0	ο,	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 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.

Page 30 of 53

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

Center: TYSON (#4)

	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	Number				Sever			
Body System/Event	Group [2]	of Pts	w/Eve	_	p value	of Events	M	ild	Mo	derate	-	ere	Unknown
CENTR & PERÍPH NERVOUS SYSTEM DISORDE	RS (cont.)									•			
TREMOR	≤63 Days (All)	102	2	(2%)	1.0000	2	2	(100%)	ļ	0			0
	s49 Days (Group 1)	68		(3%)		2		(100%)	- 1	0	0		0
	50-56 Days (Group 2)	25	0			0	0	(1001)		0	0		0
	57-63 Days (Group 3)	9 .	0			0	0			0	ŏ		0
NASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	. ≤63 Days (All)	102	60 (59%)	0.9501	104	42	(40%)	,	4 (33%)	28	(27%)	•
	≤49 Days (Group 1)	68	-	60%)		69	27	(39%)		4 (354)	18	(26%)	0
	50-56 Days (Group 2)	25		56%)		27	12	(448)		8 (30%)	7	(26%)	
	57-63 Days (Group 3)	9		561)		8	3	(384)		2 (25%)	3	(38%)	0
CONSTIPATION	≤63 Days (All)	102	1 (<1%)	1.0000	,	0			. (1001)			_
	≤49 Days (Group 1)	68		(1%)	1.0000	;	0			1 (100%)	0		0
	50-56 Days (Group 2)	25	0	(14)		•	0			1 (100%)	0		0
	57-63 Days (Group 3)	9	0			o	0			0 0	0		0
DIARRHEA	≤63 Days (All)	102	19 (1	19%)	0.7838	22	14	(64%)		. (200)			_
	≤49 Days (Group 1)	68	-	18%)	0.7030	14		(71%)		4 (18%)	•	(18%)	0
,	50-56 Days (Group 2)	25		201)		6	10 3	(50%)		2 (14%)	2	(14%)	0
	57-63 Days (Group 3)	9		22%)		2	.1	(50%)	!	2 (33%) 0	1	(17%) (50%)	0
DYSPEPSIA	≰63 Days (All)	102	2	(2%)	0.55781	1	1	(228)		^		(= = 4)	
	≤49 Days (Group 1)	68		(24) (1 %)	0.3378	,	_	(33%)		0	2	(67%)	0
	50-56 Days (Group 2)	25		(4%)	\		1	(100%)	• ,	0 1	0	/1008\	0
real fraction of the second of	57-63 Days (Group 3)	9	Ô	(40)		. 2	0	,i	i.	0 ,		(100%)	0
	o. oz zaya (ozoup ay	,	·			U	U	ř		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.

Page 31 of 53

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	Numb of P		Fisher's exact	Number				Severi	tv		
Body System/Event	Group [2]	of Pts	w/Ev		p-value	of Events		ild		rate	Sev	ere	Unknown
GASTRO-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		(100%)	ŏ		n		0
	50 56 Days (Group 2)	25	0			ō	0	(1001)	ő		0		0
	57-63 Days (Group 3)	9 ·	0			0	ō		o		0		0
NAUSEA	≤63 Days (All)	102	43	(42%)	1.0000	45	10	(42%)	13	(29%)	13	(29%)	•
	≰49 Days (Group 1)	68		(43%)	1.0000	31	11	(35%)	10	(32%)	10	(321)	0
	50-56 Days (Group 2)	25		(40%)		10	6	(60%)	2	(201)	2	(20%)	0
	57-63 Days (Group 3)	9		(44%)		- 4	2	(50%)	1	(25%)	1	(25%)	0
VOMITING	≤63 Days (All)	102	26	(25%)	1.0000	31	6	(19%)	16	(52%)	•	(205)	
	s49 Days (Group 1)	68		(26%)	1.0000	20	3	(15 %)	11	(52 %)	9	(29%)	0
	50-56 Days (Group 2)	25		(24%)		9	3	(33%)	11	(44%)	6	(30%)	0
	57-63 Days (Group 3)	9		(221)		2	0	(334)	1	(50%)	2 1	(22%) (50%)	0
ESPIRATORY SYSTEM DISORDERS							,						
ANY EVENT	≤63 Days (All)	102	1	(<1%)	0.3333	1	1	(100%)	0		0		•
	≤49 Days (Group 1)	68	Ô	(-10)	0.3333	Ô	ō	(1004)	0		0		0
t '	50-56 Days (Group 2)	25	1	(4%)		1	•	(100%)	. 0		•		0
	57-63 Days (Group 3)	9	ō	1/		ō	ō	(1001)	0		0		0 0
DYSPNOEA	≤63 Days (All)	102	1	(<1%)	0.3333	1	1	(100%)	0		0		•
$\dot{\sigma}_{ij}$	≤49 Days (Group 1)	68	ō	,		ō	ō			1	0		0
e e 🎳 - A	50-56 Days (Group 2)	25	i	(4%)		i		(100%)	7	* !	0		0
	57-63 Days (Group 3)	9	ō	,		0	ō	7	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.

Page 32 of 53

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			• • • • • · ·	· Seve	ritv		
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mi	1đ	Mode	rate	•	/ere	Unknown
EPRODUCTIVE DISORDERS, PENALE												· · · · · · · · · · · · · · · · · · ·
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	(444)		(100%)	0
	50 56 Days (Group 2)	25	5 (20%)		5	ō		1	(20%)		(80%)	0
	57 63 Days (Group 3)	9 .	1 (11%)		1	0		ō	(200)		(100%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	102	7 (7%)	0.0060	7	0		1	(14%)	6	(86%)	0
ľ	≤49 Days (Group 1)	68	1 (1%)		1	o		0	(111)		(100%)	0
	50-56 Days (Group 2)	25	5 (20%)		5	0		1	(20%)		(80%)	0
	57-63 Days (Group 3)	9	1 (11%)		. 1	ō		0	(200,		(100%)	0
DDY 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	(221)	0
	50-56 Days (Group 2)	25	24 (96%)		65	23	(35%)	26	(40%)	16	(25%)	Ö
	57-63 Days (Group 3)	9	9 (100%)		16	5	(31%)	3	•	8	(50%)	0
ABDOMINAL PAIN	≤63 Days; (All)	102	98 (96%)	1.0000	226	78	(35%)	90	(40%)	58	(26%)	•
	≰49 Days (Group 1)	68	65 (96%)	1.0000	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		8	(50%)	0
The second secon		1	. ,,			_	13247	,	(134)	, .	(304)	U
ASTHENIA	≤63 Days (All)	102	4 (4%)	0.0828	4	2	(50%)	1	. (251)	i	(25%)	0
	<pre>s49 Days (Group 1)</pre>	68	1 (1%)		. 1	0			4. (1	(100%)	ō
• a · • · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	25	3 (12%)		• 3	2	(67\$)	1	4.1	0		o
•	57-63 Days (Group 3)	9	0		0	0	•	0		0		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 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.

Page 33 of 53

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		Sever:	it v	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
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 (134)	Ŏ
	57-63 Days (Group 3)	9	0		0	o	0	Ö	0
FATIGUE	≤63 Days (All)	102	3 (3%)	1.0000	4	1 (25%)	2 (50%)	1 (25%)	•
t .	≤49 Days (Group 1)	68	2 (3%)		1	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		ō	ō	0	ő	0
MALAISE	≤63 Days (All)	102	1 (<1%)	0.3333	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	0		- O:	n	0	0	0
;	50-56 Days (Group 2)	25	1 (4%)		1	n	1 (100%)	•	0
	57-63 Days (Group 3)	9	0		o	o	0	ő	0
RIGORS	≤63 Days (All)	102	8 (8%)	0.4991	8	6 (75%)	2 (25%)	O	•
•	≤49 Days (Group 1)	68	5 (7%)		5	4 (80%)	1 (20%)	Ô	0
	50-56 Days (Group 2)	25	3 (12%)		3	2 (67%)	1 (33%)	ň	Ď
	57-63 Days (Group 3)	9	0		0	0	0	o	ō
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	o	0
	≰49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0 -	0	Ö
ở .	50-56 Days (Group 2)	25	0		0	0	0.	Ô	0
	57-63 Days (Group 3)	9	0		• 0	0	0 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.

Page 34 of 53

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			OCTE	ity	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RESISTANCE NECHANISM 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
· ·	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	ο .	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.

Page 35 of 53

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	•	
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mi	1d	Moderate	Severe	Unknow
•										
ANY EVENT	≤63 Days (All)	44	43 (98%)	0.1818	166	84	(51%)	60 (36%)	22 (13%)	0
	≤49 Days (Group 1)	13	13 (100%)		41	21	(51%)	17 (41%)	3 (7%)	0
	50-56 Days (Group 2)	23	23 (100%)		97	47	(48%)	32 (33%)	18 (19%)	0
	57 63 Days (Group 3)	8 .	7 (88%)		28	16	(57%)	11 (39%)	1 (4%)	0
INTR & PERIPH NERVOUS SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	44	10 (23%)	0.2801	14	1	(7%)	10 (71%)	3 (21%)	0
	≤49 Days (Group 1)	13	4 (31%)		5	0		5 (100%)	0.	0
	50-56 Days (Group 2)	23	6 (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 (5%)	1.0000	2	1	(50%)	1 (50%)	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	≤63 Days (All)	44	8 (18%)	0.3926	12	0		9 (75%)	3 (25%)	0
	≤49 Days (Group 1)	13	3 (23%)		4	0		4 (100%)	0	0
T .	50 56 Days (Group 2)	23	5 (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 (64%)	0.7071	49	31	(63%)	10 (20%)	8 (16%)	0
s in 💰 🔭	≤49 Days (Group 1)	13	7 (54%)		. 14	8	(57%)	4 (291)	2 (14%)	0
	50-56 Days (Group 2)	23	16 (70%)		26	16	(621)	4 (15%)	6 (23%)	0
	57-63 Days (Group 3)	8	5 (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.

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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Page 36 of 53

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/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
JASTRO-INTESTINAL SYSTEM DISORDERS (COD	t.)		******						
DIARRHEA	≤63 Days (All)	44	5 (11%)	0.6850	6	2 (33%)	2 (33%)	2 (33%)	0
	≰49 Days (Group 1)	13	2 (15%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	23	3 (13%)		4	1 (25%)	1 (25%)	2 (50%)	0
	57-63 Days (Group 3)	8 .	0		0	0	0	0	0
FLATULENCE	≤63 Days (All)	44	1 (2%)	1.0000	2	0	1 (50%)	1 (50%)	0
t .	≤49 Days (Group 1)	13	0		0	0	0 ,	0	ŏ
	50-56 Days (Group 2)	23	1 (4%)		2	0	1 (50%)	1 (50%)	Õ
	57-63 Days (Group 3)	8	0		. 0	ō	0	0	0
NAUSEA	≤63 Days (All)	44	28 (64%)	0.7071	32	24 (75%)	4 (13%)	4 (13%)	۸
	≰49 Days (Group 1)	13	7 (54%)		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	5 (100%)	0	0	0
VOMITING	s63 Days (All)	44	7 (16%)	0.0601	9	5 (56%)	3 (33%)	1 (11%)	0
	≤49 Days (Group 1)	13	4 (31%)		4	2 (50%)	1 (25%)	1 (25%)	Ö
,	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	Ô
•	57-63 Days (Group 3)	8	2 (25%)		4	2 (50%)	2 (50%)	ō	0
SPRODUCTIVE DISORDERS, FEMALE						ii .			
ANY EVENT	±63 Days (All)	44	1 (2%)	1.0000	3	0	3 (100%)	0	0
4	≤49 Days (Group 1)	13	0		0	0	0 4.1	0	0
V A A A	50-56 Days (Group 2)	23	1 (4%)	;	. 3	o ,i	3 (100%)	0	0
•	57-63 Days (Group 3)	8	0		0	0	01	ō	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 misepristone 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.

Page 37 of 53

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					
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
BREAST ENGORGEMENT	≰63 Days (All)	44	1 (2%)	1.0000	2	0	2 (100%)	0	0
	s49 Days (Group 1)	13	0		0	0	0	0	O
	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	s63 Days (All)	44	1 (2%)	1.0000	1	0 +	1 (100%)	0	0
1	≰49 Days (Group 1)	13	0		0	ο '	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (10ó %)	b ·	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
	s49 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
,	•					1			
ABDOMINAL PAIN	≤63 Days (All)	44	43 (98%)	0.1818	95	52 (55%)	33 (35%)	10 (11%)	0
	s49 Days (Group 1)	13	13 (100%)		21	13 (62%)	7 (33%)	1 (5%)	0
f	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%)	B (44%)	1 (6%)	0
FEVER	≰63 Days (All)	44	1 (2%)	1.0000	1	0	1 (100%)	0	0
÷. ,	<pre>s49 Days (Group 1)</pre>	13	0		0	ο.	0 1	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0 ;	1 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	o ;	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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FINAL

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

Page 38 of 53

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			·Severi	itv	
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)								· · · · · · · · · · · · · · · · · · ·
LEG PAIN	≤63 Days (All)	44	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 (Åll)	44	1 (2%)	1.0000	1	0	0	1 (100%)	0
•	≤49 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
	≤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

^[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.

Page 39 of 53

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				Sever	ltv		
Body System/Event	Group (2)	of Pts	w/Event	p-value	of Events		11d		erate	-	ere	Unknown
•			-									
ANY EVENT	≰63 Days (All)	64	59 (92%)	0.8202	255	109	(434)	92	(36%)	54	(21%)	0
	≰49 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 (100%)		44	18	(41%)	18	(41%)	8	(18%)	0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	64	12 (19%)	0.2844	21	8	(38%)	9	(43%)	4	(19%)	0
	≤49 Days (Group 1)	36	6 (17%)		9	3	(33%)	5		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 (8%)		2	1	(50%)	1	(50%)	0		0
DIZZINESS	≤63 Days (All)	64	3 (5%)	1.0000	31	3	(100%)	0		0		0
	≤49 Days (Group 1)	36	2 (6%)		2		(100%)	0		Ö		ō
A control of the cont	50-56 Days (Group 2)	16	1 (6%)		1		(100%)	0		0		Ó
	57-63 Days (Group 3)	12	0		0	0	, ,	0		0		Ö
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	1 . 11	1		0
r · · · · ·	50-56 Days (Group 2)	16	4 (25%)		9	3	(33%)	3		3	(33%)	0
	57-63 Days (Group 3)	12	1 (8%)		2	1	(50%)	1		0	,,	0
PARAESTHESIA	≤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		o
· 1 • • · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	16	0		• 0	0				Ō		ō
•	57-63 Days (Group 3)	12	0		0	0	ji I P	0	•	0		Ö

^[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.

Page 40 of 53

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

Center: BORGATTA (#6)

Age i	Total Number	Number of Pts	Fisher' exact			Sever	itv	
Group [2]	of Pts	w/Event	p value		Mild	Moderate	Severe	Unknown
								
≤63 Days (All)	64	4 (6	1) 0.3760	4	2 (50%)	2 (50%)	0	0
≤49 Days (Group 1)	36	4 (1)	*)	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
≤63 Days (All)	64	1 (2	*) 1.0000	1	0	1 (100%)	0	0
. ≤49 Days (Group 1)	36	1 (%)	1	0	1 (100%)	0	0
50-56 Days (Group 2)	16	0		o	0	0	0	0
57-63 Days (Group 3)	12	0		0	0	0	0	0
s63 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
≤63 Days (All)	64	1 (2	1.0000	1	1 (100%)	0	0	0
≤49 Days (Group 1)	36	1 (*)	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
s63 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	, ٠. ٥	O' ¦	0	0
57-63 Days (Group 3)	12	0		• 0	О ;	0	0	0
	≤63 Days (All) ≤49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) ≤63 Days (All) ≤49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3) ≤63 Days (All) ≤49 Days (Group 1) 50-56 Days (Group 3) ≤63 Days (Group 3) ≤63 Days (Group 3) ≤63 Days (Group 1) 50-56 Days (Group 1) 50-56 Days (Group 3) ≤63 Days (Group 3) ≤63 Days (Group 3) ≤63 Days (Group 1) 50-56 Days (Group 1) 50-56 Days (Group 1) 50-56 Days (Group 1)	\$63 Days (All) 64 \$49 Days (Group 1) 36 50-56 Days (Group 2) 16 57-63 Days (Group 3) 12 \$63 Days (All) 64 \$49 Days (Group 1) 36 50-56 Days (Group 2) 16 57-63 Days (Group 3) 12 \$63 Days (All) 64 \$49 Days (Group 3) 12 \$63 Days (Group 1) 36 50-56 Days (Group 2) 16 57-63 Days (Group 3) 12 \$63 Days (All) 64 \$49 Days (Group 3) 12 \$63 Days (All) 64 \$49 Days (Group 1) 36 50-56 Days (Group 3) 12 \$63 Days (All) 64 \$49 Days (Group 3) 12 \$63 Days (Group 1) 36 50-56 Days (Group 3) 12	<pre> ≤63 Days (All) 64 4 (6 ≤49 Days (Group 1) 36 4 (11 50-56 Days (Group 2) 16 0 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12 0 0 0 0 0 #65 Days (Group 3) 12 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	x63 Days (Al1) 64 4 (6%) 0.3760 4 2 (50%) 2 (50%) x49 Days (Group 1) 36 4 (11%) 4 2 (50%) 2 (50%) 50.56 Days (Group 2) 16 0 0 0 0 57-63 Days (Group 3) 12 0 0 0 0 x63 Days (Al1) 64 1 (2%) 1.0000 1 0 1 (100%) x49 Days (Group 1) 36 1 (3%) 1 0 0 0 57-63 Days (Group 3) 12 0 0 0 0 0 x63 Days (Al1) 64 1 (2%) 1.0000 1 0 1 (100%) x49 Days (Group 1) 36 1 (3%) 1 0 0 0 x63 Days (Group 3) 12 0 0 0 0 0 x63 Days (Group 3) 12 0 0 0 0 0 x63 Days (Group 1) 36 1 (3%) 1 1 (100%) 0 0 0 x63 Days (Group 1) 36 1 (3%) 1	x63 Days (All) 64 4 (6%) 0.3760 4 2 (50%) 2 (50%) 0 x49 Days (Group 1) 36 4 (11%) 4 2 (50%) 2 (50%) 0 50.56 Days (Group 2) 16 0 0 0 0 0 57.63 Days (Group 3) 12 0 0 0 0 0 x63 Days (All) 64 1 (2%) 1.0000 1 0 1 (100%) 0 x49 Days (Group 1) 36 1 (3%) 1 0 0 0 0 57.63 Days (Group 2) 16 0 0 0 0 0 57.63 Days (Group 3) 12 0 0 0 0 0 57.63 Days (Group 3) 12 0 0 0 0 0 x63 Days (Group 3) 12 0 0 0 0 0 x63 Days (Group 1) 36 1 (3%) 1 0 0 1 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^[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.

Page 41 of 53

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			Sever	ity	
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events	Mi	1 d	Moderate	Severe	Unknow
GASTRO-INTESTINAL SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	64	40 (63%	0.3372	78	35	(45%)	25 (32%)	18 (23%)	0
	≰49 Days (Group 1)	36	25 (69%)	51	21	(41%)	16 (31%)	14 (27%)	0
	50-56 Days (Group 2)	16	B (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	≰63 Days (All)	64	13 (20%	0.5833	13	7	(54%)	4 (31%)	2 (15%)	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	s63 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%)	ì	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%)	14 (30%)	10 (22%)	0
	≰49 Days (Group 1)	36	21 (58%)	29	12	(41%)	9 (31%)	8 (28%)	0
- 1 , , , , , , , , , , , , , , , , , , ,	50-56 Days (Group 2)	16	8 (50%)	9	5	(56%)	3 (331)	1 (11%)	0
	57-63 Days (Group 3)	12	6 (50%)	. 8	5	(63,1)	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 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.

Page 42 of 53

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	Num of		Fisher's exact				la.	
Body System/Event	Group (2)	of Pts		vent	p value	Number of Events	Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)										
VOMITING	≤63 Days (All)	64	13	(20%)	0.3300	16	6 (38%)	5 (31%)	5 (31%)	0
	≤49 Days (Group 1)	36	10			13	5 (38%)	4 (31%)	4 (31%)	0
	50-56 Days (Group 2)	16	2	(13%)		2	1 (50%)	0	1 (50%)	0
	57 63 Days (Group 3)	12	1	(8%)		1	0	1 (100%)	0	0
ESPIRATORY SYSTEM DISORDERS										
ANY EVENT	s63 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	ň
	50-56 Days (Group 2)	16	0			0	0	0	0	Ô
	57-63 Days (Group 3)	12	0			0	0	0	0	o
SINUSITIS	≤63 Days (All)	64	1	(2%)	1.0000	1	1 (100%)	0	0	0
	s49 Days (Group 1)	36	1	(3%)		1	1 (100%)	0	Ô	Ô
	50-56 Days (Group 2)	16	0			0	0	0	0	Ô
	57-63 Days (Group 3)	12	0			0	0	0	ō	o
RED BLOOD CELL DISORDERS										
ANY EVENT	≤63 Days (All)	64	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1	(3%)		1	1 (100%)	o	o o	Ô
	50-56 Days (Group 2)	16	0	•		Õ	0	o o	Ô	0
	57 63 Days (Group 3)	12	0			0	o	o	0	0
4	•									

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol obserwation 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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42

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

Page 43 of 53

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	Number				
Body System/Event	Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS (cont.)									
ANAEMIA	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	n
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	Ö	Ō	n
	50-56 Days (Group 2)	16	0		0	0	0	o o	n
	57-63 Days (Group 3)	12 .	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE							1		
ANY EVENT	≤63 Days (All)	64	1 (2%)	1.0000	1	o '	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	n
	57-63 Days (Group 3)	12	0		0	0	Ö	ō	Ö
UTERINE DISORDER NOS	≰63 Days (All)	64	1 (2%)	1.0000	1	0	0	1 (100%)	n
	≤49 Days (Group 1)	36	1 (3%)		1	0	Ô	1 (100%)	ŏ
	50-56 Days (Group 2)	16	0		0	0	0	0	n
	57-63 Days (Group 3)	1.2	0		0	o	Ō	ō	Ö
ODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	64	57 (89%)	0.3526	148	62 (42%)	55 (37%)	31 (21%)	o
· · · · · · · · · · · · · · · · · · ·	s49 Days (Group 1)	36	30 (83%)		82	41 (50%)	26 (32%)	15 (18%)	0
,		16							0
	57-63 Days (Group 3)	12	12 (100%)		30	11 (37%)	13 (43%)	6 (20%)	0
	50-56 Days (Group 2) 57-63 Days (Group 3)				36 30	10 (28%) 11 (37%)	16 (44%) 13 (43%)	10 6	

^[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 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.

Page 44 of 53

Appendix D, Table Sc (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			_ •	Sever	it v		
Body System/Event	Group [2]	of Pts	w/Event	p value	of Events		11d		erate	•	ere	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)											
ABDOMINAL PAIN	≤63 Days (All)	64	57 (89%)	0.3526	131	53	(40%)	50	(38%)	28	(21%)	0
	s49 Days (Group 1)	36	30 (83%)		70	35	(50%)	22		13	(19%)	Ö
	50 56 Days (Group 2)	16	15 (94%)		32	8	(25%)	15		9	(28%)	0
	57-63 Days (Group 3)	12	12 (100%)		29	10	(34%)	13		6		0
BACK PAIN	≤63 Days (All)	64	4 (6%)	0.8096	6	3	(50%)	1	(17%)	2	(33%)	0
1	49 Days (Group 1)	36	3 (8%)		5	2	(40%)	1		2	(40%)	0
	50-56 Days (Group 2)	16	1 (6%)		1	1	(100%)	0		0	,,,,,	Ô
	57 63 Days (Group 3)	12	0		0	0		0		0		Ö
FATIGUE	s63 Days (All)	64	5 (8%)	1.0000	6	2	(33%)	4	(67%)	0		0
	≰49 Days (Group 1)	36	3 (8%)		3	0		3	(100%)	0		0
	50-56 Days (Group 2)	16	1 (6%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	12	1 (8%)		1	1	(100%)	0		0		0
HOT FLUSHES	≤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
LEG PAIN	≤63 Days (All)	64	2 (3%)	0.6875	2	1	(50%)	0		1	(50%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	1	(100%)	0		0	•	0
-	50-56 Days (Group 2)	16	1 (6%)		1	0	•	. 0	4. 1	1	(100%)	0
	57-63 Days (Group 3)	12	0		• 0	0			•	6		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.

Page 45 of 53

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

Center: BORGATTA (#6)

	Gestational	Total	Number	Fisher's					
Body System/Event	Age Group (2)	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	ity Severe	Unknown
	-		.,						
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
MALAISE	≰63 Days (All)	64	1 (2	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3	b)	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
RIGORS	≤63 Days (All)	64	1 (2	1.0000	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	36	1 (3	b)	1	1 (100%)	0	0	0
	50456 Days (Group 2)	16	0		0	0	o .	0	0
	57 63 Days (Group 3)	12	0		0	0	0	0	0
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	64	1 (2	0.4375	1:	0	1 (100%)	0	0
:	≤49 Days (Group 1)	36	0		0	0	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
INFECTION VIRAL	≤63 Days (All)	64	1 (2	0.4375	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
,	50-56 Days (Group 2)	16	1 (6	b)	1	0	1 (100%)	0	o
	57-63 Days (Group 3)	12	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.

Page 46 of 53

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

Center: MALLOY (#7)

	Gestational	Total Number	Numb		Fisher's	Marin II							
Body System/Event	Age Group (2)	of Pts	of Pts w/Event		exact p-value	Number of Events		ld		Sever	•	ere	Unknow
•													
ANY EVENT	≤63 Days (All)	52	52 ((100%)		259	100	(39%)	92	(36%)	67	(26%)	0
	s49 Days (Group 1)	19	19 ((100%)		84	31	(37%)	28	(33%)	25	(30%)	0
	50-56 Days (Group 2)	11	11 ((100%)		58	27	(47%)	21	(36%)	10	(17%)	0
	57-63 Days (Group 3)	22	22 ((100%)		117	42	(36%)	43	(37%)	32		0
INTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≰63 Days (All)	52	11	(21%)	0.7522	26	11	(42%)	11	(42%)	4	(15%)	0
	s49 Days (Group 1)	19	3	(16%)		5	1	(20%)	4	(80%)	0		0
	50-56 Days (Group 2)	11	3	(27%)		6	5	(83%)	0		1	(17%)	0
	57-63 Days (Group 3)	22	5	(23%)		15	5	(33%)	7	(47%)	3	(20%)	0
DIZZINESS	≤63 Days (All)	52	4	(8%)	1.0000	7	4	(57%)	2	(29%)	1	(14%)	0
	≤49 Days (Group 1)	19	1	(5%)		1	0			(100%)	0		0
	50 56 Days (Group 2)	11	1	(9%)		1	1	(100%)	0		0		0
	57 63 Days (Group 3)	22	2	(91)		5	3	(60%)	1	(20%)	1	(20%)	0
HEADACHE	≤63 Days (All)	52	9	(17%)	0.5764	19	7	(37%)	9	(47%)	3	(16%)	0
	≤49 Days (Group 1)	19	3	(16%)		4	1	(25%)	3	(75%)	0		0
r · · · · · · ·	50-56 Days (Group 2)	11	3	(27%)		5	4	(80%)	0		1	(20%)	0
	57-63 Days (Group 3)	22	3	(14%)		10	2	(201)	6	(60%)	2		0
STRO-INTESTINAL SYSTEM DISORDERS	•												
ANY EVENT	≤63 Days (All)	52	35	(67%)	1.0000	76	30	(39%)	, 22	(29%)	24	(32%)	0
± 4 € .	s49 Days (Group 1)	19	13	(68%)		, 23	8	(35%)		(261)	9	(39%)	0
	50-56 Days (Group 2)	11	7	(64%)		18	10	(564)		(33%)	2	(11%)	0
	57-63 Days (Group 3)	22	15	(68%)		35	12	(34%)	10	(291)	13	(37%)	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 misoprostol or for which the relationship was not assessed.

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43

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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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Page 47 of 53

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

Center: MALLOY (#7)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number			-		Severi	ity	· - · - ·	
Body System/Event	Group [2]	of Pts	w/Event		p-value	of Events	Mi	ld		Mode	rate	Se	vere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)														
CONSTIPATION	≤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
DIARRHEA	≤63 Days (All)	52	10	(19%)	0.7388	11	5	(45%)		3	(27%)	3	(27%)	0
	≤49 Days (Group 1)	19	4	(21%)		4	2	(50%)		2	(50%)	0		0
	50 56 Days (Group 2)	11	1	(9%)		'n	1	(100%)		0	. ,	0		0
•	57 63 Days (Group 3)	22	5			6	2	(334)		1	(17%)	3	(50%)	0
NAUSEA	≤63 Days (All)	52	33	(63%)	0.8720	43	17	(40%)		11	(26%)	15	(35%)	0
	≰49 Days (Group 1)	19	11	(58%)		14	5	(36%)		1	(7%)	8		0
	50-56 Days (Group 2)	11	7			11	6	(55%)		4		. 1		0
	57-63 Days (Group 3)	22	15	(68%)		18	6	(33%)	1	6	(33%)	6		ō
VOMITING .	≤63 Days (All)	52	15	(29%)	0.9255	21	8	(38%)		8	(38%)	5	(24%)	0
	≰49 Days (Group 1)	19	5	(26%)		5	1	(20%)		3	(60%)	1	(20%)	0
	50 56 Days (Group 2)	11	3	(27%)		6	3	(50%)		2	(33%)	1	(17%)	0
	57 63 Days (Group 3)	22	7	(321)		10	4	(40%)		3	(30%)	3	(30%)	0
RED BLOOD CELL DISORDERS														
ANY EVENT	≤63 Days (All)	52	2	(4%)	0.0415	2	1	(50%)		1	(50%)	0		0
4. , , , , , , , , , , , , , , , , , , ,	≰49 Days (Group 1)	19	0			0	0	•	•		4. (0		0
3 A	50-56 Days (Group 2)	11	2	(18%)		. 2	1	(50Å)		1	(50%)	0		0
	57-63 Days (Group 3)	22	0			0	0	ľ		0	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.

Page 48 of 53

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

Center: MALLOY (#7)

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number -				·-··Severi	tv		
Body System/Event	Group (2)	of Pts	w/Event		p value	of Events		ld		derate	-	ere	Unknown
RED BLOOD CELL DISORDERS (cont.)		***				····							
ANAEMIA	£63 Days (All)	52	2	(4%)	0.0415	2	1	(50%)	; 1	L (50%)	0		0
	≰49 Days (Group 1)	19	0			0	0				0		0
	50-56 Days (Group 2)	11	2	(18%)		2	1	(50%)	,	(50%)	ō		0
	57-63 Days (Group 3)	22 .	0			0	0		()	0		0
TRINARY SYSTEM DISORDERS													
ANY EVENT	. s63 Days (All)	52	1	(2%)	1.0000	2	1	(50%)			1	(50%)	0
	#49 Days (Group 1)	19	0			0	0		Č		ō		0
	50-56 Days (Group 2)	11	0			0	0)	o		0
	57-63 Days (Group 3)	22	1	(5%)		2	1	(50%)	Ċ)	1	(50%)	0
URINARY TRACT INFECTION	≤63 Days (All)	52	1	(2%)	1.0000	2	1	(50%)	()	i	(50%)	0
	≤49 Days (Group 1)	19	0			0	0		()	ō	,	0
	50-56 Days (Group 2)	11	0			0	0)	Ö		0
	57-63 Days (Group 3)	22	ı	(5%)		2	1	(50%)	()	1	(50%)	0
EPRODUCTIVE DISORDERS, FEMALE			•										
ANY EVENT	≤63 Days (All)	52	1	(2%)	0.2115	1	0		1	(100%)	0		0
v.	≤49 Days (Group 1)	19	0			0	0)	0		0
	50-56 Days (Group 2)	11	1	(91)		1	0			(100%)	ō		0
	57-63 Days (Group 3)	22	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 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.

Page 49 of 53

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

Center: MALLOY (#7)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number				Severi	itv		
Body System/Event	Group (2)	of Pts	w/Event	p-value	of Events		1d		rate	•	(25%) (29%) (29%) (23%) (23%) (26%) (30%) (21%) (25%)	Unknown
EPRODUCTIVE DISORDERS, PENALE (cont.)								· · · · · · · · · · · · · · · · · · ·				
VAGINITIS	≤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
ODY AS A WHOLE - GENERAL DISORDERS									ŧ			
ANY EVENT	≰63 Days (All)	52	51 (98%)	1.0000	152	57	(38%)	57	(38.9)	38	(25%)	0
	≤49 Days (Group 1)	19	19 (100%)		56	22	(39%)	16	(32%)	16	(29%)	0
	50-56 Days (Group 2)	11	11 (100%)		-31	11	(35%)	13	(42%)	7	(23%)	0
	57-63 Days (Group 3)	22	21 (95%)		65	24	(37%)	26	(40%)	15	(23%)	0
ABDOMINAL PAIN	≰63 Days (All)	52	50 (96%)	0.5023	142	55	(39%)	50	(35%)	37	(26%)	0
	≤49 Days (Group 1)	19	19 (100%)		54	22	(41%)	16	(30%)	16	(30%)	0
	50-56 Days (Group 2)	11	11 (100%)		28	10	(36%)	12	(43%)	6	(21%)	0
	57-63 Days (Group 3)	22	20 (91%)		60	23	(38%)	22	(37%)	15	(25%)	0
BACK PAIN	≤63 Days (All)	52	7 (13%)	0.0838	7	2	(29%)	5	(71%)	0		0
	≤49 Days (Group 1)	19	0		0	0		0		0		0
· ·	50 56 Days (Group 2)	11	2 (18%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	22	5 (23%)		5	1	(20%)	4	(80%)	0		0
LEG PAIN	≤63 Days (All)	52	1 (2%)	0.5769	2	0			(100%)	0		0
÷.	≰49 Days (Group 1)	19	1 (5%)		2	0	"•	. 2	(1001)	0		0
v v • • 2	50-56 Days (Group 2)	11	0		• 0	0	, į	, 0		0		0
• .	57-63 Days (Group 3)	22	0		0	0	7	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.

Page 50 of 53

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

Center: MALLOY (#7)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts	Fisher's exact			Severity			
			w/Event	p·value	of Events	Mild	Moderate	Severe	Unknown	
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)									
RIGORS	≤63 Days (All)	52	1 (2	*) 0.2115	1	0	0	1 (100%)	0	
	s49 Days (Group 1)	19	0		0	0	0	0	0	
	50-56 Days (Group 2)	11	1 (9	\$)	ì	0	0	1 (100%)	0	
	57-63 Days (Group 3)	22 .	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 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.

Page 51 of 53

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

Center: ROTHENBERG (#8)

	Gestational Age Group (2)	Total Number		Fisher's exact p-value	Number		···Severity·····					
Body System/Event		of Pts			of Events		1 d		rate	Sev		Unknown
ANY EVENT	≤63 Days (All)	21	17 (81%)	0.2919	51	20	(39%)	19	(37%)	12	(24%)	•
	≤49 Days (Group 1)	13	9 (69%)	0.2313	23	13		7		3		0
	50-56 Days (Group 2)	5	5 (100%)		18	4	(22%)		(44%)	-	(33%)	
	57-63 Days (Group 3)	3 .	3 (100%)		10	3	(30%)	4			(30%)	0 0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS	•											
ANY EVENT	≤63 Days (All)	21	4 (19%)	0.1724	4	0		3	(75%)	1	(25%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	ō		_	(100%)	ō	(=3-,	0
	50-56 Days (Group 2)	5	2 (40%)		2	0		1		i	(50%)	Ō
	57-63 Days (Group 3)	3	1 (33%)		1	0		1	(100%)	0	,,,,,	o
HEADACHE	≤63 Days (All)	21	4 (19%)	0.1724	4	0		3	(75%)	1	(25%)	0
I a second secon	≤49 Days (Group 1)	13	1 (8%)		1	0			(100%)	0		ō
1	50-56 Days (Group 2)	5	2 (40%)		2	0		1	(50%)	1	(50%)	ō
	57-63 Days (Group 3)	3	1 (33%)		1	0		1	(100%)	0	,,,,,	0
ASTRO-INTESTINAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	21	12 (57%)	0.3140	21	12	(57%)	6	(29%)	3	(14%)	0
'	≤49 Days (Group 1)	13	6 (46%)		13	8	(62%)	3	1 1	2		Ö
	50-56 Days (Group 2)	5	3 (60%)		4	1	(25%)	2	(50%)	1		0
	57-63 Days (Group 3)	3	3 (100%)		4	3	(75%)	1	1 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

J:\USA\166A\SASPGMS\apdxd\final\ade3.SAS 24NOV98:16:20

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

Page 52 of 53

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

Center: ROTHENBERG (#8)

	Gestational Age Group [2]	Total	Number of Pts w/Event	Fisher's exact p-value	Nb.a.			Severity					
Body System/Event		Number of Pts			Number of Events	Mile			rate	Sev		Unknow	
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)										-			
DIARRHEA	≤63 Days (All)	21	5 (24%)	0.7892	6	4	(67%)	2	(33%)	0		0	
	≤49 Days (Group 1)	13	4 (31%)		5	3	(60%)	2	(40%)	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	8 (38%)	0.0394	11	7	(64%)	2	(18%)	2	(18%)	0	
1	≤49 Days (Group 1)	13	3 (23%)		6	4	(67%)	1	(17%)	1	(17%)	0	
•	50 56 Days (Group 2)	5	2 (40%)		2	0		1	(5₫%)	1 .	(50%)	0	
	57-63 Days (Group 3)	3	3 (100%)		3	3 (100%)	0		0		0	
VOMITING	≤63 Days (All)	21	4 (19%)	0.7611	4	1	(25%)	2	(50%)	1	(25%)	0	
	≤49 Days (Group 1)	13	2 (15%)		2	1	(50%)	0		1	(50%)	0	
	50-56 Days (Group 2)	5	1 (20%)		1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	3	1 (33%)		1	0		1	(100%)	0		0	
DDY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	21	15 (71%)	0.0652	26	8	(31%)	10	(38%)	8	(31%)	0	
	≤49 Days (Group 1)	13	7 (54%)		9	5	(56%)	3	(33%)	1	(11%)	0	
	50-56 Days (Group 2)	5	5 (100%)		12	3	(25%)	. 5	(42%)	4	(33%)	0	
,	57-63 Days (Group 3)	3	3 (100%)		5	0		2	(40%)	3	(60%)	0	
ABDOMINAL PAIN	≤63 Days (All)	21	15 (71%)	0.0652	25	8	(32%)	9	(36%)	8	(32%)	0	
	≤49 Days (Group 1)	13	7 (54%)		9	5	(56%)	3,	, (33%)	1	(11%)	0	
* ,	50-56 Days (Group 2)	5	5 (100%)		11	3	(27%)	1 y 4	1 (36%)	4	(36%)	0 .	
r e • i · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	3	3 (100%)		5	0		2	(40%) I	3	(60 %)	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

J:\USA\166A\SASPGMS\apdxd\final\ade3.SAS 24NOV98:16:20

FINAL

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

Page 53 of 53

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

Center: ROTHENBERG (#8)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts	Fisher's exact		Severity				
			w/Event	p value	of Events	Mild	Moderate	Severe	Unknown	
ODY AS A WHOLE - GENERAL DISORDS	IRS (cont.)									
BACK PAIN	≰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	0	
	57 63 Days (Group 3)	٦.	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.