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	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severit	v		
Body System/Event [2]	Group [3]	of Pts	w/Event		p-value	of Events			Moderate		Severe		Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS	(cont.)												
MYALGIA	≤63 Days (All)	89	1	(1%)	0.6067	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	0		0		1	(100%)	ō
	57-63 Days (Group 3)	20	0			0	0		0		0		0
ENTR & PERIPH NERVOUS SYSTEM DISC	DRDERS												
ANY EVENT	≤63 Days (All)	89	33	(37%)	0.3615	61	15	(25%)	30	(49%)	16	(26%)	0
	≤49 Days (Group 1)	35	11	(31%)		17	3	(18%)	10	(59%)	4	(24%)	ō
	50-56 Days (Group 2)	34	12	(35%)		19	7	(37%)	7	(37%)	5	(26%)	ō
	57-63 Days (Group 3)	20	10	(50%)		25	5	(20%)	13	(52%)	7		ō
DIZZINESS	s63 Days (All)	89	13	(15%)	0.5865	17	5	(29%)		(24 ¹ 8)	A	(47%)	0
	#49 Days (Group 1)	35	7	(20%)		8	2	(25%)	2	(25%)	4	(50%)	Ö
	50-56 Days (Group 2)	34	4	(12%)		5	2	(40%)	2	(40%)	1	(20%)	. 0
	57-63 Days (Group 3)	20	2	(10%)		4	1	(25%)	0	(101)	3	(75%)	ō
HEADACHE	≤63 Days (All)	89	24	(27%)	0.0079	44	10	(23%)	26	(59%)	a	(18%)	0
	s49 Days (Group 1)	35	4	(11%)		9	1	(11%)	8	(89%)	ō	, ,	ō
	50-56 Days (Group 2)	34	10	(29%)		14	5	(36%)	5	(36%)	4	(29%)	Ö
	57-63 Days (Group 3)	20	10	(50A)		21	4	(19%)	13	(62%)	4	(19%)	Ö
	•			i									-

^[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.

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

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^[2] NOS - Not otherwise specified

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

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Foup [3] 53 Days (All) 19 Days (Group 1) 19-56 Days (Group 2) 7-63 Days (Group 3) 53 Days (All)	89 35 34 20	1 0 1 0	(11) (31)	p-value 0.6067	Number of Events	Mild 0 0	Moderate 1 (100%)	Severe 0	Unknow 0
19 Days (Group 1) 0-56 Days (Group 2) 7-63 Days (Group 3) 63 Days (All)	35 34 20	-		0.6067	1 0 1	0	1 (100%)		0
19 Days (Group 1) 0-56 Days (Group 2) 7-63 Days (Group 3) 63 Days (All)	35 34 20	-		0.6067	1 0 1	0	1 (100%) 0		0
7-56 Days (Group 2) 7-63 Days (Group 3) 53 Days (All)	34 20	-			0	0	0		v
7-63 Days (Group 3)	20	-	(31)		1	Ĭ		0	0
3 Days (All)		0				0	1 (100%)	0	0
-:					0	ō	0	Ö	0
-:	89	1	(1%)	0.6067	1	0	1 (100%)	•	
9 Days (Group 1)	35	ō	,,	0.0007	•	0	1 (1004)	0	0
-56 Days (Group 2)	34	ĭ	(3%)		ĭ	0	1 (100%)	0	0
-63 Days (Group 3)	20	ō	(30)		Ō	ō	1 (100%) 0	0	0
3 Days (All)	89	5	(6%)	1.0000	6	3 (50%)	1 (17%)	2 (33%)	•
9 Days (Group 1)	35	2	(61)		2	1 (50%)	0	1 (50%)	0
-56 Days (Group 2)	34	2	(6%)		13		-		0
-63 Days (Group 3)	20	1	(51)		1	1 (100%)	0	0 (334)	0
3 Davs (All)	89	2	(21)	0 6961	,	2 (100%)	•	•	_
•		ī		0.0301	1			0	0
-		Ô	(34)		•	1 (1004)		0	0
		1	(5%)		1	1 (100%)		U	0
	•	63 Days (Group 3) 20 3 Days (All) 89 9 Days (Group 1) 35 56 Days (Group 2) 34	63 Days (Group 3) 20 1 3 Days (All) 89 2 9 Days (Group 1) 35 1 56 Days (Group 2) 34 0	63 Days (Group 3) 20 1 (5%) B Days (All) 89 2 (2%) D Days (Group 1) 35 1 (3%) 56 Days (Group 2) 34 0	-63 Days (Group 3) 20 1 (5%) 3 Days (All) 89 2 (2%) 0.6961 9 Days (Group 1) 35 1 (3%) -56 Days (Group 2) 34 0	63 Days (Group 3) 20 1 (5%) 1 B Days (All) 89 2 (2%) 0.6961 2 D Days (Group 1) 35 1 (3%) 1 56 Days (Group 2) 34 0 0	-63 Days (Group 3) 20 1 (5%) 1 1 (100%) B Days (All) 89 2 (2%) 0.6961 2 2 (100%) D Days (Group 1) 35 1 (3%) 1 1 (100%) -56 Days (Group 2) 34 0 0 0	-63 Days (Group 3) 20 1 (5%) 1 1 (100%) 0 B Days (All) 89 2 (2%) 0.6961 2 2 (100%) 0 D Days (Group 1) 35 1 (3%) 1 1 (100%) 0 -56 Days (Group 2) 34 0 0 0 0	-63 Days (Group 3) 20 1 (5%) 1 1 (100%) 0 0 B Days (All) 89 2 (2%) 0.6961 2 2 (100%) 0 0 D Days (Group 1) 35 1 (3%) 1 1 (100%) 0 0 -56 Days (Group 2) 34 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.

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

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	Gestational				Fisher's exact	Severity								
Body System/Event [2]	Age Group [3]		of Pts				Number of Events	Mi		Mode		•	ere	Unknow
SYCHIATRIC DISORDERS (co	nt.)						** **							
DEPRESSION	≤63 Days (A	11)	89	3	(3%)	0.6123	4	1	(25%)	1	(25%)	2	(50%)	0
	≤49 Days (G	roup 1)	35	1	(3%)		1	0		0		1	(100%)	0
	50-56 Days	(Group 2)	34	2	(6%)		3	1	(33%)	1	(33%)	1	(33%)	0
	57-63 Days	(Group 3)	20	0			0	0		0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS			•											
ANY EVENT	≤63 Days (Al	11)	89	57	(64%)	0.5184	126	42	(33%)	62	(49%)	22	(17%)	0
	±49 Days (G	roup 1)	35	22	(63%)		40	11	(28%)	17	(43%)	12	(30%)	0
	50-56 Days	(Group 2)	34	24	(71%)		56	16	(32%)	32	(57%)	6	(11%)	0
	57-63 Days	(Group 3)	20	11	(55%)		30	13	(43%)	13	(43%)	4	(134)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (A)	11)	89	1	(1%)	0.2247	1	0		. 0	1	1	(100%)	0
	≤49 Days (G	roup 1)	35	0			0	0		0		0		0
	50-56 Days	(Group 2)	34	0			0	0		0		0		0
	57-63 Days	(Group 3)	20	1	(5%)		1	0		0		1	(100%)	0
DIARRHEA	≤63 Days (Al	11)	89	24	(27%)	0.7512	30	13	(43%)	13	(43%)	4	(13%)	0
	s49 Days (G	roup 1)	35	10	(29%)		12	7	(58%)	4	(33%)	1	(8%)	0
	50-56 Days	(Group 2)	34	10	(29%)		13	5	(38%)	7	(54%)	1	(8%)	0
	57-63 Days	(Group 3)	20	4	(20%)		5	1	(20%)	2	(40%)	2	(40%)	0

^[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.

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

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	Gestational Age	Total Number	Numi of		Fisher's exact	Number				Severit	; y		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p·value	of Events	Mi	1d '	Mode	rate	Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												
DYSPEPSÍA	≤63 Days (All)	89	2	(2%)	0.6961	4	1	(25%)	3	(75%)	0		0
	≤49 Days (Group 1)	35	1	(3%)		1	0		1	(100%)	0		0
	50-56 Pays (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	1	(5%)		3	1	(33%)	2	(67%)	0		0
FLATULENCE	≤63 Days (All)	89	1	(1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	35	1	(3%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	89	50	(56%)	0.4256	66	25	(38%)	27	(41%)	14	(21%)	0
,	≤49 Days (Group 1)	35	17	(49%)		21	4	(19%)	. 9	(43%)	8	(38%)	0
	50-56 Days (Group 2)	34	22	(65%)		30	12	(40%)	13	(43%)	5	(17%)	0
	57-63 Days (Group 3)	20	11	(55%)		15	9	(60%)	5	(33%)	1	(7%)	0
SALIVA INCREASED	≤63 Days (All)	89	1	(1%)	0.2247	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	35	0			. 0	0		Ö		0		Ō
	50-56 Days (Group 2)	34	0			0	0		0		0		Ó
	57-63 Days (Group 3)	20	1	(5%)		1	0		1	(100%)	0		0
VOMITING	≤63 Days (All)	89	22	(25%)	0.1241	23	3	(13%)	18	(78%)	2	(9%)	0
	≤49 Days (Group 1)	35	5	(14%)		5	0		3	(60%)	2	(40%)	0
	50-56 Days (Group 2)	34	12	(35%)		13	1	(8%)	12	(92%)	0		0
	57-63 Days (Group 3)	20	5	(25%)		5	2	(40%)	3	(60%)	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.

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

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^[2] NOS - Not otherwise specified

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

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

	Gestational	Total	Numb		Fisher's	N		Severit		
Body System/Event [2]	Age Group [3]	Number of Pts	of F w/Ev		exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL										
ANY EVENT	≤63 Days (All)	89	2	(2%)	0.5174	2	0	1 (50%)	1 (50%)	0
	s49 Days (Group 1)	35	0			0	0	0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	1 (100%)	0	0
HYPOTENSION	≤63 Days (All)	89	2	(2%)	0.5174	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	35	0			0	0	0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	1 (100%)	0	0
EART RATE AND RHYTKH DISORDERS										
ANY EVENT	≤63 Days (All)	89	1	(1%)	0.2247	1	0	О '	1 (100%)	0
	s49 Days (Group 1)	35	0			0	0	0	0	0
!	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	0	1 (100%)	0
PALPITATION	≤63 Days (All)	89	1	(1%)	0.2247	1	0	0	1 (100%)	0
	s49 Days (Group 1)	35	0			0	0	0	0	0
1	50-56 Days (Group 2)	34	0			0	0	, 0	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	0	1 (100%)	0

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

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

^[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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	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severi	: v	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ESPIRATORY SYSTEM DISORDERS									···
ANY EVENT	≤63 Days (All)	89	1 (1%)	0.2247	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	ň
	50-56 Days (Group 2)	34	0		0	0	0	ō	o
	57-63 Days (Group 3)	20	1 (5%)		1	0	1 (100%)	0	ō
PULMONARY CONGESTION	≤63 Days (All)	89	1 (1%)	0.2247	1	0	1 (100%)	o [']	0
	≤49 Days (Group 1)	35	0		0	O	0	0	. 0
	50-56 Days (Group 2)	34	0		0	0	o '	i O	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	1 (100%)	! o	0
RIMARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	1 (1%)	0.6067	2	1 (50%)	0 ,	1 (50%)	0
	≤49 Days (Group 1)	35	0		0	0	o ,	0	0
	50-56 Days (Group 2)	34	1 (3%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	o
MICTURITION URGENCY	s63 Days (All)	89	1 (1%)	0.6067	1	1 (100%)	0	n	0
	≤49 Days (Group 1)	35	0		0	0	Ŏ	Õ	ő
	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	Ô	Õ
	57-63 Days (Group 3)	20	0		ō	0	0	0	n

^[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.

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

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^[2] NOS - Not otherwise specified

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

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

	Gestational Age	Total Number	Number of Pts		Fisher's exact	NumberSeverity							
Body System/Event (2)	Group [3]	of Pts		vent	p-value	of Events	Mild	Moderate	Severe	Unknow			
FRINARY SYSTEM DISORDERS	(cont.)												
URINARY TRACT INFECTION	≤63 Days (All)	89	1	(1%)	0.6067	1	0 .	0	1 (100%)	0			
	≤49 Days (Group 1)	35	0			0	0	0	0	0			
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0			
	57-63 Days (Group 3)	20	0			0	0	0	0	0			
EPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	89	11	(12%)	0.0587	14	4 (29%)	0	10 (71%)	0			
· ·	s49 Days (Group 1)	35	2	(6%)		2	2 (100%)	0	0	0			
	50-56 Days (Group 2)	34	8	(24%)		11	2 (18%)	0	9 (82%)	0			
,	57-63 Days (Group 3)	20	1	(5%)		1	0	0	1 (100%)	0			
BREAST DISCHARGE	≤63 Days (All)	89	1	(11)	1.0000	1	1 (100%)	. 0 '	0	0			
	s49 Days (Group 1)	35	1	(3%)		1	1 (100%)	0	0	0			
	50-56 Days (Group 2)	34	0			0	0	0	0	0			
	57-63 Days (Group 3)	20	0			0	0	0	0	0			
BREAST PAIN FEMALE	≤63 Days (All)	89	1	(1%)	0.6067	1	0	0	1 (100%)	0			
	≤49 Days (Group 1)	35	0			0	0	0	0	0			
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0			
	57-63 Days (Group 3)	20	0	4		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.

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

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Body System/Event [2]	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	tv	
	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, PENALE	(cont.)								
LEUKORRHOEA	≰63 Days (All)	89	1 (1%)	0.6067	,	1 (1008)	ā		
	≤49 Days (Group 1)	35	0 (31)	0.000,		1 (100%)	0	0	0
	50-56 Days (Group 2)	34	1 (31)		•	0	0	0	0
	57-63 Days (Group 3)	20	0 (34)			1 (100%)	0	0	0
	3, 24, (313 <u>p</u> 3,		v		0	0	0	0	0
OVARIAN DISORDER	≤63 Days (All)	89	1 (1%)	1.0000	-				
	≤49 Days (Group 1)	35	1 (3%)	1.0000	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34			1	1 (100%)	0	0	0
	\$7-63 Days (Group 3)	20	0		0	0	0	0	0
	v. vs buye (Group 3)	20	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	89	7 (8%)						
•	#49 Days (Group 1)	35	, ,,,,	0.0113	10	1 (10%)	. 0 ,	9 (90%)	0
	50-56 Days (Group 2)		0		O	0	0	0	0
	57-63 Days (Group 3)	34	6 (18%)		9	1 (11%)	0	8 (89%)	0
	37-03 Days (Group 3)	20	1 (5%)		' 1	0	0	1 (100%)	0
eoplash								1	
ANY EVENT	≤63 Days (All)								
		89	1 (1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	ō
	50-56 Days (Group 2)	34	0		0	0	0	ō	Õ
	57-63 Days (Group 3)	20	0		0	0	Ö	ň	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 which the relationship was not assessed.

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

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

^[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.

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

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^[2] NOS = Not otherwise specified

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

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

Center:

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	· · · · · · · · · · · · · · · · · · ·	····Severit	y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ODY AS A MHOLE - GENERAL DISORDERS	(cont.)								
BACK PAIN	≤63 Days (All)	89	7 (8%)	0.6016	7	2 (29%)	1 (14%)	4 (57%)	0
	≤49 Days (Group 1)	35	2 (6%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	34	4 (12%)		4	2 (50%)	0	2 (50%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0
CHEST PAIN	s63 Days (All)	89	1 (1%)	0.6067	2	1 (50%)	1 (50%)	o	0
	≤49 Days (Group 1)	35	0		. 0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		' 2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	89	6 (7%)	0.2181	6	2 (33%)	2 (33%)	2 (33%)	0
•	s49 Days (Group 1)	35	2 (6%)		2	0	1 (504)	1 (50%)	0
	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	3 (15%)		3	1 (33%)	1 (33%)	1 (33%)	0
FEVER	≤63 Days (All)	89	2 (2%)	1.0000	, 2	2 (100%)	0	0	0
	<pre>s49 Days (Group 1)</pre>	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
LEG PAIN	s63 Days (All)	89	1 (1%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	35	1 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0

^[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.

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

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⁽²⁾ NOS = Not otherwise specified

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

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

- 1 - 0 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	Gestational Age	Total Number	Number of Pts	Fisher's exact		Mild	Severity	Severe	Unknow
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	WIIG	moderace	Severe	OTIATION
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
PAIN	≤63 Days (All)	89	1 (1%)	0.6067	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
RIGORS	≤63 Days (All)	89	2 (2%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	89	1 (1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	35	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
1	57-63 Days (Group 3)	20	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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Num of		Fisher's exact	Number		,		Severit	y			
Body System/Event [2]	Group (3)	of Pts	w/E	vent	p value	of Events		1 d		rate	•	ere	Unk	cnown
ANY EVENT	-62 Davis (811)	125		(0.58)	0.0366								_	
7417 5 7 5 7 1 7 1	s63 Days (All)	175	151	(86%)	0.0366	428	184	(43%)	176		66			(<11
	≤49 Days (Group 1)	71	56	(79%)		136	55	(40%)	57	(42%)	24	(18%)	0	
	50-56 Days (Group 2)	72	64	(89%)		202	94	(47%)	80	(40%)	27	(13%)	1	(<1%
	57-63 Days (Group 3)	32	31	(971)		90	35	(39%)	39	(43%)	15	(17%)	1	(11
SKIN AND APPENDAGES DISORDERS												•	i	
ANY EVENT	≤63 Days (All)	175	1	(<1%)	1.0000	1	O:		1	(100%)	0		, o	
	≤49 Days (Group 1)	71	0			0	0		0		. 0		ō	
	50-56 Days (Group 2)	72	1	(1%)		1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	32	0			0	0		0	,,	ō		ō	
SWEATING INCREASED	≤63 Days (All)	175	1	(<1%)	1.0000	1	0		. ,	(100%)	0			
	≤49 Days (Group 1)	71	0	, ,		0	0		'n	(1004)	Ö		0	
	50-56 Days (Group 2)	72	1	(1%)		1	0		•	(100%)	0		0	
	57-63 Days (Group 3)	32	ō	(,		ō	ŏ		0	(1004)	0		0	
ENTR 4 PERIPH MERVOUS SYSTEM DISORDERS														
ANY EVENT	s63 Days (All)	175	2	(11)	0.3331	2	,	(100%)			•			
ANY EVENT	s49 Days (Group 1)	71	0	(44)	0.3331	2	0	(1004)	0		0		0	
	50-56 Days (Group 2)	72	1	(1%)		1	-	(1005)	0		0		0	
	- · · · · · · · · · · · · · · · · · · ·		•			1		(100%)	0		0		0	
	57-63 Dayв (Group 3)	32	1	(3%)		1	1	(100%)	0		0		0	

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

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

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^[2] NOS = Not otherwise specified

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

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

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact		•••••	Severi	t v	
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISC	RDERS (cont.)								
DIZZINEŚS	≤63 Days (All)	175	1 (<1	0.1829	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	1 (31	1)	1	1 (100%)	0	0	0
HEADACHE	≤63 Days (All)	175	1 (<1	1.0000	1	1 (100%)	0	0	0
	s49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1	1)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
ASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	65 (37)	0.0658	103	65 (63%)	35 (34%)	3 (3%)	0
	≤49 Days (Group 1)	71	19 (27)	1)	27	15 (56%)	10 (37%)	2 (7%)	0
	50-56 Days (Group 2)	72	32 (44)	1)	55	36 (65%)	18 (33%)	1 (2%)	0
	57-63 Days (Group 3)	32	14 (44)	1)	21	14 (67%)	7 (33%)	0	0
DIARRHEA	≤63 Days (All)	175	25 (14)	0.0108	25	18 (72%)	7 (28%)	0	0
	≤49 Days (Group 1)	71	4 (6)	1)	4	4 (100%)	0	0	0
	50-56 Days (Group 2)	72	13 (18	1)	13	9 (69%)	4 (31%)	0	0
	57-63 Days (Group 3)	32	8 (25	i)	8	5 (63%)	3 (38%)	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.

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

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^[2] NOS = Not otherwise specified

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

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Num of		Fisher's exact	Number				- Severit	· V ·		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Event		ild	Mode		•	ere	Unknow
JASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)				.,		14			·····			· · · · · · · · · · · · · · · · · · ·
NAUSEA	≤63 Days (All)	175	45	(26%)	0.4964	45	27	(60%)	16	(36%)	2	(4%)	0
	≤49 Days (Group 1)	71	15	(211)		15	8	(53%)	6	(40%)	1	(7%)	0
	50-56 Days (Group 2)	72	20	(28%)		20	12	(60%)	7	(35%)	1	(5%)	0
	57-63 Days (Group 3)	32	10	(31%)		10	7	(70%)	3	(30%)	0		0
VOMITING	≤63 Days (All)	175	33	(19%)	0.0055	33	20	(61%)	12	(36%)	1	(3%)	0
	≤49 Days (Group 1)	71	8	(11%)		8	3	(38%)	4	(50%)	1	(13%)	0
	50-56 Days (Group 2)	72	22	(31%)		22	15	(68%)	7	(32%)	0		0
	57-63 Days (Group 3)	32	3	(9%)		3	2	(67%)	1	(33%)	0		0
ED BLOOD CELL DISORDERS													
ANY EVENT	≤63 Days (All)	175	2	(1%)	1.0000	2	0		. 0	1	2	(100%)	0
	#49 Days (Group 1)	71	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	72	1	(1%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	32	0			0	0		0		. 0		0
ANAEMIA	≤63 Days (All)	175	2	(14)	1.0000	2	0		0		2	(100%)	0
	≤49 Days (Group 1)	71	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	72	1	(1%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	32	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.

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

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^[2] NOS * Not otherwise specified

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

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

Center: WESTHOFF (#24)

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

^[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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Num of	Pts	Fisher's exact				 Mode	Severit	•	ere		cnown
Body System/Event [2]	Group [3]	of Pts	W/E	vent	p-value	of Events	Mi	10	mode	Lace	3EV	ere		,110WI1
REPRODUCTIVE DISORDERS, FEMALE	(cont.)													
UTERINE DISORDER NOS	≰63 Days (All)	175	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	71	0			0	0		0		0		0	
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	32	0			0	0		0		0		0	
UTERINE HAEMORRHAGE	≤63 Days (All)	175	8	(51)	1.0000	9	0		0		9	(100%)	0	
	≤49 Days (Group 1)	71	3	(41)		4	0		0		4	(100%)	0	
	50-56 Days (Group 2)	72	4	(6%)		4	0		0		4	(100%)	0	
	57-63 Days (Group 3)	32	1	(3%)		1	0		0		1	(100%)	0	
BODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	175	149	(85%)	0.0539	308	116	(38%)	139	(45%)	51	(17%)	2	(<1%
	\$49 Days (Group 1)	71	55	(77%)		104	40	(38%)	47	(45%)	17	(16%)	0	
	50-56 Days (Group 2)	72	64	(89%)		138	56	(41%)	60	(43%)	21	(15%)	1	(<1%
	57-63 Days (Group 3)	32	30	(94%)		66	20	(30%)	32	(48%)	13	(20%)	1	(21
ABDOMINAL PAIN	≤63 Days (All)	175	147	(841)	0.0920	300	112	(37%)	135	(45%)	51	(17%)	2	(<1%
ABDOMINAL PAIN	s49 Days (Group 1)	71	55	(77%)		102	39	(38%)	46	(45%)	17	(17%)	0	
	50-56 Days (Group 2)	72	62	(861)		134	54	(40%)	58	(43%)	21	(16%)	1	(<1%
	57-63 Days (Group 3)	32	30	(941)		64	19	(30%)	31	(48%)	13	(20%)	1	(21

^[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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: WESTHOFF (#24)

	Gestational	Total Number	Numb of P		Fisher's exact				Severit		
Body System/Event [2]	Age Group (3)	of Pts	w/Ev		p-value	of Events	Mild		Moderate	Severe	Unknow
ODY AS A MHOLE - GENERAL DISORDERS	(cont.)										
ASTHENIA	≤63 Days (All)	175	2	(1%)	0.3331	2	0	i	2 (100%)	0	0
	≤49 Days (Group 1)	71	0			0	0		0	0	0
	50-56 Days (Group 2)	72	1	(1%)		1	0	•	1 (100%)	0	0
	57-63 Days (Group 3)	32	1	(3%)		1	0		1 (100%)	0	0
BACK PAIN	≤63 Days (All)	175	5	(3%)	0.8426	5	3 (60%)		2 (40%)	0	0
	≤49 Days (Group 1)	71	2	(3%)		2	1 (50%)		1 (50%)	0	0
	50-56 Days (Group 2)	72	3	(4%)		3	2 (67%)		1 (33%)	0	0
	57-63 Days (Group 3)	32	0			0	0		0	0	0
PALLOR	≤63 Days (All)	175	1	(<1%)	0.1829	1	1 (100%)		0	0	0
•	≤49 Days (Group 1)	71	0			0	0		0 1	0	0
	50-56 Days (Group 2)	72	0			0	0		0	0	0
	57-63 Days (Group 3)	32	1	(3%)		1	1 (100%)		0	0	0

^[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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: NICHOLS (#25)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number				Severi	t.v		
Body System/Event [2]	Group [3]	of Pts	w/1	Event	p-value	of Events		ld		rate	-	ere	Unknow
ANY EVENT													
ANT BARME	s63 Days (All)	178	173		0.3309	560	154	(28%)	223	(40%)	183	(33%)	0
	s49 Days (Group 1)	72	69	(96%)		218	63	(29%)	86	(39%)	69	(32%)	0
	50-56 Days (Group 2)	54		(100%)		174	55	(32%)	65	(37%)	54	(31%)	0
	57-63 Days (Group 3)	52	50	(96%)		168	36	(21%)	72	(43%)	60	(36%)	0
ASTRO-INTESTINAL SYSTEM DISORDERS													i
ANY EVENT	≤63 Days (All)	178	123	(69%)	0.6317	230	105	(46%)	87	(38%)	30	(175)	'
	≤49 Days (Group 1)	72	48	(67%)		81	40	(49%)	30	(37%)	38 11	(17%)	0
	50-56 Days (Group 2)	54	40	(74%)		77	40	(52%)	26	(34%)		(14%)	0
	57-63 Days (Group 3)	52	35	(67%)		72	25	(35%)	31	(43%)	11 16	(14%) (22%)	0
DIARRHEA	-63 Davis (211)										-	,,	•
	≰63 Days (All)	178	32	(18%)	0.6040	34	15	(44%)	16	(47%)	3	(9%)	0
	s49 Days (Group 1)	72	11	(15%)		11	5	(45%)	5	(45%)	1	(9%)	0
	50-56 Days (Group 2)	54	12			14	7	(50%)	6	(43%)	1	(7%)	0
	57-63 Days (Group 3)	52	9	(17%)		9	3	(33%)	5	(56%)	1	(11%)	0
NAUSEA	≤63 Days (All)	178	106	(60%)	0.9440	136	63	(46%)	46	(34%)	27	(205)	
	s49 Days (Group 1)	72	43	(60%)		49	26	(53%)	17			(20%)	0
	50-56 Days (Group 2)	54	33	(61%)		46	24	(52%)		(35%)	6	(12%)	0
	57-63 Days (Group 3)	52	30	(58%)		41	13		13	(28%)	9	(20%)	0
	in it in it is to	J.	30	(304)		7.1	13	(32%)	16	(39%)	12	(29%)	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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	of	nber Pts Vent	Fisher's exact p-value	Number of Events			Mode	Severity			Unknown
	0100p (5)	01 105	/-		p varue					1000	361		Oliknown
MASTRO-INȚESTINAL SYSTEM DISORDERS	(cont.)												
VOMITING	≤63 Days (All)	178	54	(30%)	0.3297	60	27	(45%)	25	(42%)	8	(13%)	0
	≤49 Days (Group 1)	72	19	(26%)		21	9	(43%)	8	(38%)	4	(19%)	0
	50.56 Days (Group 2)	54	15	(28%)		17	9	(53%)	7	(41%)	1	(6%)	0
	57-63 Days (Group 3)	52	20	(38%)		22	9	(41%)	10	(45%)	3	(14%)	0
REPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	178	4	(2%)	1.0000	5	0		0		5	(100%)	0
	≤49 Days (Group 1)	72	2	(3%)		2	0		0			(100¥)	0
	50-56 Days (Group 2)	54	1	(2%)		1	0		0			(100%)	0
	57-63 Days (Group 3)	52	1	(2%)		2	0		0			(100%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	178	4	(2%)	1.0000	5	0		. 0	1	5	(100%)	0
	\$49 Days (Group 1)	72	2	(3%)		2	ō		0			(100%)	ō
	50-56 Days (Group 2)	54	1	(2%)		1	ō		0		_	(100%)	ō
	57-63 Days (Group 3)	52	1	(2%)		2	o		0			(100%)	ō
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	178	171	(96%)	0.4932	325	49	(15%)	136	(42%)	140	(43%)	О
	≤49 Days (Group 1)	72	69	(96%)		135	23	(17%)	56	(41%)	56		ō
	50-56 Days (Group 2)	54	53	(98%)		96	15	(16%)	39	(41%)	42		ő
	57-63 Days (Group 3)	52	49	(94%)		94	11	(12%)	41	(44%)	42		ŏ

^[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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age	Total Number	of	ber Pts	Fisher's exact	Number				Severi	•		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p value	of Events	M1	1 d	Mode	rate	Sev	ere	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)												
ABDOMINAL PAIN	≤63 Days (All)	178	171	(96%)	0.4932	321	48	(15%)	135	(42%)	138	(43%)	0
	≤49 Days (Group 1)	72	69	(964)		132	22	(17%)	56	(42%)	54	(41%)	0
	50-56 Days (Group 2)	54	53	(98%)		95	15	(16%)	38	(40%)	42	(44%)	0
	57-63 Days (Group 3)	52	49	(94%)		94	11	(12%)	41	(44%)	42	(45%)	0
BACK PAIN	≤63 Days (All)	178	3	(2%)	0.7812	4	1	(25%)	1	(25%)	2	(50%)	0
	≤49 Days (Group 1)	72	2	(3%)		3	1	(33%)	0		2	(67%)	0
	50-56 Days (Group 2)	54	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	52	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.

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

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^[2] NOS - Not otherwise specified

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

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	. tv	• • • • • • • • • •
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
<u>.</u>	•								
ANY EVENT	≤63 Days (All)	179	178 (>99%)	1.0000	787	284 (36%)	363 (46%)	139 (18%)	1 (<1
	≤49 Days (Group 1)	63	62 (98%)		. 250	91 (36%)	124 (50%)	34 (14%)	1 (<19
	50-56 Days (Group 2)	59	59 (100%)		262	87 (33%)	124 (47%)	51 (19%)	0
	57-63 Days (Group 3)	57	57 (100%)		275	106 (39%)	115 (42%)	54 (20%)	0
KIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	179	2 (1%)	0.2076	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	63	0 :		0	0	0	0	ō
	50 56 Days (Group 2)	59	2 (3%)		2	1 (50%)	0	1 (50%)	Ö
	57-63 Days (Group 3)	57	0		0	0	0	0	ō
PRURITUS	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	. 0 '	0	0
	≤49 Days (Group 1)	63	o		0	0	0	0	o
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	Ö	Ō	0
	57-63 Days (Group 3)	57	0		0	0	0	0	o
SWEATING INCREASED	≤63 Days (All)	179	1 (<1%)	0.6480	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	Ö
	50-56 Days (Group 2)	59	1 (2%)		1	0	0	1 (100%)	ŏ
	57-63 Days (Group 3)	57	0		0	0	Ŏ	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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number -			Severit	; y		
Body System/Event [2]	Group [3]	of Pts	w/Ever	nt	p-value	of Events	Mild '	Mode	rate	Sev	ere	Unknown
USCULO-SKELETAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	179	1 (<	(14)	1.0000	1	1 (100%)	0		0		0
	≤49 Days (Group 1)	63	1 ((2%)		1	1 (100%)	0		Ô		Ô
	50-56 Days (Group 2)	59	0			0	0	ō		Ö		ō
	57-63 Days (Group 3)	57	0			0	0	0		0		ō
MYALGIA	≤63 Days (All)	179	1 (<	(14)	1.0000	1	1 (100%)	0		0		0
	≤49 Days (Group 1)	63	1 ((2%)		1	1 (100%)	0		ō		0
	50-56 Days (Group 2)	59	0			; O	0	0		0		Ō
i	57-63 Days (Group 3)	57	0			' o	0	0		0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	179	22 (1	12%)	0.6856	30	4 (13%)	- 25	(83)	1	(3%)	0
	≤49 Days (Group 1)	63		10%)		8	1 (13%)	7	(88%)	ō	131,	o
	50-56 Days (Group 2)	59		15%)		13	1 (8%)	11	(85%)	1	(8%)	Ô
	57-63 Days (Group 3)	57		12%)		9	2 (22%)	7	(78%)	ō	• • • • • • • • • • • • • • • • • • • •	ō
DIZZINESS	≤63 Days (All)	179	6 ((3%)	0.6916	, 8	3 (38%)	4	(50%)	1	(13%)	0
	≤49 Days (Group 1)	63	2 ((3%)		2	1 (50%)	1	(50%)	0		0
	50-56 Days (Group 2)	59	3 ((5%)		5	1 (20%)	3	(60%)	1	(20%)	0
	57-63 Days (Group 3)	57	1 ((2%)		1	1 (100%)	0	•	0		ō

^[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.

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

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^[2] NOS = Not otherwise specified

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

Center: SHEEHAN (#26)

	Gestational	Total	Numb		Fisher's							
Body System/Event [2]	Age Group [3]	Number of Pts	of P w/Ev		exact p value	Number - of Events		11d		Severit erate	Severe	Unknow
CENTR & PERIPH NERVOUS SYSTEM DISC	RDERS (cont.)			•								
HEADACHE	s63 Days (All)	179	18	(10%)	0.7431	22	1	(5%)	21	(95%)	0	0
	s49 Days (Group 1)	63	5	(8%)		6	0		6	(100%)	0	0
	50-56 Days (Group 2)	59	6	(10%)		8	0		8	(100%)	0	0
	57-63 Days (Group 3)	57	7	(12%)		8	1	(13%)	7	(88%)	0	0
SYCHIATRIC DISORDERS												
ANY EVENT	≤63 Days (All)	179	4	(2%)	0.2703	4	1	(25%)	3	(75%)	0	0
	≤49 Days (Group 1)	63	3	(5%)		3	0		3	(100%)	0	0
	50-56 Days (Group 2)	59	0			0	0		0)	0	0
	57-63 Days (Group 3)	57	1	(2%)		1	1	(100%)	0	•	0	0
ANXIETY	≤63 Days (All)	179	2	(1%)	0.3302	2	0		. 2	(100%)	0	0
	≤49 Days (Group 1)	63	2	(3%)		2	0		2	(100%)	0	0
İ	50-56 Days (Group 2)	59	0			0	0		0)	0	0
	57-63 Days (Group 3)	57	0			0	0		a		0	0
EMOTIONAL LABILITY	≤63 Days (All)	179	. 2	(1%)	0.7667	2	1	(50%)	1	(50%)	0 .	0
	≤49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0	0
	50-56 Days (Group 2)	59	0			0	0		0)	0	0
!	57-63 Days (Group 3)	57	1	(21)		1	1	(100%)	0)	0	0

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

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

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^[2] NOS = Not otherwise specified

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

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

Center: SHEEHAN (#26)

-	Gestational Age	Total Number		mber Pts	Fisher's exact	Number		· 		- Severi	tv		
Body System/Event [2]	Group [3]	of Pts	w/E	Event	p-value	of Events		ild '		rate	•	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS					· · · · · · · · · · · · · · · · · · ·						·		
ANY EVENT	≤63 Days (All)	179	144	(BO%)	0.8417	241	117	(49%)		(200)			
	≤49 Days (Group 1)	63	50	(79%)	0.0417	78	37	-	95	(39%)	29	(12%)	0
	50-56 Days (Group 2)	59	49	(83%)		82		(47%)	33	(42%)	8	(10%)	0
	57-63 Days (Group 3)	57	45	(79%)		81	35	(43%)	37	(45%)	10	(12%)	0
		3,	43	(,,,,,		9.1	45	(56%)	25	(31%)	11	(14%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	179	2	(1%)	0.3302	•		/===1	_			i	
	≤49 Days (Group 1)	63	2	(3%)	0.3302	2	1	(50%)	1	,	0	,	0
	50-56 Days (Group 2)	59	0	(30)		2	<u>.</u>	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	57	0			0	0		0		, 0		0
	ov os says (oroap 3)	3,	U			0	0		0		! 0		0
DIARRHEA .	≤63 Days (All)	179	23	(13%)	0.7556	24							
•	≤49 Days (Group 1)	63	9	(14%)	0.7556	24	13	(54%)	11	(46%)	0		0
	50-56 Days (Group 2)	59	6	(10%)		9	3	(33%)	. 6	(67,8)	0		0
	57-63 Days (Group 3)	57				6	4	(67%)	2	(33%)	0		0
	s, os baya (Group 3)	37	-	(14%)		9	6	(67%)	3	(33%)	0	1	0
DYSPEPSIA	≤63 Days (All)	179	2	(10)		_							
	≤49 Days (Group 1)			(1%)	0.2076	2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	63	0			0	0		0		0		0
		59	2	(3%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	57	0			0	0		0		0		0
NAUSEA	s63 Days (All)	170		(244)									
	•	179	136	(76%)	0.6704	169	92	(54%)	53	(31%)	24	(148)	0
	≤49 Days (Group 1)	63	46	(73%)		56	31	(55%)	17	(30%)	8	(14%)	0
	50-56 Days (Group 2)	59	47	(80%)		57	27	(47%)	22	(39%)	8	(14%)	0
	57-63 Days (Group 3)	57	43	(75%)		56	34	(61%)	14	(25%)	8	(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 which the relationship was not assessed.

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

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^[2] NOS = Not otherwise specified

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

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Numb of 1		Fisher's exact	Number				Severi	.v		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events		1 d		erate		ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												
VOMITING	≤63 Days (All)	179	39	(22%)	0.2601	44	10	(23%)	29	(66%)	5	(11%)	0
	≤49 Days (Group 1)	63	10	(16%)		11	2	(18%)	9	(82%)	ő	(114)	Ô
	50-56 Days (Group 2)	59	13	(22%)		17	3	(18%)	12		2	(12%)	0
•	57-63 Days (Group 3)	57	16	(28%)		16	5	(31%)	8		3		0
CARDIOVASCULAR DISORDERS, GENERAL													
ANY EVENT	≤63 Days (All)	179	1	(<1%)	0.3184	1	0		,	(100%)	0		
	≤49 Days (Group 1)	63	ō	, ,	0.3101	n	ō		0	(1004)	0		0
	50-56 Days (Group 2)	59	ō			Ô	٥		0		0		0
	57-63 Days (Group 3)	57	1	(2%)		1	Ö		1	(100%)	0		0
·													
HYPOTENSION	≤63 Days (All)	179	1	(<1%)	0.3184	1	0		· 1	(10d%)	0		0
	≤49 Days (Group 1)	63	0			0	0		0		0		0
	50-56 Days (Group 2)	59	0			0	0		0		0		. 0
	57-63 Days (Group 3)	57	1	(2%)		1	0		1	(100%)	0		0
RESPIRATORY SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	179	1	(<1%)	1.0000	1	0		,	(100%)			•
	≤49 Days (Group 1)	63	1	(2%)	2.000	•	0			(100%)	0		0
	50-56 Days (Group 2)	59	Ô	124/		•	۸		1	(1004)	0		U
	57-63 Days (Group 3)	57	0			0	0		0		0		Ü
	37 03 Days (Group 3)	3,	U			U	U		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.

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

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^[2] NOS = Not otherwise specified

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

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Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	_	Fisher's exact	Number -				Severit	:v	• • • • • • • • • • • • • • • • • • •	
Body System/Event [2]	Group [3]	of Pts	w/Eve:	nt	p-value	of Events	Mi	.1 d '	Mode	rate	•	/ere	Unknow
ESPIRATORY SYSTEM DISORDERS	(cont.)							·					
DYSPNOER	≤63 Days (All)	179	1 (-	<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	63	1	(2%)		1	0			(100%)	0		o
	50-56 Days (Group 2)	59	0			0	0		0	, ,	o		Ô
	57-63 Days (Group 3)	57	0	1		0	0		0		0		ō
ED BLOOD CELL DISORDERS													
ANY EVENT	≤63 Days (All)	179	20 (1	11%)	0.2500	20	11	(55%)	7	(35%)	2	(10%)	n
	≤49 Days (Group 1)	63		(6%)		4	3	(75%)	1		0	(/	ň
	50-56 Days (Group 2)	59	7 (1	121)		7	4	(57%)	2		1	(14%)	n
	57-63 Days (Group 3)	57	9 (1			9	4	(44%)	4		1		Ö
ANAEMIA	s63 Days (All)	179	19 (1	114)	0.2482	19	10	(53%)	. 7	(37%)	2	(11%)	0
	≤49 Days (Group 1)	63		(6%)		14	3	(75%)	1	•	0	(***/	n
	50-56 Days (Group 2)	59		10%)		6	3	(50%)	2		ĭ	(17%)	Ô
	57-63 Days (Group 3)	57		(6%)		9	4	(44%)	4		1		o
ANAEMIA HYPOCHROMIC	≤63 Days (All)	179	1 (<	(14)	0.6480	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	63	0			ō	ō	• • • •	0		0		0
	50-56 Days (Group 2)	59		(21)		1	-	(100%)	0		0		0
	57-63 Days (Group 3)	57	ō	/		0	Ô	(+ + + + + + + + + + + + + + + + + + +	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.

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

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^[2] NOS = Not otherwise specified

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

Center: SHEEHAN (#26)

	Gestational	Total	Numb		Fisher's									
Body System/Event [2]	Age	Number	of E		exact	Number	· · · -			Severi	ty	• • • • • • •		• • •
	Group [3]	of Pts	w/E	vent	p-value	of Events	M:	11d	Mode	rate	Se	vere	Unk	nown
REPRODUCTAVE DISORDERS, FEMALE														
ANY EVENT	≤63 Days (All)	179	12	(7%)	0.0842	14	1	(7%)	3	(21%)	10	(71%)	0	
	≤49 Days (Group 1)	63	1	(2%)		2	0		ő	(44-)		(100%)	0	
	50-56 Days (Group 2)	59	5	(8%)		6	1	(17%)	2	(33%)	2	(50%)		
	57-63 Days (Group 3)	57	6	(11%)		6	ō	(2.0)	1	(17%)	5		0	
BREAST DISCHARGE	≤63 Days (All)	179	1	(<1%)	0.6480	,		(1005)	_		_			
	≤49 Days (Group 1)	63	ō	(414)	0.0480	7		(100%)	0		0		0	
	50-56 Days (Group 2)	59	1	(2%)		•	0	(1000)	0		0		0	
	57-63 Days (Group 3)	57	ō	(24)		0	0	(100%)	0		0		0	
UTERINE ATONY	-63 Dave (811)		_										-	
	<pre>s63 Days (All) s49 Days (Group 1)</pre>	179	2	(1%)	0.1002	2	0		. 1	(50%)	1	(50%)	0	
		63	0			0	0		0		0		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	2	(4%)		2	0		1	(50%)	1	(50%)	0	
UTERINE HAEMORRHAGE	≤63 Days (All)	179	10	(6%)	0.1981	11	0		2	(18%)	9	(82%)	0	
	≤49 Days (Group 1)	63	1	(2%)		2	0		0			(100%)	ō	
	50-56 Days (Group 2)	59	5	(#8)		5	0		2	(40%)	3	(60%)	o	
	57-63 Days (Group 3)	57	4	(7%)		4	0		0		4	(100%)	0	
ODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	179	174	(97%)	0.1300	472	148	(31%)	228	(48%)	95	(20%)	1	(<1
	<pre>s49 Days (Group 1)</pre>	63	59	(94%)		152	49	(32%)	79	(521)	23	(15%)	i	(<11
	50-56 Days (Group 2)	59	58	(98%)		152	45	(30%)	72	(47%)	35	(23%)	0	,
	57-63 Days (Group 3)	57	57 (100%)	1	168	54	(32%)	77	(46%)	37	(221)	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.

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

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

Center: SHEEHAN (#26)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number			.	Severit	:v			
Body System/Event [2]	Group [3]	of Pts	w/E	Event	p value	of Events		.1d '		rate	-	ere	Unk	nown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)													
ABDOMINAL PAIN	≤63 Days (All)	179	173	(97%)	0.0495	447	140	(31%)	217	(49%)	89	(20%)	1	(<1%
	≤49 Days (Group 1)	63	58	(92%)		142	46	(32%)	73	(51%)	22	(15%)	1	(<1%
	50-56 Days (Group 2)	59	58	(98%)		146	42	(29%)	71	(49%)	33	(23%)	0	
	57-63 Days (Group 3)	57	57	(100%)		159	52	(33%)	73	(46%)	34	(21%)	0	
ASTHENIA	≤63 Days (All)	179	1	(<1%)	0.3184	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	63	0			. 0	0		0		0		0	
	50-56 Days (Group 2)	59	0			; o	0		0		0		0	
	57-63 Days (Group 3)	57	1	(2%)		1	0		1	(100%)	0		0	
BACK PAIN	≤63 Days (All)	179	7	(4%)	0.7036	9	4	(44%)	4	(44%)	1	(11%)	0	
•	≤49 Days (Group 1)	63	3	(5%)		5	1	(20%)	. 4	(8Q%)	0		0	
	50-56 Days (Group 2)	59	3	(5%)		3	2	(67%)	0		1	(33%)	0	
	57-63 Days (Group 3)	57	1	(21)		1	1	(100%)	0		0		0	
FATIGUE	≤63 Days (All)	179	6	(3%)	0.2197	6	3	(50%)	2	(33%)	1	(17 %)	0	
	≤49 Days (Group 1)	63	3	(5%)		. 3	2	(67%)	0		1	(33%)	0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	3	(5%)		3	1	(334)	2	(67%)	0		0	
FEVER	s63 Days (All)	179	2	(1%)	0.7667	2	0		2	(100%)	0		0	
	s49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	1	(2%)		1	0		1	(100%)	0		0	

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

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

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^[2] NOS = Not otherwise specified

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

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

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact:	Number		Severit	y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
SODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
HYPOVOLAEMIA	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	· 0	1 (100%)	0
	≰49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	, o	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
MALAISE	s63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1 .	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
OEDEMA	≤63 Days (All)	179	2 (1%)	0.2076	2	0	1 (50%)	1 (50%)	0
'	s49 Days (Group 1)	63	0		0	0	. 0 .	0	0
	50-56 Days (Group 2)	59	2 (3%)		2	0	1 (50%)	1 (50%)	0
!	57-63 Days (Group 3)	57	0		0	0	0	0	0
PAIN	≤63 Days (All)	179	. 1 (<1%)	0.3184	1	0	o	1 (100%)	0
	s49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
•	57-63 Days (Group 3)	57	1 (2%)		1	0	o	1 (100%)	0
RIGORS	s63 Days (All)	179	1 (<1%)	1.0000	1	· o '	1 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)	3	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0	-	0	0	0	0	0
	57-63 Days (Group 3)	57	0	ļ	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.

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

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^[2] NOS = Not otherwise specified

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

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severi	Pu	
Body System/Event (2)	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ODY AS A MHOLE - GENERAL DISORDERS	(cost.)								
SYNCOPE	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	0		0	0	n	0	0
	50-56 Days (Group 2)	59	0		0	0	n	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	ō	0	1 (100%)	o
SISTANCE NECHANISH DISORDERS									
ANY EVENT	s63 Days (All)	179	1 (<1%)	1.0000	1	ď	0	1 (100%)	0
	≰49 Days (Group 1)	63	1 (2%)		1	o	0	1 (100%)	0
	50-56 Days (Group 2)	59	0		0	0	0	0	n
	57-63 Days (Group 3)	57	0		0	0	ō	ō	0
INFECTION VIRAL	s63 Days (All)	179	1 (<1%)	1.0000	1	0	. 0 .	1 (100%)	^
	≤49 Days (Group 1)	63	1 (2%)		1	o	0 '	1 (100%)	0
	50-56 Days (Group 2)	59	0		ō	0	0	1 (1004)	0
	57-63 Days (Group 3)	57	0		ō	Ö	ŏ	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.

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

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⁽²⁾ NOS = Not otherwise specified

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

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

Center: DEAN (#27)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severi	tv			
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events		ild		rate	-	ere	Unk	nown
ANY EVENT	≤63 Days (All)	191	187 (98%)	0.0313	1028	350	(34%)	388	(38%)	264	(26%)	26	(31)
	s49 Days (Group 1)	29	27 (93%)		129	38	(29%)	59	(46%)	32	(25%)	0	
	50-56 Days (Group 2)	73	71 (97%)		384	150		142	(37%)	81		11	(3%)
	57-63 Days (Group 3)	89	89 (100%)		515	162	(31%)	187	(36%)	151	(29%)	15	(31)
SKIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	191	3 (2%)	0.5453	3	2	(67%)	0		1	(33%)	0	
	s49 Days (Group 1)	29	1 (3%)		1	1	(100%)	0		0		0	
	50-56 Days (Group 2)	73	1 (1%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	89	1 (1%)		1	0		0		1	(100%)	0	
RASH	≤63 Days (All)	191	1 (<1%)	0.1518	1	1	(100%)	. 0	•	0		0	
	≤49 Days (Group 1)	29	1 (3%)		1	1	(100 %)	0		0		0	
	50-56 Days (Group 2)	73	0		0	0		0		0		0	
	57-63 Days (Group 3)	89	0		0	0		0		0		0	
SWEATING INCREASED	≤63 Days (All)	191	1 (<1%)	1.0000	1	0		0		1	(100%)	0	
	#49 Days (Group 1)	29	0		0	0		0		0		0	
	50-56 Days (Group 2)	73	0		0	0		0		0		0	
	57-63 Days (Group 3)	89	1 (14)		1	0		0		. 1	(100%)	0	
			i						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.

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

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^[2] NOS - Not otherwise specified

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

Center: DEAN (#27)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severi	tv			
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events		1d		rate		ere	Unk	nown
SKIN AND APPENDAGES DISORDERS	(cont.)								- /	······				
URTICARIA	≤63 Days (All)	191	1	(<1%)	0.5340	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	29	0			0	0		0		0		0	
	50-56 Days (Group 2)	73	1	(1,%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	89	0			0	0		0		0		o	
CENTR & PERIPH NERVOUS SYSTEM DISC	DRDERS													
ANY EVENT	≤63 Days (All)	191	38	(20%)	0.9103	57	11	(19%)	34	(60%)	10	(18%)	2	(48
	≤49 Days (Group 1)	29	5	(17%)		8	1	(13%)	6	(75%)	1		0	
	50-56 Days (Group 2)	73	14	(19%)		22	4	(18%)	14	(64%)	3		1	(5%)
	57-63 Days (Group 3)	89	19	(21%)		27	6	(22%)	14	(52%)	6	(22%)	1	(4%
DIZZINESS	≤63 Days (All)	191	8	(4%)	0.2868	9	1	(11%)	. 3	(334)	5	(56%)	0	
	≤49 Days (Group 1)	29	0			0	0		0		0	, ,	ō	
	50-56 Days (Group 2)	73	2	(3%)		2	0		1	(50%)	1	(50%)	Ō	
	57-63 Days (Group 3)	89	6	(7%)		7	1	(14%)	2		. 4	(57%)	ō	
HEADACHE	≤63 Days (All)	191	34	(18%)	0.9661	48	10	(21%)	31	(65%)	5	(10%)	2	(48)
	≤49 Days (Group 1)	29	5	(17%)		8	1	(13%)	6	(75%)		(13%)	ō	
	50-56 Days (Group 2)	73	14	(19%)		20	4	(20%)	13	(65%)	2		ì	(5%)
	57-63 Days (Group 3)	89	15	(17%)		20	5	(25%)	12	(60%)	2		1	(5%)

^[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.

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

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^[2] NOS = Not otherwise specified

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

Center: DEAN (#27)

	Gestational Age	Total Number			Fisher's exact	Number	Severity								
Body System/Event [2]	Group (3)	of Pts		Event	p-value	Number of Events	Mi			derate			ere		known
PSYCHIATRIC DISORDERS								········			· · · · ·				
ANY EVENT	≤63 Days (All)	191	1	(<1%)	0.5340	1	0			1 (100	%)	0		0	
•	≤49 Days (Group 1)	29	0			0	0			0		ō		0	
	50-56 Days (Group 2)	73	1	(1%)		1	0			1 (100	%)	0		0	
	57-63 Days (Group 3)	89	0			0	0			0		0		0	
INSOMNIA	≤63 Days (All)	191	1	(<1%)	0.5340	1	0			1 (100	*)	0		0	
	#49 Days (Group 1)	29	0			0	0			0	•	ō		0	
	50-56 Days (Group 2)	73	1	(1%)		1	0			1 (100	%)	0		0	
	57-63 Days (Group 3)	89	0			0	0			0		0		0	
GASTRO-INTESTINAL SYSTEM DISORDERS				·											
ANY EVENT	≤63 Days (All)	191	129	(68%)	0.0171	284	114	(40%)	' 10	0 (35	%)	69	(24%)	1	(<1%
	≰49 Days (Group 1)	29	13	(45%)		24	9	(38%)		7 (29	%)	8	(33%)	0	
	50-56 Days (Group 2)	73	50	(68%)		99	46	(46%)	3	9 (39	%)	14	(14%)	0	
	57-63 Days (Group 3)	89	66	(74%)		161	59	(37%)	5	4 (34	*)	47	(29%)	1	(<1%
DIARRHEA	≤63 Days (All)	191	53	(28%)	0.1914	69	36	(52%)	2	5 (36	%)	8	(12%)	0	
	≤49 Days (Group 1)	29	5	(17%)		6	4	(67%)		1 (17		1	(17%)	0	
	50-56 Days (Group 2)	73	18	(25%)		25	16	(64%)		7 (28	%)	2	(81)	0	
	57-63 Days (Group 3)	89	30	(34%)		38	16	(42%)	1	7 (45		5		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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: DEAN (#27)

Body System/Event [2]	Gestational Age	Total Number			Fisher's exact	Number		,		Severit	y		
	Group [3]	of Pts			p-value	of Events	Mi			rate	-	vere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)												
DYSPEPSIA	≤63 Days (All)	191	2	(1%)	1.0000	2	0		0		1	(50%)	1 (50%
	≤49 Days (Group 1)	29	0			0	0		0		0		0
	50-56 Days (Group 2)	73	1	(1%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	89	1	(1%)		1	0		0		0		1 (100%
FLATULENCE	≰63 Days (All)	191	1	(<1%)	1.0000	2	0		1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	29	0			0	0		0		0		0
	50-56 Days (Group 2)	73	0			0	0		0		0		0
	57-63 Days (Group 3)	89	1	(1%)		2	0		1	(50%)	1	(50%)	0
NAUSEA	≤63 Days (All)	191	110	(58%)	0.1075	155	66	(43%)	50	(32%)	39	(25%)	0
•	s49 Days (Group 1)	29	13	(45%)		15	5	(33%)	. 6	(40%)	4	(27%)	0
	50-56 Days (Group 2)	73	39	(53%)		54	27	(50%)	21	(39%)	6	(11%)	0
	57-63 Days (Group 3)	89	5 8	(65%)		86	34	(40%)	23	(27%)	29	(34%)	0
VOMITING	≤63 Days (All)	191	40	(21%)	0.1042	56	12	(21%)	24	(43%)	20	(36%)	0
	≤49 Days (Group 1)	29	2	(7%)		3	0		0		3	(100%)	0
	50-56 Days (Group 2)	73	16	(22%)		19	3	(16%)	11	(58%)	5	(26%)	0
	57-63 Days (Group 3)	89	22	(25%)		34	9	(26%)	13	(38%)	12	(35%)	0
RESPIRATORY SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	29	0			0	0		0		0		0
	50-56 Days (Group 2)	73	0			0	0		0		0		0
	57-63 Days (Group 3)	89	1	(1%)		1	0		1	(100%)	0		0

^[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⁾ NOS - Not otherwise specified

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

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Center: DEAN (#27)

Body System/Event [2]	Gestational Age	Total Number	Number of Pts		Fisher's exact	Mumbas	Severity						
	Group [3]	of Pts	w/E		p value	Number - of Events	Mild		Moderate	Severe	Unknowr		
RESPIRATORY SYSTEM DISORDERS	(cont.)	1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-								-			
hyperventilation	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		1 (100%)	0	0		
	≤49 Days (Group 1)	29	0			0	0	4	0	0	ō		
	50-56 Days (Group 2)	73	0			0	0	ł	0	0	0		
	57-63 Days (Group 3)	89	1	(1%)		1	0		1 (100%)	0	0		
RED BLOOD CELL DISORDERS													
ANY EVENT	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		1 (100%)	0	0		
	≤49 Days (Group 1)	29	0			0	0		0	0	Ö		
	50-56 Days (Group 2)	73	0			0	0		0	0	0		
	57-63 Days (Group 3)	89	1	(1%)		1	0		1 (100%)	o	o		
ANAEMIA	≤63 Days (All)	191	1	(<1%)	1.0000	1	0		1 (100%)	0	•		
	≤49 Days (Group 1)	29	ō	,		- n	Ö		0	o o	0		
	50-56 Days (Group 2)	73	Ö			Ô	Ŏ		0	0	0		
1	57-63 Days (Group 3)	89	ì	(1%)		1	Ŏ		1 (100%)	Ö	0		
SPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≰63 Days (All)	191	13	(7%)	0.0163	18	1 (6%)		B (44%)	9 (50%)	0		
	≤49 Days (Group 1)	29	1	(3%)	,	3	0		0	3 (100%)	Ö		
!	50-56 Days (Group 2)	73	1	(1%)		2	0		2 (100%)	0	ŏ		
	57-63 Days (Group 3)	89	11	(12%)		13	1 (8%)		6 (46%)	6 (46%)	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.

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

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^[2] NOS - Not otherwise specified

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

Center: DEAN (#27)

Body System/Event [2]	Gestational	Total	Number	Fisher's								
	Age Group [3]	Number of Pts	of Pts w/Event	exact p·value	Number of Events	Mild	Moderate	Severe	Unknow			
REPRODUCTIVE DISORDERS, FEMALE	(cont.)								·			
LEUKORRHOEA	≤63 Days (All)	191	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0			
	≤49 Days (Group 1)	29	0		0	0	0	0	0			
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0			
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	o ;	. 0			
UTERINE HAEMORRHAGE	≤63 Days (All)	191	10 (5%)	0.0069	14	0	6 (43%)	8 (571)	0			
	#49 Days (Group 1)	29	1 (3%)		3	o ,	0 1	3 (100%)	0			
	50-56 Days (Group 2)	73	0		0	O	0 '	. 0	0			
	57-63 Days (Group 3)	89	9 (10%)		11	O	6 (55%)	5 (45%)	0			
VAGINAL DISCOMFORT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0			
•	≤49 Days (Group 1)	29	0		0	0	. 0 1	0	0			
	50-56 Days (Group 2)	73	0		0	0	0	0	0			
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0			
VAGINITIS	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	1 (100%)	0	0			
	≤49 Days (Group 1)	29	0		0	0	0	0	0			
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0			
	57-63 Days (Group 3)	89	0		0	0	0	0	0			
ODY AS A WHOLE - GENERAL DISORDERS												
ANY EVENT	≤63 Days (All)	191	187 (98%)	0.0313	662	221 (33%)	243 (37%)	175 (26%)	23 (
	s49 Days (Group 1)	29	27 (93%)		93	27 (29%)	46 (49%)	20 (22%)	0			
	50-56 Days (Group 2)	73	71 (97%)		258	98 (38%)	86 (33%)	64 (25%)	10 (
	57-63 Days (Group 3)	89	89 (100%)		311	96 (31%)	111 (36%)	91 (29%)	13 (

^[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] NOS - Not otherwise specified

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

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

Center: DEAN (#27)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	. .			- Severi	ty			
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mi	14	Mode	rate	Sev	rere	Unk	nown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)												
ABDOMINAL PAIN	≤63 Days (All)	191	187 (98	0.0313	624	209	(33%)	230	(37%)	166	(27%)	19	(3%
	≤49 Days (Group 1)	29	27 (93	k)	89	26	(29%)	43	(48%)	20	(22%)	0	
	50-56 Days (Group 2)	73	71 (97	1)	239	90	(38%)	78	(33%)	61	(26%)	10	(4%
	57-63 Days (Group 3)	89	89 (100	1)	296	93	(31%)	109	(37%)	85	(29%)	9	(3\$
ASTHENIA	≤63 Days (All)	191	2 (1	1.0000	2	1	(50♦)	1	(50%)	0		0	
	≤49 Days (Group 1)	29	0		0	0		0		0		0	
	50-56 Days (Group 2)	73	1 (1	i)	1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	89	1 (1	i)	1	1	(100%)	0		0		0	
BACK PAIN	s63 Days (All)	191	13 (7	1.0000	22	5	(23%)	9	(41%)	4	(18%)	4	(18%
•	≤49 Days (Group 1)	29	2 (7	1)	2	1	(50%)	1	(50%)	0		0	
	50-56 Days (Group 2)	73	5 (7	i)	11	4	(36%)	6	(55%)	1	(9%)	0	
	57-63 Days (Group 3)	89	6 (7)	9	0		2	(221)	3	(33%)	4	(44%
FATIGUE	≤63 Days (All)	191	4 (2	0.2093	4	2	(50%)	2	(50%)	o		0	
	s49 Days (Group 1)	29	2 (7	1)	2	0		2	(100%)	0		0	
	50-56 Days (Group 2)	73	1 (1	1)	1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	89	1 (1	i)	1	1	(100%)	0		o		0	
FEVER	≤63 Days (All)	191	2 (1	0.4261	3	3	(100%)	0		. 0		0	
	#49 Days (Group 1)	29	0		0	0		0		0		0	
	50-56 Days (Group 2)	73	2 (3	1)	3	3	(100%)	0		, 0		0	
	57-63 Days (Group 3)	89	0		0	0		0		lo		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.

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

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^[2] NOS = Not otherwise specified

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

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

Center: DEAN (#27)

	Gestational Age	Total Number	Number of Pts	-	Fisher's exact	Number		·Severity	y	
Body System/Event [2]	Group [3]	of Pts	w/Ever	nt	p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A MHOLE - GENERAL DISORDERS	(cost.)									
HOT FLUSHES	≤63 Days (All)	191	1 (<	<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0	1		0	0	0	0	0
	50-56 Days (Group 2)	73	0	:		0	0	0	0	0
	57-63 Days (Group 3)	89	1 ((1%)		1	0	0	1 (100%)	0
MALAISE	≤63 Dayş (All)	191	1 (<	<1%)	0.5340	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0			0	0	0	0	0
	50-56 Days (Group 2)	73	1 ((1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	89	0			0	0	0	0	0
SYNCOPE	≤63 Days (All)	191	4	(2%)	1.0000	5	1 (20%)	1 (20%)	3 (60%)	0
•	s49 Days (Group 1)	29	0			0	0	. 0 .	0	0
	50-56 Days (Group 2)	73	2	(3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	2	(2%)		3	1 (33%)	0	2 (67%)	0
ESISTANCE NECHANISH DISORDERS									•	
ANY EVENT	≤63 Days (All)	191	1 (<1%)	0.5340	1	1 (100%)	0	0	0
	s49 Days (Group 1)	29	0			0	0	0	o [:]	0
	50-56 Days (Group 2)	73	1	(1%)		1	1 (100%)	0	0 .	0
	57-63 Days (Group 3)	89	0			0	0	0	0	0

^[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.

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

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^[2] NOS = Not otherwise specified

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

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events		Severi	ty Severe	Unknown
RESISTANCE MECHANISM DISORDERS	(cont.)				· · · · · · · · · · · · · · · · · · ·			· · · · · · · · · · · · · · · · · · ·	
SISTANCE HECHANISH DISORDERS INFECTION VIRAL	≤63 Days (All)	191	1 (<1%)	0.5340	1	1 (100%)	0	0	0
•	≤49 Days (Group 1)	29	0		0	0	0	0	0
·	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	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.

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

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^[2] NOS - Not otherwise specified

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

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

Center: CREININ (#28)

	Gestational Age	Total Number	Numi of		Fisher's exact;	Number				·Severit	·V		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events		1 d '		rate	Seve		Unknown
USCULO-SEBLETAL SYSTEM DISORDERS	(cont.)												
SKELETAL PAIN	≤63 Days (All)	115	1	(<1%)	0.5652	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	23	0			0	0		0	•	0		ō
	50-56 Days (Group 2)	50	0			0	0		0		0		o
	57-63 Days (Group 3)	42	1	(21)		1	0		1	(100%)	0		0
ENTR & PERIPH NERVOUS SYSTEM DISC	RDERS												
NY EVENT	≰63 Days (All)	115	19	(17%)	0.0277	26	8	(31%)	17	(65%)	1	(4%)	0
	≤49 Days (Group 1)	23	0			O	0		0		0	,	ō
	50-56 Days (Group 2)	50	9	(18%)		14	3	(21%)	10	(71%)	1	(7%)	o
	57-63 Days (Group 3)	42	10	(24%)		12	5	(42%)	7	(58%)	0		0
IZZINESS	≤63 Days (All)	115	4	(3%)	0.8288	5	3	(60%)	. 2	(40%)	0		O
	≤49 Days (Group 1)	23	0			0	0	• • •	0	,,,,,	0		0
	50-56 Days (Group 2)	50	2	(4%)		3	2	(67%).	1	(33%)	0		ō
	57-63 Days (Group 3)	42	2	(5%)		2	1	(50%)	1	(50%)	0		0
HEADACHE	≤63 Days (All)	115	17	(15%)	0.0388	21	5	(24%)	15	(71%)	1	(5%)	0
	s49 Days (Group 1)	23	0			0	0	·	0		Ō	•	ō
	50-56 Days (Group 2)	50	8	(16%)		11	1	(9%)	9	(82%)	1	(9%)	0
	57-63 Days (Group 3)	42	9	(21%)		10	4	(40%)	6		0		ō

^[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.

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

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^[2] NOS = Not otherwise specified

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

Center: CREININ (#28)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	· · · · · · · · · · · · · · · · · · ·	Severit	. y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
SYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	115	3 (3%)	0.5960	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	Ō
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	o
	57-63 Days (Group 3)	42	2 (5%)		4	2 (50%)	2 (50%)	0	0
ANOREXIA	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	o '	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	o	Ô
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
DEPRESSION	≤63 Days (All)	115	1 (<1%)	0.5652	3	1 (33%)	2 (67%)	0	0
•	≤49 Days (Group 1)	23	0		0	0	0 1	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
1	57-63 Days (Group 3)	42	1 (2%)		3	1 (33%)	2 (67%)	0	ō
DYSPAREUNIA	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	23	0		0	0	0	ō	ō
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
ı	57-63 Days (Group 3)	42	0		0	0	0	0	0
ASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	78 (68%)	0.2134	144	61 (42%)	55 (38%)	28 (19%)	0
	≤49 Days (Group 1)	23	12 (52%)	1	22	9 (41%)	7 (32%)	6 (27%)	0
	50-56 Days (Group 2)	50	36 (72%)	ļ	65	22 (34%)	31 (48%)	12 (18%)	0
	57-63 Days (Group 3)	42	30 (71%)	•	57	30 (53%)	17 (30%)	10 (18%)	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.

^[2] NOS = Not otherwise specified

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

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

Center: CREININ (#28)

	Gestational Age	Total Number	Numb		Fisher's exact	Number			. .	Severit	V		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events		ild	Mode		•	ere	Unknown
JASTRO-INȚESTINAL SYSTEM DISORDERS	(cont.)											***	
CONSTIPATION	≤63 Days (All)	115	1	(<1%)	0.5652	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	23	0			0	0		0		0		0
	50-56 Days (Group 2)	50	0			0	0		0		0		0
	57-63 Days (Group 3)	42	1	(2%)		1	1	(100%)	0		0		0
DIARRHEA	≤63 Days (All)	115	42	(37%)	0.7693	48	27	(56%)	14	(29%)	7	(15%)	O
	s49 Days (Group 1)	23	7	(30%)		9	4	(44%)	3	(38%)	2	(221)	0
	50-56 Days (Group 2)	50	20	(40%)		23	10	(43%)	9	(394)	; 4	(17%)	0
	57-63 Days (Group 3)	42	15	(36%)		16	13	(81%)	2	(13%)	1	(6%)	0
FLATULENCE	≤63 Days (All)	115	1	(<1%)	0.5652	1	1	(100%)	0		0		0
·	#49 Days (Group 1)	23	0			0	0		. 0		0		0
	50-56 Days (Group 2)	50	0			0	0		0		0		o
	57-63 Days (Group 3)	42	1	(2%)		1	1	(100%)	0		0		0
NAUSEA	≤63 Days (All)	115	63	(55%)	0.4213	73	27	(37%)	29	(40%).	17	(23%)	0
	≤49 Days (Group 1)	23	10	(43%)		11	4	(36%)	4	(36%)	3	(27%)	Ŏ
	50-56 Days (Group 2)	50	30	(60%)		33	10		15	(45%)	8	(24%)	Ō
	57-63 Days (Group 3)	42	23	(55%)		29	13	(45%)	10	(34%)	6	-	ō
VOMITING	≤63 Days (All)	115	19	(17%)	0.5801	21	5	(24%)	12	(57%)	4	(19%)	0
	≤49 Days (Group 1)	23	2	(9%)		2	1	(50%)	0	•	1	(50%)	ō
	50-56 Days (Group 2)	50	9	(18%)		9	2	(22%)	7	(78%)	Ō		0
	57-63 Days (Group 3)	42	8	(191)		10	2	(20%)	5		3	(30%)	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.

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

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^[2] NOS = Not otherwise specified

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

Center: CREININ (#28)

s63 Days (All) s49 Days (Group 1) 50-56 Days (Group 2)	of Pts 115 23	w/Event 2 (2%)	p-value 0.1699	of Events	Mild	Moderate	Severe	Unknow
s49 Days (Group 1) 50-56 Days (Group 2)			0.1699	_				
s49 Days (Group 1) 50-56 Days (Group 2)			0.1699	_				
50-56 Days (Group 2)	23	_		2	1 (50%)	1 (50%)	0	0
		0		0	0	0	ō	o
	50	0		0	0	0	Ō	Ô
57-63 Days (Group 3)	42	2 (5%)		2	1 (50%)	1 (50%)	0	ō
≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	n	0
		0		0	0		ň	ň
, ,		0		6	0	•	Ô	n
57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	Ö	ō	ŏ
≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
≤49 Days (Group 1)	23	0		0	o .	0 '	n	ň
	50	0		0	Ô	ō	n	ň
57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	o	Ö
≤63 Days (All)	115	10 (9%)	1.0000	12	3 (25%)	1 (8%)	8 (67%)	0
*	23	2 (9%)		3				0
	50	- ,- ,		4		-		n
57-63 Days (Group 3)	42			5		0	·	0
	<pre>\$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 1)</pre>	<pre> s63 Days (All)</pre>	<pre></pre>	<pre> s63 Days (All)</pre>	<pre> s63 Days (All)</pre>	x63 Days (All) 115 1 (<1%)	x63 Days (All) 115 1 (<1%)	x63 Days (All) 115 1 (<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.

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

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^[2] NOS = Not otherwise specified

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

Center: CREININ (#28)

	Gestational Age	Total Number	Num of		Fisher's exact	Number				Severit	· v		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi.	ld '	Mode	rate	•	vere	Unknow
REPRODUCTIVE DISORDERS, PENALE	(cont.)				·				·				
BREAST DISCHARGE	≤63 Days (All)	115	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	23	0			0	0		0		0		ō
	50-56 Days (Group 2)	50	1	(2%)		1	1	(100%)	0		Ó		ō
	57-63 Days (Group 3)	42	0	•		0	0		0		0		ō
ENDOMETRITIS	≤63 Days (All)	115	1	(<1%)	0.2000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	23	1	(4%)		1		(100%)	0		ō		Õ
	50-56 Days (Group 2)	50	0			0	Ö		ō		0		ō
	57-63 Days (Group 3)	42	0			0	0		o		ō		Ŏ
TERINE HAEMORRHAGE	≤63 Days (All)	115	7	(6%)	0.6803	8	0		1	(13%)	7	(88%)	0
i i	≤49 Days (Group 1)	23	2	(9%)		2	ŏ			(134)		(100%)	0
	50-56 Days (Group 2)	50	2	(4%)		1 2	ō		ì	(50¥)		(50%)	0
	57-63 Days (Group 3)	42	3	(7%)		4	o		0	(301)		(190%)	Ö
VAGINITIS	≤63 Days (All)	115	2	(2%)	1.0000	2	1	(50%)	0		1	(50%)	0
	s49 Days (Group 1)	23	ō			0	0	,,,,	ō		_	(300)	0
	50-56 Days (Group 2)	50	1	(2%)		i	ō		ŏ		ĭ	(100%)	0
	57-63 Days (Group 3)	42	1	(2%)		1	1	(100%)	ō		ō	(1000)	Ŏ
DDY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	115	109	(95%)	0.5723	322	85	(26%)	110	(34%)	127	(39%)	0
	≤49 Days (Group 1)	23	22	(96%)		59	20	(34%)	20	(34%)	19	(321)	0
	50-56 Days (Group 2)	50	46	(92%)		135	33	(24%)	43	(32%)	59	(44%)	0
	57-63 Days (Group 3)	42	41	(98%)		128	32	(25%)	47	(37%)	49	(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.

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

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Center: CREININ (#28)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number				Severi	ty		
Body System/Event [2]	Group [3]	of Pts	W/E	Event	p-value	of Events	Mi	14	Mode	rate	Sev	/ere	Unknow
BODY AS A4WHOLE - GENERAL DISORDERS	(cont.)			***************************************				-					
ABDOMINAL PAIN	≤63 Days (All)	115	109	(95%)	0.5723	303	76	(25%)	104	(34%)	123	(41%)	0
•	≤49 Days (Group 1)	23	22	(96%)		57	19	(33%)	20	(35%)	18	(32%)	0
	50-56 Days (Group 2)	50	46	(92%)		129	30	(23%)	41	(32%)	58	(45%)	n
	57-63 Days (Group 3)	42	41			117	27	(23%)	43	(37%)	47	(40%)	ō
BACK PAIN	≤63 Days (All)	115	11	(10%)	0.0452	13	5	(38%)	5	(38%)	3	(23%)	0
	s49 Days (Group 1)	23	1	(4%)		1	0	,,,,,	ō	,,,,,	-	(100%)	0
	50-56 Days (Group 2)	50	2	: (4%)		2	1	(50%)	1	(50%)	0	(1000)	ő
	57-63 Days (Group 3)	42	8	(191)		10	4	(40%)	4	(40%)	2	(20%)	ō
CHEST PAIN	≤63 Days (All)	115	1	(<1%)	1.0000	1	,	(100%)	0		0		0
·	s49 Days (Group 1)	23	0	, ,		0	0	(1000)	. 0		0		0
	50-56 Days (Group 2)	50	1	(2%)		1	-	(100%)	.0		•		•
	57-63 Days (Group 3)	42	ō	(20)		0	ō	(1004)	0		0		0
FATIGUE	≤63 Days (All)	115	2	(21)	0.3173	2	,	(100%)	0		0		0
	≤49 Days (Group 1)	23	1	(4%)		1		(100%)	Ö		0		0
	50-56 Days (Group 2)	50	0	,		0	ō	120007	Ö		0		0
	57-63 Days (Group 3)	42	1	(2%)		1	-	(100%)	ō		0		0
LEG PAIN	≤63 Days (All)	115	2	(2%)	0.6796	2	1	(50%)	1	(50%)	0		•
	s49 Days (Group 1)	23	0	,		ō	0	, 500,		, 50 4 ,	0		0
	50-56 Days (Group 2)	50	2	(4%)		2	1	(50%)	1	(50%)	ő		0
	57-63 Days (Group 3)	42	0	, ,		0	0	. 30 4 ,	0	. 30 • /	0		0
		==	-			•	J		v		v		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.

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

The Population Council Protocol 166B

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

Center: CREININ (#28)

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

^[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.

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

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^[2] NOS = Not otherwise specified

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

Center: SOGOR (#29)

	Gestational Age	Total Number	Num of		Fisher's exact	Number		,		Severi	· V		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events		.1d		derate	•	ere	Unknown
ANY EVENT	(2) Davis (233)			(000)					_				
WII BACKI	≤63 Days (All)	83	75	(90%)	1.0000	223	46			2 (37%)	95		0
	≤49 Days (Group 1)	28	25	(89%)		69	13	(19%)	3		19	(28%)	0
	50-56 Days (Group 2)	37	34	(92%)		106	22	(21%)	. 3		49	(46%)	0
	57-63 Days (Group 3)	18	16	(89%)		48	11	(23%)	1	0 (21%)	27	(56%)	0
INTR & PERIPH NERVOUS SYSTEM DISORDERS												•	İ
ANY EVENT	≤63 Days (All)	83	7	(8%)	0.3605	7	2	(29%)		4 (57%)	1	(14%)	o o
	#49 Days (Group 1)	28	2	(7%)		2	1	(50%)		1 (50%)	0		ō
	50-56 Days (Group 2)	37	2	(5%)		2	0			2 (100%)	0		Ô
,	57-63 Days (Group 3)	18	3	(17%)		3	1	(33%)		1 (33%)	1	(33%)	o
DIZZINESS	≤63 Days (All)	83	4	(5%)	0.4250	4	2	(50%)		2 (50%)	0		0
	≤49 Days (Group 1)	28	1	(4%)		1	_	(100%)		0	ő		n
· ·	50-56 Days (Group 2)	37	1	(3%)		1	ō	(1001)		1 (100%)	0		0
•	57-63 Days (Group 3)	18	2	(11%)		2	1	(50%)		1 (50%)	ō		0
HEADACHE	≤63 Days (All)	83	. 3	(4%)	1.0000	3	0			2 (67%)	1	(33%)	0
	s49 Days (Group 1)	28	1	(4%)		1	ŏ			1 (100%)	Ô	(334)	^
	50-56 Days (Group 2)	37	1	(3%)		1	Ö			1 (100%)	0		0
!	57-63 Days (Group 3)	18	•	(6%)		•	0	1		0	-	(100%)	0
	3. 33 bays (Group 3)	10	•	(00)			U	;		J	1	(100%)	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.

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

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^[2] NOS = Not otherwise specified

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

The Population Council Protocol 166B

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

Center: SOGOR (#29)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number -				Severi	ty		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	1d '	Mode		•	ere	Unknow
LASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	83	28	(34%)	0.2500	57	5	(98)	17	(30%)	35	(61%)	0
	≤49 Days (Group 1)	28	6	(21%)		11	0		4	(36%)	7	(64%)	0
	50-56 Days (Group 2)	37	15	(414)		32	3	(9%)	12	(38%)	17	(53%)	0
	57-63 Days (Group 3)	18	7	(39%)		14	2	(14%)	1	(71)	11	(79%)	0
DIARRHEA	≤63 Days (All)	83	12	(14%)	0.4010	12	2	(17%)	3	(25%)	7	(58%)	0
	s49 Days (Group 1)	28	2	(7%)		2	0		0	1	2	(100%)	0
	50-56 Days (Group 2)	37	7	(19%)		7	ĺ	(14%)	3	(43%)	3	(43%)	0
	57-63 Days (Group 3)	18	3	(17%)		3	1	(33%)	0		2	(67%)	0
DYSPEPSIA	≤63 Days (All)	83	1	(1%)	0.2169	1	1	(100%)	0		0		0
·	s49 Days (Group 1)	28	0			0	0		. 0	,	0		0
	50-56 Days (Group 2)	37	0			0	0		0		0		0
	57-63 Days (Group 3)	18	1	(61)		1	1	(100%)	0		0	š.	0
NAUSEA	≤63 Days (All)	83	21	(25%)	0.0692	23	2	(9%)	7	(30%)	14	(61%)	0
t e	≤49 Days (Group 1)	28	3	(11%)		4	0		1	(25%)	3	(75%)	0
	50-56 Days (Group 2)	37	13	(35%)		14	2	(14%)	5	(36%)	7	(50 %)	0
	57-63 Days (Group 3)	18	5	(28%)		5	0		1	(20%)	4	(80%)	0
VOMITING	≤63 Days (All)	83	20	(24%)	0.6742	21	0		7	(33%)	14		0
	s49 Days (Group 1)	28	5	(18%)		5	0		3	(60%)	2	(40%)	0
	50-56 Days (Group 2)	37	10	(27%)		11	0		4	(36%)	7	(64%)	0
	57-63 Days (Group 3)	18	5	(28%)		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.

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

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^[2] NOS = Not otherwise specified

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

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number -	Severity					
	Group [3]	of Pts	w/Eve	nt	p-value	of Events	Mild	Moderate	Severe	Unknow		
LATELET, BLEEDING & CLOTTING DISORDERS										·····		
ANY EVENT	≤63 Days (All)	83	1	(1%)	1.0000	1	0	n	1 (100%)	0		
	≤49 Days (Group 1)	28	0	-		. 0	ō	n	0	0		
	50-56 Days (Group 2)	37	1	(3%)		1	Ö	0	1 (100%)	0		
	57-63 Days (Group 3)	18	0	, . ,		0	o	ō	0	0		
EPISTAXIS	≤63 Days (All)	83	1	(1%)	1.0000	1	0	٥	1 (100%)			
	≤49 Days (Group 1)	28	0	(17)	1.5555	'n	0	0	0	0		
	50-56 Days (Group 2)	37	ĭ	(3%)		i	0	0	1 (100%)	0		
	57-63 Days (Group 3)	18	0			0	Ö	ő	0	0		
PRODUCTIVE DISORDERS, PENALE												
ANY EVENT	s63 Days (All)	83	2	(2%)	0.6956	2	0	. 0 ,	2 (100%)	•		
	s49 Days (Group 1)	28	0	,		0	Ô	0	0	0		
	50-56 Days (Group 2)	37	1	(3%)		1	ñ	0	1 (100%)	0		
	57-63 Days (Group 3)	18		(6%)		i	Ŏ	ő	1 (1004)	0 0		
UTERINE HAEMORRHAGE	s63 Days (All)	83	2	(2%)	0.6956	2	0	0	2 (100%)	•		
	s49 Days (Group 1)	28	0	,		0	Ŏ	0	0	0		
	50-56 Days (Group 2)	37	•	(3%)		1	0	0	•	0		
	57-63 Days (Group 3)	18		(6%)		,	0	0	1 (100%)	0		
	,		•	,,,,		•	· ·	U	1 (100%)	0		

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

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

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^[2] NOS = Not otherwise specified

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

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number	Severity						
	Group (3)	of Pts	w/E	vent	p value	of Events	Mi	1d '		rate	•	ere	Unknow
BODY AS A WHOLE - GENERAL DISORDERS								_				·	
ANY EVENT	≤63 Days (All)	83	70	(84%)	0.5023	155	39	(25%)	60	(39%)	56	(36%)	0
	≤49 Days (Group 1)	28	25	(89%)		56	12	(21%)	32	(57%)	12	(21%)	ō
	50-56 Days (Group 2)	37	31	(84%)		69	19	(28%)	20	(29%)	30	(43%)	ō
	57-63 Days (Group 3)	18	14	(78%)		30	8	(27%)	8	(27%)	14	(47%)	ŏ
ABDOMINAL PAIN	≤63 Days (All)	83	69	(83%)	0.8059	150	38	(25%)	56	(37%)	56	(37%)	0
	≤49 Days (Group 1)	28	24	(86%)		53	11	(21%)	30	(57%)	12	(23%)	0
	50-56 Days (Group 2)	37	31	(84%)		67	19	(28%)	18	(27%)	30	(45%)	Ŏ
	57-63 Days (Group 3)	18	14	(78%)		30	8	(27%)	8	(27%)	14	(47%)	ō
BACK PAIN	≤63 Days (All)	83	1	(1%)	0.5542	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	28	1	(4%)		1	0		. 1	(100%)	0		0
	50-56 Days (Group 2)	37	0			. 0	0		0	•	0		0
	57-63 Days (Group 3)	18	0			0	0		0		0		0
FEVER	≤63 Days (All)	83	2	(2%)	1.0000	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	28	1	(4%)		1	1	(100%)	0		0		Ō
	50-56 Days (Group 2)	37	1	(3%)		1	0		1	(100%)	0		Ö
	57-63 Days (Group 3)	18	0			0	0		0		0		0
MALAISE	≤63 Days (All)	83	2	(2%)	1.0000	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	28	1	(4%)		1	0			(100%)	0		0
	50-56 Days (Group 2)	37	1	(3%)		1	0			(100%)	Ō		ō
	57-63 Days (Group 3)	18	0			0	0		0		0		ō

^[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.

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

The Population Council Protocol 166B

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

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age	Total Number	Number of Pts	Fisher's exact		NumberSeverity						
	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown			
ESISTANCE NECHANISM DISORDERS					-							
ANY EVENT	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0			
	≤49 Days (Group 1)	28	0		0	0	0	0	0			
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0			
	57-63 Days (Group 3)	18	0		0	0	0	0	0			
•						•						
INFECTION	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0			
	≤49 Days (Group 1)	28	0		0	0	0	0	0			
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0			
	57-63 Days (Group 3)	18	0		0	0	0	0	0			

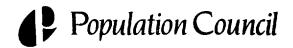
^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship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

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

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^[2] NOS - Not otherwise specified

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



ORIGINAL

ORIG AMENDMENT;

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June 25, 1999

Division of Reproductive and Urologic Drug Products (HFD-580)

Attention: Document Control Room 17B-20 Office of Drug Evaluation II Center for Drug Evaluation and Research Food and Drug Administration 5600 Fisher's Lane Rockville, MD 20857



Re: NDA 20-687, Mifepristone 200 mg Oral Tablets
Amendment 027 - Revised Physician and Patient Labeling

Per your request at our April 9, 1999 meeting with the FDA and in response to the NDA Approvable Letter from dated September 18, 1996, we are submitting revised physician and patient labeling for mifepristone. This letter describes our general responses to the FDA's requests and highlights the key changes we have made to our proposed labeling draft contained in NDA 20-687, submitted March 14, 1996. Although interim physician and patient labeling have been submitted previously to the FDA (Amendment 007 dated March 31, 1997, and Amendment 010 dated November 26, 1997), as you requested we are enclosing four copies of the revised labeling (Appendix A) and the proposed labeling, marked to show changes from the March 14, 1996 version (Appendix B). Many of the highlighted changes are due to the inclusion of the U.S. clinical trials data (previously submitted in Amendment 010, dated November 26, 1997 and submitted in final form in Amendment 024, dated June 3,1999).

This document constitutes trade secret and confidential commercial information exempt from public disclosure under 21 C.F.R. § 20.61. Should FDA tentatively determine that any portion of this document is disclosable in response to a request for inspection or copying, or in response to a request under the Freedom of Information Act, Danco Laboratories, Inc. requests immediate notification and an opportunity for consultation in accordance with 21 C.F.R. § 20.45. Contact telephone number is

Population Council

Van der Schoot, P. and Baumgarten, R. "Effects of treatment of male and female rats in infancy with mifepristone on reproductive function in adulthood." J Reprod Fertil, 1990, 90(1):255-66. in the "Carcinogenesis, Mutagenesis, Impairment of Fertility" subsection.

Copies of these articles are enclosed.

Thank you for your consideration of these changes. We look forward to your responses and working together to reach agreement upon the final labeling for this drug.

Sincerely,

Fr Sandra P. Arnold Vice President, Corporate Affairs

Fred H. See A

Population Council

President and Chief Executive Officer

The Danco Group

cc:

Frederick H. Schmidt, Ph.D., Population Council Patricia C. Vaughan, Esq., Population Council

enclosures:

Appendix A: revised labeling

Appendix B: marked labeling Appendix C: letter from USAN

Appendix D: misoprostol administration

Appendix E: articles referenced in cover letter Appendix F: articles referenced in Appendix D

Appendix C Letter from USAN



UNITED STATES ADOPTED NAMES COUNCIL

American Medical Association 515 North State Street Chicago, Illinois 60610

Telefax: 312-464-4184 E-mail: Sophia_Fuerst@ama-assn.org

SOPHIA V. FUERST, Associate Secretary (312) 464-5352

February 25, 1998

KK-48

The Population Council Center for Biomedical Research 1230 York Avenue New York, New York 10021

Attn: Frederick H. Schmidt, PhD

Scientist

Dear Dr. Schmidt:

It is my pleasure to inform you that the USAN Council adopted mifepristone as the United States Adopted Name for RU 486; RU 38486; MifegyneTM; The Population Council's sponsored progesterone antagonist used in the induction of abortion

Enclosed is a copy of the Statement of Adoption on mifepristone. Please review this information for accuracy, initial, and return the statement to me within 45 days of the date listed above. The information will be then forwarded to Mosby for publication in the journal of Clinical Pharmacology and Therapeutics and to the United States Pharmacopeial Convention, Inc., for publication in the USP Dictionary of USAN and International Nonproprietary Names.

Sincerely yours,

Sophia V. Fuerst Associate Secretary

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USAN Council

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Enclosure: N98;08

Appendix D

Misoprostol Administration

Appendix D

Misoprostol Administration

We have included an option in the label of either returning to the clinic for misoprostol administration or administering it at home for several reasons: first, clinical evidence from the Population Council's U.S. trials demonstrates that an obligatory four-hour clinic wait following administration of misoprostol is medically unnecessary. Second, empirical evidence from various trials of medical abortion regimens demonstrates home administration to be safe and, for the majority of women, preferable to clinic administration. Finally, the current standard of care in medical abortion regimens in the U.S. includes home administration of misoprostol.

Population Council's U.S. Trials: Clinical Evidence

Safety evaluable data available from 859 women in the Population Council's U.S. trials. which supplement the pivotal trials in the NDA, suggest that requiring women to return to the clinic and remain under observation for four or more hours after the administration of misoprostol is not medically necessary since adverse outcomes requiring medical intervention were less likely to occur during this time than after the first four hours. The one woman in the relevant gestational age group (≤49 days LMP) who was given a blood transfusion received it four days after taking misoprostol. Furthermore, six of the nine women who were given IV fluids received them after being discharged from the second visit. Finally, the other less severe adverse events that women experienced during this four-hour observation period were similar to the adverse events experienced during the remainder of the study period when they were not under medical observation. (I. Spitz et al. "Early pregnancy termination with mifepristone and misoprostol in the United States." N Engl J Med 1998: 338:1241-7). Overall, 65.2% of the women reported that they would have felt comfortable taking misoprostol at home, while clinicians felt that 85.5% of the women could have safely administered misoprostol at home (B. Winikoff et al. "Acceptability and feasibility of early pregnancy termination by mifepristonemisoprostol," Arch Fam Med 1998: 7:360-6).

Clinical Trials With Home Administration of Misoprostol: Empirical Evidence In addition, substantial empirical evidence has shown that home administration of misoprostol as part of a medical abortion regimen is safe and, for most women, preferable. Four clinical trials in the U.S., testing slightly different mifepristone-misoprostol medical abortion regimens, have given women the option of taking misoprostol at home or at the clinic. Of the 4,037 American women enrolled in these four trials to date, over 99% have chosen to self-administer misoprostol at home; nearly 90% of those women found this option acceptable. The home administration regimens used in these studies have proved safe and highly effective, achieving an overall average

success rate of 98%. Echoing the findings from the Population Council's U.S. trials, these trials found that women were eight times less likely to need a surgical intervention for bleeding or to experience other adverse events requiring medical treatment during the four hour period after taking misoprostol than during the remainder of the study period. Results of two of these trials are published (E. Schaff et al., "Vaginal misoprostol administered at home after mifepristone (RU486) for abortion." *J Fam Pract* 1997: 44:353-60 and E. Schaff et al., "Low-dose mifepristone 200 mg and vaginal misoprostol for abortion," *Contraception* 1999: 59:1-6), while the two others are on-going and thus involve preliminary data.

In addition, preliminary results from Population Council sponsored trials in Tunisia and Vietnam, which used 200 mg mifepristone and gave women the option of taking 400 μg oral misoprostol at home or at the clinic, found that about 85% of women chose to take misoprostol at home. Over 90% of the women who took misoprostol at home reported that they would choose this option again and all of these women were able to manage the side effects associated with misoprostol (unpublished data, available upon request). Finally, in Guadeloupe the regimen of 600 mg mifepristone taken at the clinic and 400 μg oral misoprostol taken at home has been the standard of care for medical abortion since 1992. A small home administration study of 92 women in Guadeloupe achieved a high success rate of 95% and a low incidence of complications (J.P. Guengant *et al.*, "Mifepristone-misoprostol medical abortion: Home administration of misoprostol in Guadeloupe," submitted to *Contraception*). Home administration of misoprostol did not pose any serious risks to women's health or safety in any of these studies.

Furthermore, numerous clinical trials verify the safety and high acceptability of home administration of misoprostol following methotrexate for medical abortions (M. Creinin et al., "Medical abortion with oral methotrexate and vaginal misoprostol," Obstet Gynecol 1997: 90:611-6; J. Carbonell et al., "Oral methotrexate and vaginal misoprostol for early abortion," Contraception 1998: 57:83-88; J. Carbonell et al., "Misoprostol 3, 4, or 5 days after methotrexate for early abortion: a randomized trial," Contraception 1997: 56:169-174).

Clinical Practice in the U.S.: Standard of Care

Since our initial application in 1996, clinical practice has evolved considerably, making home administration of misoprostol in medical abortion regimens the current standard of care in the U.S. For example, the National Abortion Federation's (NAF) 1999 textbook "A Clinician's Guide to Medical and Surgical Abortion" includes various protocols for methotrexate-misoprostol abortions, all of which involve home administration of misoprostol. Following a clinical trial of over 2,000 women in 27 Planned Parenthood affiliates in the U.S., the Planned Parenthood Federation of America adopted home administration of misoprostol as its standard protocol for methotrexate-misoprostol abortions. Most other methotrexate abortion providers in the U.S. also follow Planned Parenthood's home administration protocol.

The above studies along with extensive clinical experience show that home administration of misoprostol does not compromise the safety, efficacy or acceptability of medical abortion methods. Indeed, the vast majority of providers and clients agree that giving women the option of taking misoprostol at home significantly improves medical abortion services by making them less cumbersome, less expensive, more private, and more comfortable. Given the overwhelming evidence that this practice is clinically sound, we believe that the label should offer women this important choice.

APPEARS THIS WAY
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Appendix E

Articles Referenced in Cover Letter