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

Center: [redacted]

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	Severity: Mild	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%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	33 (37%)	0.3615	61	15 (25%)	30 (49%)	16 (26%)	0
	≤49 Days (Group 1)	35	11 (31%)		17	3 (18%)	10 (59%)	4 (24%)	0
	50-56 Days (Group 2)	34	12 (35%)		19	7 (37%)	7 (37%)	5 (26%)	0
	57-63 Days (Group 3)	20	10 (50%)		25	5 (20%)	13 (52%)	7 (28%)	0
DIZZINESS	≤63 Days (All)	89	13 (15%)	0.5865	17	5 (29%)	4 (24%)	8 (47%)	0
	≤49 Days (Group 1)	35	7 (20%)		8	2 (25%)	2 (25%)	4 (50%)	0
	50-56 Days (Group 2)	34	4 (12%)		5	2 (40%)	2 (40%)	1 (20%)	0
	57-63 Days (Group 3)	20	2 (10%)		4	1 (25%)	0	3 (75%)	0
HEADACHE	≤63 Days (All)	89	24 (27%)	0.0079	44	10 (23%)	26 (59%)	8 (18%)	0
	≤49 Days (Group 1)	35	4 (11%)		9	1 (11%)	8 (89%)	0	0
	50-56 Days (Group 2)	34	10 (29%)		14	5 (36%)	5 (36%)	4 (29%)	0
	57-63 Days (Group 3)	20	10 (50%)		21	4 (19%)	13 (62%)	4 (19%)	0

[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
VISION DISORDERS									
ANY EVENT	≤63 Days (All)	89	1 (1%)	0.6067	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
BLEPHARITIS	≤63 Days (All)	89	1 (1%)	0.6067	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	89	5 (6%)	1.0000	6	3 (50%)	1 (17%)	2 (33%)	0
	≤49 Days (Group 1)	35	2 (6%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	34	2 (6%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0
ANOREXIA	≤63 Days (All)	89	2 (2%)	0.6961	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0

[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS	(cont.)								
DEPRESSION	≤63 Days (All)	89	3 (3%)	0.6123	4	1 (25%)	1 (25%)	2 (50%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	0	0	1 (100%)	0
	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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	57 (64%)	0.5184	126	42 (33%)	62 (49%)	22 (17%)	0
	≤49 Days (Group 1)	35	22 (63%)		40	11 (28%)	17 (43%)	12 (30%)	0
	50-56 Days (Group 2)	34	24 (71%)		56	18 (32%)	32 (57%)	6 (11%)	0
	57-63 Days (Group 3)	20	11 (55%)		30	13 (43%)	13 (43%)	4 (13%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	89	1 (1%)	0.2247	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0
DIARRHEA	≤63 Days (All)	89	24 (27%)	0.7512	30	13 (43%)	13 (43%)	4 (13%)	0
	≤49 Days (Group 1)	35	10 (29%)		12	7 (58%)	4 (33%)	1 (8%)	0
	50-56 Days (Group 2)	34	10 (29%)		13	5 (38%)	7 (54%)	1 (8%)	0
	57-63 Days (Group 3)	20	4 (20%)		5	1 (20%)	2 (40%)	2 (40%)	0

[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)								
DYSPEPSIA	≤63 Days (All)	89	2 (2%)	0.6961	4	1 (25%)	3 (75%)	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		3	1 (33%)	2 (67%)	0	0
FLATULENCE	≤63 Days (All)	89	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤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	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	1 (100%)	0	0
VOMITING	≤63 Days (All)	89	22 (25%)	0.1241	23	3 (13%)	18 (78%)	2 (9%)	0
	≤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.
[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

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	89	2 (2%)	0.5174	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	1 (100%)	0	0
HYPOTENSION	≤63 Days (All)	89	2 (2%)	0.5174	2	0	1 (50%)	1 (50%)	0
	≤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
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	89	1 (1%)	0.2247	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0
PALPITATION	≤63 Days (All)	89	1 (1%)	0.2247	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0

[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: ~~~

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	Severity: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	1 (1%)	0.2247	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	1 (100%)	0	0
PULMONARY CONGESTION	≤63 Days (All)	89	1 (1%)	0.2247	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	1 (100%)	0	0
URINARY 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	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
MICTURITION URGENCY	≤63 Days (All)	89	1 (1%)	0.6067	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0

[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

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
URINARY 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
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	89	11 (12%)	0.0587	14	4 (29%)	0	10 (71%)	0
	≤49 Days (Group 1)	35	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	34	8 (24%)		11	2 (18%)	0	9 (82%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0
BREAST DISCHARGE	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	89	1 (1%)	0.6067	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0

[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

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	(cont.)								
LEUKORRHOEA	≤63 Days (All)	89	1 (1%)	0.6067	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
OVARIAN DISORDER	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	89	7 (8%)	0.0113	10	1 (10%)	0	9 (90%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	6 (18%)		9	1 (11%)	0	8 (89%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0
NEOPLASM									
ANY EVENT	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0
	≤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

[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
NEOPLASM	(cont.)								
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.
[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - 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	≤63 Days (All)	89	1 (1%)	0.6067	2	1 (50%)	1 (50%)	0	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
	≤49 Days (Group 1)	35	2 (6%)		2	0	1 (50%)	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
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
LEG PAIN	≤63 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 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

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
BODY 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
	≤49 Days (Group 1)	35	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0

[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: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	175	151 (86%)	0.0366	428	184 (43%)	176 (41%)	66 (15%)	2 (<1%)
	≤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 (97%)		90	35 (39%)	39 (43%)	15 (17%)	1 (1%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	175	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	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
SWEATING INCREASED	≤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
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	2 (1%)	0.3331	2	2 (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	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.
[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
DIZZINESS	≤63 Days (All)	175	1 (<1%)	0.1829	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	1 (100%)	0	0	0
HEADACHE	≤63 Days (All)	175	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	65 (37%)	0.0658	103	65 (63%)	35 (34%)	3 (3%)	0
	≤49 Days (Group 1)	71	19 (27%)		27	15 (56%)	10 (37%)	2 (7%)	0
	50-56 Days (Group 2)	72	32 (44%)		55	36 (65%)	18 (33%)	1 (2%)	0
	57-63 Days (Group 3)	32	14 (44%)		21	14 (67%)	7 (33%)	0	0
DIARRHEA	≤63 Days (All)	175	25 (14%)	0.0108	25	18 (72%)	7 (28%)	0	0
	≤49 Days (Group 1)	71	4 (6%)		4	4 (100%)	0	0	0
	50-56 Days (Group 2)	72	13 (18%)		13	9 (69%)	4 (31%)	0	0
	57-63 Days (Group 3)	32	8 (25%)		8	5 (63%)	3 (38%)	0	0

[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)								
NAUSEA	≤63 Days (All)	175	45 (26%)	0.4964	45	27 (60%)	16 (36%)	2 (4%)	0
	≤49 Days (Group 1)	71	15 (21%)		15	8 (53%)	6 (40%)	1 (7%)	0
	50-56 Days (Group 2)	72	20 (28%)		20	12 (60%)	7 (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
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	175	2 (1%)	1.0000	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	71	1 (1%)		1	0	0	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 (1%)	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.
[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
URINARY 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
REPRODUCTIVE 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
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	0	0	1 (100%)	0

[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	(cont.)								
UTERINE DISORDER NOS	≤63 Days (All)	175	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	175	8 (5%)	1.0000	9	0	0	9 (100%)	0
	≤49 Days (Group 1)	71	3 (4%)		4	0	0	4 (100%)	0
	50-56 Days (Group 2)	72	4 (6%)		4	0	0	4 (100%)	0
	57-63 Days (Group 3)	32	1 (3%)		1	0	0	1 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	175	149 (85%)	0.0539	308	116 (38%)	139 (45%)	51 (17%)	2 (<1%)
	≤49 Days (Group 1)	71	55 (77%)		104	40 (38%)	47 (45%)	17 (16%)	0
	50-56 Days (Group 2)	72	64 (89%)		138	56 (41%)	60 (43%)	21 (15%)	1 (<1%)
	57-63 Days (Group 3)	32	30 (94%)		66	20 (30%)	32 (48%)	13 (20%)	1 (2%)
ABDOMINAL PAIN	≤63 Days (All)	175	147 (84%)	0.0920	300	112 (37%)	135 (45%)	51 (17%)	2 (<1%)
	≤49 Days (Group 1)	71	55 (77%)		102	39 (38%)	46 (45%)	17 (17%)	0
	50-56 Days (Group 2)	72	62 (86%)		134	54 (40%)	58 (43%)	21 (16%)	1 (<1%)
	57-63 Days (Group 3)	32	30 (94%)		64	19 (30%)	31 (48%)	13 (20%)	1 (2%)

[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ASTHENIA	≤63 Days (All)	175	2 (1%)	0.3331	2	0	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	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.
[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

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	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	178	173 (97%)	0.3309	560	154 (28%)	223 (40%)	183 (33%)	0
	≤49 Days (Group 1)	72	69 (96%)		218	63 (29%)	86 (39%)	69 (32%)	0
	50-56 Days (Group 2)	54	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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	178	123 (69%)	0.6317	230	105 (46%)	87 (38%)	38 (17%)	0
	≤49 Days (Group 1)	72	48 (67%)		81	40 (49%)	30 (37%)	11 (14%)	0
	50-56 Days (Group 2)	54	40 (74%)		77	40 (52%)	26 (34%)	11 (14%)	0
	57-63 Days (Group 3)	52	35 (67%)		72	25 (35%)	31 (43%)	16 (22%)	0
DIARRHEA	≤63 Days (All)	178	32 (18%)	0.6040	34	15 (44%)	16 (47%)	3 (9%)	0
	≤49 Days (Group 1)	72	11 (15%)		11	5 (45%)	5 (45%)	1 (9%)	0
	50-56 Days (Group 2)	54	12 (22%)		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 (20%)	0
	≤49 Days (Group 1)	72	43 (60%)		49	26 (53%)	17 (35%)	6 (12%)	0
	50-56 Days (Group 2)	54	33 (61%)		46	24 (52%)	13 (28%)	9 (20%)	0
	57-63 Days (Group 3)	52	30 (58%)		41	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.
[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: NICHOLS (#25)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL 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	2 (100%)	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	52	1 (2%)		2	0	0	2 (100%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	178	4 (2%)	1.0000	5	0	0	5 (100%)	0
	≤49 Days (Group 1)	72	2 (3%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	52	1 (2%)		2	0	0	2 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	178	171 (96%)	0.4932	325	49 (15%)	136 (42%)	140 (43%)	0
	≤49 Days (Group 1)	72	69 (96%)		135	23 (17%)	56 (41%)	56 (41%)	0
	50-56 Days (Group 2)	54	53 (98%)		96	15 (16%)	39 (41%)	42 (44%)	0
	57-63 Days (Group 3)	52	49 (94%)		94	11 (12%)	41 (44%)	42 (45%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] 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

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	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	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 (96%)		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.
[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

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

Center: SHEEHAN (#26)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
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 (<1%)
	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
SKIN 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	0
	50-56 Days (Group 2)	59	2 (3%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
PRURITUS	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
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	0
	50-56 Days (Group 2)	59	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[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

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

Center: SHEEHAN (#26)

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	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT†	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
MYALGIA	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	22 (12%)	0.6856	30	4 (13%)	25 (83%)	1 (3%)	0
	≤49 Days (Group 1)	63	6 (10%)		8	1 (13%)	7 (88%)	0	0
	50-56 Days (Group 2)	59	9 (15%)		13	1 (8%)	11 (85%)	1 (8%)	0
	57-63 Days (Group 3)	57	7 (12%)		9	2 (22%)	7 (78%)	0	0
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	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] 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)

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	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
HEADACHE	≤63 Days (All)	179	18 (10%)	0.7431	22	1 (5%)	21 (95%)	0	0
	≤49 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
PSYCHIATRIC 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
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	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 (2%)		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.
[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

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

Center: SHEEHAN (#26)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	144 (80%)	0.8417	241	117 (49%)	95 (39%)	29 (12%)	0
	≤49 Days (Group 1)	63	50 (79%)		78	37 (47%)	33 (42%)	8 (10%)	0
	50-56 Days (Group 2)	59	49 (83%)		82	35 (43%)	37 (45%)	10 (12%)	0
	57-63 Days (Group 3)	57	45 (79%)		81	45 (56%)	25 (31%)	11 (14%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	179	2 (1%)	0.3302	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	63	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	179	23 (13%)	0.7556	24	13 (54%)	11 (46%)	0	0
	≤49 Days (Group 1)	63	9 (14%)		9	3 (33%)	6 (67%)	0	0
	50-56 Days (Group 2)	59	6 (10%)		6	4 (67%)	2 (33%)	0	0
	57-63 Days (Group 3)	57	8 (14%)		9	6 (67%)	3 (33%)	0	0
DYSPEPSIA	≤63 Days (All)	179	2 (1%)	0.2076	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	179	136 (76%)	0.6704	169	92 (54%)	53 (31%)	24 (14%)	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 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: SHEEHAN (#26)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: 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%)	0	0
	50-56 Days (Group 2)	59	13 (22%)		17	3 (18%)	12 (71%)	2 (12%)	0
	57-63 Days (Group 3)	57	16 (28%)		16	5 (31%)	8 (50%)	3 (19%)	0
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤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		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
HYPOTENSION	≤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		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	1 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[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

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

Center: SHEEHAN (#26)

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	Severity: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS	(cont.)								
DYSPNOEA	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	179	20 (11%)	0.2500	20	11 (55%)	7 (35%)	2 (10%)	0
	≤49 Days (Group 1)	63	4 (6%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	59	7 (12%)		7	4 (57%)	2 (29%)	1 (14%)	0
	57-63 Days (Group 3)	57	9 (16%)		9	4 (44%)	4 (44%)	1 (11%)	0
ANAEMIA	≤63 Days (All)	179	19 (11%)	0.2482	19	10 (53%)	7 (37%)	2 (11%)	0
	≤49 Days (Group 1)	63	4 (6%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	59	6 (10%)		6	3 (50%)	2 (33%)	1 (17%)	0
	57-63 Days (Group 3)	57	9 (16%)		9	4 (44%)	4 (44%)	1 (11%)	0
ANAEMIA HYPOCHROMIC	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[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

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

Center: SHEEHAN (#26)

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE 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	0	2 (100%)	0
	50-56 Days (Group 2)	59	5 (8%)		6	1 (17%)	2 (33%)	3 (50%)	0
	57-63 Days (Group 3)	57	6 (11%)		6	0	1 (17%)	5 (83%)	0
BREAST DISCHARGE	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
UTERINE ATONY	≤63 Days (All)	179	2 (1%)	0.1002	2	0	1 (50%)	1 (50%)	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	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	2 (100%)	0
	50-56 Days (Group 2)	59	5 (8%)		5	0	2 (40%)	3 (60%)	0
	57-63 Days (Group 3)	57	4 (7%)		4	0	0	4 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	179	174 (97%)	0.1300	472	148 (31%)	228 (48%)	95 (20%)	1 (<1%)
	≤49 Days (Group 1)	63	59 (94%)		152	49 (32%)	79 (52%)	23 (15%)	1 (<1%)
	50-56 Days (Group 2)	59	58 (98%)		152	45 (30%)	72 (47%)	35 (23%)	0
	57-63 Days (Group 3)	57	57 (100%)		168	54 (32%)	77 (46%)	37 (22%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] 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

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

Center: SHEEHAN (#26)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY 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		0	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 (80%)	0	0
	50-56 Days (Group 2)	59	3 (5%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	57	1 (2%)		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 (33%)	2 (67%)	0	0
FEVER	≤63 Days (All)	179	2 (1%)	0.7667	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	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.
[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

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

Center: SHEEHAN (#26)

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	Severity: Mild	Moderate	Severe	Unknown
BODY 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	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
MALAISE	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
OEDEMA	≤63 Days (All)	179	2 (1%)	0.2076	2	0	1 (50%)	1 (50%)	0
	≤49 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	0	1 (100%)	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	0	1 (100%)	0
RIGORS	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[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

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

Center: SHEEHAN (#26)

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
SYNCOPE	≤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	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[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)

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	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	191	187 (98%)	0.0313	1028	350 (34%)	388 (38%)	264 (26%)	26 (3%)
	≤49 Days (Group 1)	29	27 (93%)		129	38 (29%)	59 (46%)	32 (25%)	0
	50-56 Days (Group 2)	73	71 (97%)		384	150 (39%)	142 (37%)	81 (21%)	11 (3%)
	57-63 Days (Group 3)	89	89 (100%)		515	162 (31%)	187 (36%)	151 (29%)	15 (3%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	191	3 (2%)	0.5453	3	2 (67%)	0	1 (33%)	0
	≤49 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 (1%)		1	0	0	1 (100%)	0

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

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

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	Severity: Mild	Moderate	Severe	Unknown
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	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	38 (20%)	0.9103	57	11 (19%)	34 (60%)	10 (18%)	2 (4%)
	≤49 Days (Group 1)	29	5 (17%)		8	1 (13%)	6 (75%)	1 (13%)	0
	50-56 Days (Group 2)	73	14 (19%)		22	4 (18%)	14 (64%)	3 (14%)	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 (33%)	5 (56%)	0
	≤49 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	6 (7%)		7	1 (14%)	2 (29%)	4 (57%)	0
HEADACHE	≤63 Days (All)	191	34 (18%)	0.9661	48	10 (21%)	31 (65%)	5 (10%)	2 (4%)
	≤49 Days (Group 1)	29	5 (17%)		8	1 (13%)	6 (75%)	1 (13%)	0
	50-56 Days (Group 2)	73	14 (19%)		20	4 (20%)	13 (65%)	2 (10%)	1 (5%)
	57-63 Days (Group 3)	89	15 (17%)		20	5 (25%)	12 (60%)	2 (10%)	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.
[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

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

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	Severity: Mild	Moderate	Severe	Unknown
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	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
INSOMNIA	≤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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	129 (68%)	0.0171	284	114 (40%)	100 (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%)	39 (39%)	14 (14%)	0
	57-63 Days (Group 3)	89	66 (74%)		161	59 (37%)	54 (34%)	47 (29%)	1 (<1%)
DIARRHEA	≤63 Days (All)	191	53 (28%)	0.1914	69	36 (52%)	25 (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 (8%)	0
	57-63 Days (Group 3)	89	30 (34%)		38	16 (42%)	17 (45%)	5 (13%)	0

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

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

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	Severity: Mild	Moderate	Severe	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
	≤49 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	58 (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.
[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

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

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
RESPIRATORY SYSTEM DISORDERS	(cont.)								
HYPERVENTILATION	≤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
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	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
ANAEMIA	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	191	13 (7%)	0.0163	18	1 (6%)	8 (44%)	9 (50%)	0
	≤49 Days (Group 1)	29	1 (3%)		3	0	0	3 (100%)	0
	50-56 Days (Group 2)	73	1 (1%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	89	11 (12%)		13	1 (8%)	6 (46%)	6 (46%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] 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)

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	Severity: Mild	Moderate	Severe	Unknown
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	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	191	10 (5%)	0.0069	14	0	6 (43%)	8 (57%)	0
	≤49 Days (Group 1)	29	1 (3%)		3	0	0	3 (100%)	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	9 (10%)		11	0	6 (55%)	5 (45%)	0
VAGINAL DISCOMFORT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0
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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	191	187 (98%)	0.0313	662	221 (33%)	243 (37%)	175 (26%)	23 (3%)
	≤49 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 (4%)
	57-63 Days (Group 3)	89	89 (100%)		311	96 (31%)	111 (36%)	91 (29%)	13 (4%)

[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

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

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	Severity: Mild	Moderate	Severe	Unknown
BODY 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%)		89	26 (29%)	43 (48%)	20 (22%)	0
	50-56 Days (Group 2)	73	71 (97%)		239	90 (38%)	78 (33%)	61 (26%)	10 (4%)
	57-63 Days (Group 3)	89	89 (100%)		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%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0
BACK PAIN	≤63 Days (All)	191	13 (7%)	1.0000	22	5 (23%)	9 (41%)	4 (18%)	4 (18%)
	≤49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	73	5 (7%)		11	4 (36%)	6 (55%)	1 (9%)	0
	57-63 Days (Group 3)	89	6 (7%)		9	0	2 (22%)	3 (33%)	4 (44%)
FATIGUE	≤63 Days (All)	191	4 (2%)	0.2093	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	29	2 (7%)		2	0	2 (100%)	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	1 (100%)	0	0	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%)		3	3 (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.
[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

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

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
HOT FLUSHES	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0
MALAISE	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	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
	≤49 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
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤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.
[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

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

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	Severity: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS	(cont.)								
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.
[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

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

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL 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	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	19 (17%)	0.0277	26	8 (31%)	17 (65%)	1 (4%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	9 (18%)		14	3 (21%)	10 (71%)	1 (7%)	0
	57-63 Days (Group 3)	42	10 (24%)		12	5 (42%)	7 (58%)	0	0
DIZZINESS	≤63 Days (All)	115	4 (3%)	0.8288	5	3 (60%)	2 (40%)	0	0
	≤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	0
	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
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	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 (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.
[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

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

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC 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	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
	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	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
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	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		3	1 (33%)	2 (67%)	0	0
DYSPAREUNIA	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
GASTRO-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%)		22	9 (41%)	7 (32%)	6 (27%)	0
	50-56 Days (Group 2)	50	36 (72%)		65	22 (34%)	31 (48%)	12 (18%)	0
	57-63 Days (Group 3)	42	30 (71%)		57	30 (53%)	17 (30%)	10 (18%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] 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

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

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL 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%)	0
	≤49 Days (Group 1)	23	7 (30%)		9	4 (44%)	3 (33%)	2 (22%)	0
	50-56 Days (Group 2)	50	20 (40%)		23	10 (43%)	9 (39%)	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	0
	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%)	0
	50-56 Days (Group 2)	50	30 (60%)		33	10 (30%)	15 (45%)	8 (24%)	0
	57-63 Days (Group 3)	42	23 (55%)		29	13 (45%)	10 (34%)	6 (21%)	0
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%)	0
	50-56 Days (Group 2)	50	9 (18%)		9	2 (22%)	7 (78%)	0	0
	57-63 Days (Group 3)	42	8 (19%)		10	2 (20%)	5 (50%)	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.
[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

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

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	2 (2%)	0.1699	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	2 (5%)		2	1 (50%)	1 (50%)	0	0
DYSURIA	≤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
URINARY TRACT INFECTION	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	115	10 (9%)	1.0000	12	3 (25%)	1 (8%)	8 (67%)	0
	≤49 Days (Group 1)	23	2 (9%)		3	1 (33%)	0	2 (67%)	0
	50-56 Days (Group 2)	50	4 (8%)		4	1 (25%)	1 (25%)	2 (50%)	0
	57-63 Days (Group 3)	42	4 (10%)		5	1 (20%)	0	4 (80%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] 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)

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	(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	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
ENDOMETRITIS	≤63 Days (All)	115	1 (<1%)	0.2000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	115	7 (6%)	0.6803	8	0	1 (13%)	7 (88%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	50	2 (4%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	42	3 (7%)		4	0	0	4 (100%)	0
VAGINITIS	≤63 Days (All)	115	2 (2%)	1.0000	2	1 (50%)	0	1 (50%)	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	1 (2%)		1	1 (100%)	0	0	0
BODY 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 (32%)	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.
[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

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

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - 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%)	0
	57-63 Days (Group 3)	42	41 (98%)		117	27 (23%)	43 (37%)	47 (40%)	0
BACK PAIN	≤63 Days (All)	115	11 (10%)	0.0452	13	5 (38%)	5 (38%)	3 (23%)	0
	≤49 Days (Group 1)	23	1 (4%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	50	2 (4%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	42	8 (19%)		10	4 (40%)	4 (40%)	2 (20%)	0
CHEST PAIN	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	115	2 (2%)	0.3173	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	1 (100%)	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
LEG PAIN	≤63 Days (All)	115	2 (2%)	0.6796	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	2 (4%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0

[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)

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
RIGORS	≤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.
[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

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 Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	83	75 (90%)	1.0000	223	46 (21%)	82 (37%)	95 (43%)	0
	≤49 Days (Group 1)	28	25 (89%)		69	13 (19%)	37 (54%)	19 (28%)	0
	50-56 Days (Group 2)	37	34 (92%)		106	22 (21%)	35 (33%)	49 (46%)	0
	57-63 Days (Group 3)	18	16 (89%)		48	11 (23%)	10 (21%)	27 (56%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	7 (8%)	0.3605	7	2 (29%)	4 (57%)	1 (14%)	0
	≤49 Days (Group 1)	28	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	37	2 (5%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	18	3 (17%)		3	1 (33%)	1 (33%)	1 (33%)	0
DIZZINESS	≤63 Days (All)	83	4 (5%)	0.4250	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	2 (11%)		2	1 (50%)	1 (50%)	0	0
HEADACHE	≤63 Days (All)	83	3 (4%)	1.0000	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	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.
[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

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 Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	28 (34%)	0.2500	57	5 (9%)	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 (41%)		32	3 (9%)	12 (38%)	17 (53%)	0
	57-63 Days (Group 3)	18	7 (39%)		14	2 (14%)	1 (7%)	11 (79%)	0
DIARRHEA	≤63 Days (All)	83	12 (14%)	0.4010	12	2 (17%)	3 (25%)	7 (58%)	0
	≤49 Days (Group 1)	28	2 (7%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	37	7 (19%)		7	1 (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
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	1 (100%)	0	0	0
NAUSEA	≤63 Days (All)	83	21 (25%)	0.0692	23	2 (9%)	7 (30%)	14 (61%)	0
	≤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 (67%)	0
	≤49 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.
[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

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 Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
EPISTAXIS	≤63 Days (All)	83	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	83	2 (2%)	0.6956	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	0	1 (100%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	83	2 (2%)	0.6956	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	0	1 (100%)	0

[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

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 Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	83	70 (84%)	0.5823	155	39 (25%)	60 (39%)	56 (36%)	0
	≤49 Days (Group 1)	28	25 (89%)		56	12 (21%)	32 (57%)	12 (21%)	0
	50-56 Days (Group 2)	37	31 (84%)		69	19 (28%)	20 (29%)	30 (43%)	0
	57-63 Days (Group 3)	18	14 (78%)		30	8 (27%)	8 (27%)	14 (47%)	0
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%)	0
	57-63 Days (Group 3)	18	14 (78%)		30	8 (27%)	8 (27%)	14 (47%)	0
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	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
MALAISE	≤63 Days (All)	83	2 (2%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0

[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: SOGOR (#29)

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	Severity: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM 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.
[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

Population Council

ORIGINAL

ORIG AMENDMENT

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 [redacted] 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

One Dag Hammarskjold Plaza, New York, New York 10017
Telephone: (212) 339-0500 Facsimile: (212) 755-6052 Email: pubinfo@popcouncil.org http://www.popcouncil.org

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,

Frederick H. Schmidt

for Sandra P. Arnold
Vice President, Corporate Affairs
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

USAN

UNITED STATES ADOPTED NAMES COUNCIL

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

American Medical Association
515 North State Street
Chicago, Illinois 60610

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

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; Mifegyne™; 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

Sophia V. Fuerst
Associate Secretary
USAN Council

SF

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 mifepristone-misoprostol," *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
ON ORIGINAL

Appendix E

Articles Referenced in Cover Letter