

STUDY NAME: DRUG13-LAC

Ring voor vaginale toediening van lactaet

Plaatsing - verwijdering vaginale ring
 Deel 1 (AN001-002) 06sep14 - 16sep14
 Deel 2 Cohort 1 (AN003-004) 01dec14 - 08dec14
 Deel 2 Cohort 2 (AN005-006) 10dec14 - 17dec14

DRUG RESEARCH UNIT GHENT

update: 13JAN15

CLINICAL ADVERSE EVENTS FORM

Allocation number	Adverse Event	Start Date	Start Time	Stop Date	Stop Time	Intensity	Frequency	*Relationship to study medication	Serious (no / yes)	Duration	**Outcome	***Action taken with study medication	Comments
001	runny nose break through bleeding	11-Sep-14 15-Sep-14	7:00 7:00	12-Sep-14 22-Sep-14	18:00 7:00	mild mild	intermittent continuous	1 1	no no		1 1	1 1	
002	post procedural hemorrhage pressure sensation of lower abdomen pain in jaw	8-Sep-14 8-Sep-14 13-Sep-14	9:45 19:00 20:00	8-Sep-14 9-Sep-14 ongoing	17:00 17:00 NAP	mild mild mild	intermittent intermittent continuous	1 1 1	no no no	7 Hours & 15 Minutes 22 Hours	1 1 4	1 1 1	
003	none												
004	none												
005	vulval irritation vulval irritation	10-Dec-14 10-Dec-14	11:00 13:31	10-Dec-14 10-Dec-14	13:30 14:30	mild mild	continuous intermittent	1 1	no no	2 Hours & 30 Minutes 59 Minutes	1 1	1 1	procedure related procedure related
006	vaginal foreign body feeling sore throat bronchitis	10-Dec-14 13-Dec-14 16-Dec-14	21:30 14:00 9:31	11-Dec-14 16-Dec-14 11-Jan-15	7:15 9:30 8:30	mild mild moderate	continuous continuous continuous	2 1 1	no no no	9 Hours & 45 Minutes	1 1 1	1 1 1	

*Relation to study medication

1	definitely not related
2	probably not related
3	possibly related
4	probably related
5	definitely related

**Outcome

1	Recovered/Resolved
2	Recovering/Resolving
3	Recovered/Resolved with Sequelae
4	Not Recovered/Not resolved
5	Fatal
6	Unknown

***Action taken with study medication

1	None
2	Reduced
3	Interrupted
4	Discontinued
5	Increased
6	Not Applicable
7	Unknown

APPROVED BY AC+DB
 13 JAN. 2015

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 04 FEB 2015