



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2016
EMA/34528/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: misoprostol (gynaecological indication - termination of pregnancy)

Procedure no.: PSUSA/00010354/201505



Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Gymiso		3400936249943	Linepharma International Limited	France
Topogyne	NL/H/2355/001/DC	BE433002 \$ BE433011	Exelgyn Sa	Belgium
Misoone	NL/H/2355/001	13-0015	Exelgyn Sa	Latvia
Misoone	NL/H/2355/001	3400927383366 \$ 3400927383427 \$ 3400927426513 \$ 3400927426681 \$ 3400958496455 \$ 3400958496516 \$ 3400958496684 \$ 3400958496745	Exelgyn Sa	France
Misoone	NL/H/2355/001	49597	Exelgyn Sa	Denmark
Misoone	NL/H/2355/001	86194.00.00	Exelgyn Sa	Germany
Misoone	NL/H/2355/001	RVG 110664	Exelgyn Sa	Netherlands
Misoone	NL/H/2355/001/DC	041926015 \$ 041926027 \$ 041926039 \$ 041926041 \$ 041926054 \$ 041926066 \$ 041926078 \$ 041926080	Exelgyn Sa	Italy
Misoone	NL/H/2355/001/DC	11-8648	Exelgyn Sa	Norway
Misoone	NL/H/2355/001/DC	606449-8 \$ 606451-1 \$ 696848-2 \$ 702410-1	Exelgyn Sa	Spain
Misoprostol Exelgyn		RVG 113032	Exelgyn Sa	Netherlands
Mispregnol	NL/H/2355/001	54/246/13-C	Exelgyn Sa	Czech Republic
Topogyne	NL/H/2355/001	46903	Exelgyn Sa	Sweden
Topogyne	NL/H/2355/001	5466/2013/01 \$ 5466/2013/02 \$ 5466/2013/03 \$ 5466/2013/04 \$ 5466/2013/05 \$ 5466/2013/06 \$ 5466/2013/07 \$ 5466/2013/08	Exelgyn Sa	Romania
Topogyne	NL/H/2355/001/DC	1-31715	Exelgyn Sa	Austria
Topogyne	NL/H/2355/001/DC	H/13/01541/001 \$ H/13/01541/002 \$ H/13/01541/003 \$ H/13/01541/004	Exelgyn Sa	Slovenia

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Topogyne	NL/H/2355/001/DC	801412	Exelgyn Sa	Estonia
Topogyne	NL/H/2355/001/DC	PL 16152/0003	Exelgyn Sa	United Kingdom
топогин	NL/H/2355/001	20130303	Exelgyn Sa	Bulgaria
Misoone	NL/H/2355/001	30188	Exelgyn Sa	Finland
Topogyne	NL/H/2355/001	2013060197	Exelgyn Sa	Luxembourg
Topogyne	NL/H/2355/001		Exelgyn Sa	Portugal
Mispregnot	NL/H/2355/001	2011/06460-REG	Exelgyn Sa	Slovak Republic