



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 January 2018
EMA/9690/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00010354/201705



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® 200 microgrammes, comprimé	not available	3400936249943	LINEPHARMA INTERNATIONAL LIMITED	FR
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	EXELGYN SA	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	EXELGYN SA	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	EXELGYN SA	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	EXELGYN SA	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	EXELGYN SA	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	EXELGYN SA	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	EXELGYN SA	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	EXELGYN SA	NL
MisoOne 400 microgrammes, comprimé	NL/H/2355/001	3400927383366	EXELGYN SA	FR
MisoOne 400 microgrammes, comprimé	NL/H/2355/001	3400927383427	EXELGYN SA	FR
MisoOne 400 microgrammes, comprimé	NL/H/2355/001	3400927426513	EXELGYN SA	FR
MisoOne 400 microgrammes, comprimé	NL/H/2355/001	3400927426681	EXELGYN SA	FR
MisoOne 400 microgrammes, comprimé	NL/H/2355/001	3400958496455	EXELGYN SA	FR
MisoOne 400 microgrammes, comprimé	NL/H/2355/001	3400958496516	EXELGYN SA	FR

MisoOne 400 microgrammes, comprimé	NL/H/2355/001	3400958496684	EXELGYN SA	FR
MisoOne 400 microgrammes, comprimé	NL/H/2355/001	3400958496745	EXELGYN SA	FR
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926066	EXELGYN SA	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926054	EXELGYN SA	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926080	EXELGYN SA	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926027	EXELGYN SA	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926041	EXELGYN SA	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926039	EXELGYN SA	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926078	EXELGYN SA	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926015	EXELGYN SA	IT
MisoOne 400 microgramos comprimidos	NL/H/2355/001	606449-8	EXELGYN SA	ES
MisoOne 400 microgramos comprimidos	NL/H/2355/001	702410-1	EXELGYN SA	ES
MisoOne 400 microgramos comprimidos	NL/H/2355/001	606451-1	EXELGYN SA	ES
MisoOne 400 microgramos comprimidos	NL/H/2355/001	696848-2	EXELGYN SA	ES
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	EXELGYN SA	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	EXELGYN SA	NO

Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	EXELGYN SA	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	EXELGYN SA	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	EXELGYN SA	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	EXELGYN SA	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	EXELGYN SA	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	EXELGYN SA	NO
Misoone 400 mikrogrami tabletes	NL/H/2355/001/DC	13-0015	EXELGYN SA	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001/DC	13-0015	EXELGYN SA	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001/DC	13-0015	EXELGYN SA	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001/DC	13-0015	EXELGYN SA	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001/DC	13-0015	EXELGYN SA	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001/DC	13-0015	EXELGYN SA	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001/DC	13-0015	EXELGYN SA	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001/DC	13-0015	EXELGYN SA	LV
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.0	EXELGYN SA	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.0	EXELGYN SA	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.0	EXELGYN SA	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.0	EXELGYN SA	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.0	EXELGYN SA	DE

MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.0	EXELGYN SA	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.0	EXELGYN SA	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.0	EXELGYN SA	DE
MisoOne, tabletter	NL/H/2355/001	49597	EXELGYN SA	DK
MisoOne, tabletter	NL/H/2355/001	49597	EXELGYN SA	DK
MisoOne, tabletter	NL/H/2355/001	49597	EXELGYN SA	DK
MisoOne, tabletter	NL/H/2355/001	49597	EXELGYN SA	DK
MisoOne, tabletter	NL/H/2355/001	49597	EXELGYN SA	DK
MisoOne, tabletter	NL/H/2355/001	49597	EXELGYN SA	DK
MisoOne, tabletter	NL/H/2355/001	49597	EXELGYN SA	DK
MisoOne, tabletter	NL/H/2355/001	49597	EXELGYN SA	DK
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	EXELGYN SA	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	EXELGYN SA	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	EXELGYN SA	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	EXELGYN SA	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	EXELGYN SA	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	EXELGYN SA	NL
Mispregnol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-02	EXELGYN SA	HR
Mispregnol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-03	EXELGYN SA	HR
Mispregnol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-04	EXELGYN SA	HR

Mispregnol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-04	EXELGYN SA	HR
Mispregnol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-03	EXELGYN SA	HR
Mispregnol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-02	EXELGYN SA	HR
Mispregnol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-01	EXELGYN SA	HR
Mispregnol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-01	EXELGYN SA	HR
Mispregnol 400 mikrogramov tablety	NL/H/2355/001	81/0147/13-S	EXELGYN SA	SK
Mispregnol 400 mikrogramov tablety	NL/H/2355/001	81/0147/13-S	EXELGYN SA	SK
Mispregnol 400 mikrogramov tablety	NL/H/2355/001	81/0147/13-S	EXELGYN SA	SK
Mispregnol 400 mikrogramov tablety	NL/H/2355/001	81/0147/13-S	EXELGYN SA	SK
Mispregnol 400 mikrogramov tablety	NL/H/2355/001	81/0147/13-S	EXELGYN SA	SK
Mispregnol 400 mikrogramov tablety	NL/H/2355/001	81/0147/13-S	EXELGYN SA	SK
Mispregnol 400 mikrogramov tablety	NL/H/2355/001	81/0147/13-S	EXELGYN SA	SK
Mispregnol 400 mikrogramov tablety	NL/H/2355/001	81/0147/13-S	EXELGYN SA	SK
Mispregnol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	EXELGYN SA	CZ
Mispregnol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	EXELGYN SA	CZ
Mispregnol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	EXELGYN SA	CZ
Mispregnol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	EXELGYN SA	CZ
Mispregnol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	EXELGYN SA	CZ
Mispregnol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	EXELGYN SA	CZ

Mispregnol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	EXELGYN SA	CZ
Mispregnol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	EXELGYN SA	CZ
Topogyne 400 microgram tablets	NL/H/2355/001	PL 16152/0003	EXELGYN SA	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 16152/0003	EXELGYN SA	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 16152/0003	EXELGYN SA	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 16152/0003	EXELGYN SA	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 16152/0003	EXELGYN SA	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 16152/0003	EXELGYN SA	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 16152/0003	EXELGYN SA	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 16152/0003	EXELGYN SA	UK
Topogyne 400 micrograme, Comprimate	NL/H/2355/001	5466/2013/08	EXELGYN SA	RO
Topogyne 400 micrograme, Comprimate	NL/H/2355/001	5466/2013/07	EXELGYN SA	RO
Topogyne 400 micrograme, Comprimate	NL/H/2355/001	5466/2013/06	EXELGYN SA	RO
Topogyne 400 micrograme, Comprimate	NL/H/2355/001	5466/2013/04	EXELGYN SA	RO
Topogyne 400 micrograme, Comprimate	NL/H/2355/001	5466/2013/03	EXELGYN SA	RO
Topogyne 400 micrograme, Comprimate	NL/H/2355/001	5466/2013/02	EXELGYN SA	RO
Topogyne 400 micrograme, Comprimate	NL/H/2355/001	5466/2013/01	EXELGYN SA	RO
Topogyne 400 micrograme, Comprimate	NL/H/2355/001	5466/2013/05	EXELGYN SA	RO
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433011	EXELGYN SA	BE

Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433011	EXELGYN SA	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433002	EXELGYN SA	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433002	EXELGYN SA	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433002	EXELGYN SA	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433011	EXELGYN SA	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433002	EXELGYN SA	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433011	EXELGYN SA	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001/DC	2013060197	EXELGYN SA	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001/DC	2013060197	EXELGYN SA	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001/DC	2013060197	EXELGYN SA	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001/DC	2013060197	EXELGYN SA	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001/DC	2013060197	EXELGYN SA	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001/DC	2013060197	EXELGYN SA	LU

Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	EXELGYN SA	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	EXELGYN SA	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	EXELGYN SA	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	EXELGYN SA	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	EXELGYN SA	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	EXELGYN SA	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	EXELGYN SA	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	EXELGYN SA	SE
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	EXELGYN SA	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	EXELGYN SA	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	EXELGYN SA	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	EXELGYN SA	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	EXELGYN SA	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	EXELGYN SA	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	EXELGYN SA	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	EXELGYN SA	AT
Topogyne 400 mikrogramov tablete	NL/H/2355/001	5363-I-1767/13	EXELGYN SA	SI
Topogyne 400 mikrogramov tablete	NL/H/2355/001	5363-I-1768/13	EXELGYN SA	SI
Topogyne 400 mikrogramov tablete	NL/H/2355/001	5363-I-1766/13	EXELGYN SA	SI

Topogyne 400 mikrogramov tablete	NL/H/2355/001	5363-I-1765/13	EXELGYN SA	SI
Topogyne, 400 mikrogrammi, tabletid	NL/H/2355/001	801412	EXELGYN SA	EE
Topogyne, 400 mikrogrammi, tabletid	NL/H/2355/001	801412	EXELGYN SA	EE
Topogyne, 400 mikrogrammi, tabletid	NL/H/2355/001	801412	EXELGYN SA	EE
Topogyne, 400 mikrogrammi, tabletid	NL/H/2355/001	801412	EXELGYN SA	EE
Topogyne, 400 mikrogrammi, tabletid	NL/H/2355/001	801412	EXELGYN SA	EE
Topogyne, 400 mikrogrammi, tabletid	NL/H/2355/001	801412	EXELGYN SA	EE
Topogyne, 400 mikrogrammi, tabletid	NL/H/2355/001	801412	EXELGYN SA	EE
Топогин 400 микрограма, таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG
Топогин 400 микрограма, таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG
Топогин 400 микрограма, таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG
Топогин 400 микрограма, таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG
Топогин 400 микрограма, таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG
Топогин 400 микрограма, таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG
Топогин 400 микрограма, таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG
Топогин 400 микрограма, таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG