



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2018
EMA/9653/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: mifepristone

Procedure no.: PSUSA/00002060/201705



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
Mifegyne	NL/H/2937/002	30741	EXELGYN SA	DK
Mifegyne	NL/H/2937/002	30741	EXELGYN SA	DK
Mifegyne	NL/H/2937/002	30741	EXELGYN SA	DK
Mifegyne	NL/H/2937/002	30741	EXELGYN SA	DK
Mifegyne 200 mg compresse	NL/H/2937/002	038704021/M	EXELGYN SA	IT
Mifegyne 200 mg compresse	NL/H/2937/002	038704019/M	EXELGYN SA	IT
Mifegyne 200 mg comprimés	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 200 mg comprimés	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 200 mg comprimés	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 200 mg comprimés	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 200 mg comprimidos	NL/H/2937/002	62728	EXELGYN SA	ES
Mifegyne 200 mg comprimidos	NL/H/2937/002	62728	EXELGYN SA	ES
Mifegyne 200 mg comprimidos	NL/H/2937/002	5403217	EXELGYN SA	PT
Mifegyne 200 mg comprimidos	NL/H/2937/002	5403209	EXELGYN SA	PT
Mifegyne 200 mg comprimidos	NL/H/2937/002	5178264	EXELGYN SA	PT
Mifegyne 200 mg comprimidos	NL/H/2937/002	5178256	EXELGYN SA	PT
Mifegyne 200 mg tablete	NL/H/2937/002/DC	5363-I-1293/13	EXELGYN SA	SI
Mifegyne 200 mg tablete	NL/H/2937/002/DC	5363-I-1293/13	EXELGYN SA	SI
Mifegyne 200 mg tablete	NL/H/2937/002/DC	5363-I-1293/13	EXELGYN SA	SI

Mifegyne 200 mg tablete	NL/H/2937/002/DC	5363-I-1293/13	EXELGYN SA	SI
Mifegyne 200 mg tablettes	NL/H/2937/002	02-0229	EXELGYN SA	LV
Mifegyne 200 mg tabletit	NL/H/2937/002	14064	EXELGYN SA	FI
Mifegyne 200 mg tabletit	NL/H/2937/002	14064	EXELGYN SA	FI
Mifegyne 200 mg tabletit	NL/H/2937/002	14064	EXELGYN SA	FI
Mifegyne 200 mg tabletit	NL/H/2937/002	14064	EXELGYN SA	FI
Mifegyne 200 mg tablets	NL/H/2937/002	PL 16152/0001	EXELGYN SA	UK
Mifegyne 200 mg tablets	NL/H/2937/002	PL 16152/0001	EXELGYN SA	UK
Mifegyne 200 mg tablets	NL/H/2937/002	PL 16152/0001	EXELGYN SA	UK
Mifegyne 200 mg tablets	NL/H/2937/002	PL 16152/0001	EXELGYN SA	UK
Mifegyne 200 mg Tabletten	NL/H/2937/002	1-23220	EXELGYN SA	AT
Mifegyne 200 mg Tabletten	NL/H/2937/002	1-23220	EXELGYN SA	AT
Mifegyne 200 mg Tabletten	NL/H/2937/002	1-23220	EXELGYN SA	AT
Mifegyne 200 mg Tabletten	NL/H/2937/002	1-23220	EXELGYN SA	AT
Mifegyne 200 mg Tabletten	NL/H/2937/002	46038.00.00	EXELGYN SA	DE
Mifegyne 200 mg Tabletten	NL/H/2937/002	46 038.00.00	EXELGYN SA	DE
Mifegyne 200 mg Tabletten	NL/H/2937/002	46038.00.00	EXELGYN SA	DE
Mifegyne 200 mg Tabletten	NL/H/2937/002	46038.00.00	EXELGYN SA	DE
Mifegyne 200 mg tabletter	NL/H/2937/002	99-01943	EXELGYN SA	NO
Mifegyne 200 mg tabletter	NL/H/2937/002	99-01943	EXELGYN SA	NO

Mifegyne 200 mg tablette	NL/H/2937/002	99-01943	EXELGYN SA	NO
Mifegyne 200 mg tablette	NL/H/2937/002	99-01943	EXELGYN SA	NO
Mifegyne 200 mg tablette	NL/H/2937/002	11642	EXELGYN SA	SE
Mifegyne 200 mg tablette	NL/H/2937/002	11642	EXELGYN SA	SE
Mifegyne 200 mg tablette	NL/H/2937/002	11642	EXELGYN SA	SE
Mifegyne 200 mg tablette	NL/H/2937/002	11642	EXELGYN SA	SE
Mifegyne 200 mg tablety	NL/H/2937/002	54/245/13-C	EXELGYN SA	CZ
Mifegyne 200 mg tablety	NL/H/2937/002	54/245/13-C	EXELGYN SA	CZ
Mifegyne 200 mg tablety	NL/H/2937/002	54/245/13-C	EXELGYN SA	CZ
Mifegyne 200 mg tablety	NL/H/2937/002	54/245/13-C	EXELGYN SA	CZ
Mifegyne 200 mg tablety	NL/H/2937/002	54/0523/12-S	EXELGYN SA	SK
Mifegyne 200 mg tablety	NL/H/2937/002	54/0523/12-S	EXELGYN SA	SK
Mifegyne 200 mg tablety	NL/H/2937/002	54/0523/12-S	EXELGYN SA	SK
Mifegyne 200 mg tablety	NL/H/2937/002	54/0523/12-S	EXELGYN SA	SK
Mifegyne 200 mg δισκία	NL/H/2937/002	245500103	EXELGYN SA	GR
Mifegyne 200 mg δισκία	NL/H/2937/002	245500101	EXELGYN SA	GR
Mifegyne 200 mg δισκία	NL/H/2937/002	245500104	EXELGYN SA	GR
Mifegyne 200 mg δισκία	NL/H/2937/002	245500102	EXELGYN SA	GR
Mifegyne 200 mg, comprimate	NL/H/2937/002	1983/2009/04	EXELGYN SA	RO
Mifegyne 200 mg, comprimate	NL/H/2937/002	1983/2009/03	EXELGYN SA	RO

Mifegyne 200 mg, comprimate	NL/H/2937/002	1983/2009/02	EXELGYN SA	RO
Mifegyne 200 mg, comprimate	NL/H/2937/002	1983/2009/01	EXELGYN SA	RO
Mifegyne 600 mg Tabletten	NL/H/2937/001	90069.00.00	EXELGYN SA	DE
Mifegyne 600 mg Tabletten	NL/H/2937/001	90069.00.00	EXELGYN SA	DE
Mifegyne 600 mg Tabletten	NL/H/2937/001	90069.00.00	EXELGYN SA	DE
Mifegyne 600 mg Tabletten	NL/H/2937/001	90069.00.00	EXELGYN SA	DE
Mifegyne 600 mg, comprimate	NL/H/2937/001	7152/2014/01	EXELGYN SA	RO
Mifegyne 600 mg, comprimate	NL/H/2937/001	7152/2014/02	EXELGYN SA	RO
Mifegyne 600 mg, comprimate	NL/H/2937/001	7152/2014/04	EXELGYN SA	RO
Mifegyne 600 mg, comprimate	NL/H/2937/001	7152/2014/03	EXELGYN SA	RO
Mifegyne 600 mg, tabletten	NL/H/2937/001	RVG 113563	EXELGYN SA	NL
Mifegyne 600 mg, tabletten	NL/H/2937/001	RVG 113563	EXELGYN SA	NL
Mifegyne 600 mg, tabletten	NL/H/2937/001	RVG 113563	EXELGYN SA	NL
Mifegyne 600 mg, tabletten	NL/H/2937/001	RVG 113563	EXELGYN SA	NL
Mifegyne Combikit 600 mg / 400 microgram tablets	NL/H/2938/001	PL 16152/0005	EXELGYN SA	UK
Mifegyne Combikit 600 mg / 400 microgram tablets	NL/H/2938/001	PL 16152/0005	EXELGYN SA	UK
Mifegyne Combikit 600 mg / 400 microgram tabletten	NL/H/2938/001	RVG 113565	EXELGYN SA	NL

Mifegyne Combikit 600 mg / 400 microgram tabletten	NL/H/2938/001	RVG 113565	EXELGYN SA	NL
Mifegyne Combikit 600 mg / 400 Mikrogramm Tabletten	NL/H/2938/001	90070.00.00	EXELGYN SA	DE
Mifegyne Combikit 600 mg / 400 Mikrogramm Tabletten	NL/H/2938/001	90070.00.00	EXELGYN SA	DE
Mifegyne Combikit 600 mg/400 micrograme comprimat	NL/H/2938/001	7153/2014/02	EXELGYN SA	RO
Mifegyne Combikit 600 mg/400 micrograme comprimat	NL/H/2938/001	7153/2014/01	EXELGYN SA	RO
Mifegyne, 200 mg tabletid	NL/H/2937/002	413903	EXELGYN SA	EE
Mifegyne, 200 mg tabletid	NL/H/2937/002	413903	EXELGYN SA	EE
Mifegyne, 200 mg tabletid	NL/H/2937/002	413903	EXELGYN SA	EE
Mifegyne, 200 mg tabletid	NL/H/2937/002	413903	EXELGYN SA	EE
Mifegyne, tabletten 200 mg	NL/H/2937/002	RVG 24206	EXELGYN SA	NL
Mifegyne, tabletten 200 mg	NL/H/2937/002	RVG 24206	EXELGYN SA	NL
Mifegyne, tabletten 200 mg	NL/H/2937/002	RVG 24206	EXELGYN SA	NL
Mifegyne, tabletten 200 mg	NL/H/2937/002	RVG 24206	EXELGYN SA	NL
MIFEGYNE® 200 mg, comprimé	NL/H/2937/002	3400958210617	EXELGYN SA	FR
MIFEGYNE® 200 mg, comprimé	NL/H/2937/002	3400958210556	EXELGYN SA	FR
MIFEGYNE® 200 mg, comprimé	NL/H/2937/002	3400936513471	EXELGYN SA	FR
MIFEGYNE® 200 mg, comprimé	NL/H/2937/002	3400936912526	EXELGYN SA	FR

MIFEGYNE® 200 mg, comprimé	NL/H/2937/002	1181/00/11/0052	EXELGYN SA	LU
Mifepriston "Linepharma" tabletter	SE/H/0986/001	46567	LINEPHARMA INTERNATIONAL LIMITED	DK
Mifepriston Linepharma 200 mg Tabletten	SE/H/0986/001	135003	LINEPHARMA INTERNATIONAL LIMITED	AT
Mifepristona Linepharma 200 mg comprimate	SE/H/0986/001	8866 /2016/01	LINEPHARMA INTERNATIONAL LIMITED	RO
Mifepristona Linepharma 200 mg comprimate	SE/H/0986/001	8866/2016/02	LINEPHARMA INTERNATIONAL LIMITED	RO
Mifepristona Linepharma 200 mg comprimidos	SE/H/0986/001	77617	LINEPHARMA INTERNATIONAL LIMITED	ES
Mifepristona Linepharma 200 mg comprimidos	SE/H/0986/001	5622915	LINEPHARMA INTERNATIONAL LIMITED	PT
Mifepristona Linepharma 200 mg comprimidos	SE/H/0986/001	5622923	LINEPHARMA INTERNATIONAL LIMITED	PT
MIFEPRISTONE EXELGYN 200 mg, comprimé	not available	3400938328011	EXELGYN SA	FR
MIFEPRISTONE EXELGYN 200 mg, comprimé	not available	3400938327939	EXELGYN SA	FR
Mifepristone Linepharma 200 mg Tablet	SE/H/986/E02	II-23586	LINEPHARMA INTERNATIONAL LIMITED	BG
Mifepristone Linepharma 200 mg tableta	SE/H/0986/001	5363-I-1337/13	LINEPHARMA INTERNATIONAL LIMITED	SI
Mifepristone Linepharma 200 mg tableta	SE/H/0986/001	5363-I-1338/13	LINEPHARMA INTERNATIONAL LIMITED	SI
Mifepristone Linepharma 200 mg tablete	SE/H/0986/001	LT/1/13/3335/001	LINEPHARMA INTERNATIONAL LIMITED	LT
Mifepristone Linepharma 200 mg tablete	SE/H/0986/001	LT/1/13/3335/002	LINEPHARMA INTERNATIONAL LIMITED	LT
Mifepristone Linepharma 200 mg Tablettes	SE/H/0986/001	13-0151	LINEPHARMA INTERNATIONAL LIMITED	LV
Mifepristone Linepharma 200 mg tablets	SE/H/0986/001	PL 43680/0001	LINEPHARMA INTERNATIONAL LIMITED	UK
Mifepristone Linepharma 200 mg tablett	SE/H/0986/001	10-7423	LINEPHARMA INTERNATIONAL LIMITED	NO
Mifepristone Linepharma 200 mg tabletter	SE/H/0986/001	43888	LINEPHARMA INTERNATIONAL LIMITED	SE

Mifepristone Linepharma 200 mg tabletti	SE/H/0986/001	28529	LINEPHARMA INTERNATIONAL LIMITED	FI
Mifepristone Linepharma 200 mg tabletti	SE/H/0986/001	28529	LINEPHARMA INTERNATIONAL LIMITED	FI
Mifepristone Linepharma 200 mg töflur	SE/H/0986/001	IS/1/10/096/01	LINEPHARMA INTERNATIONAL LIMITED	IS
Mifepristone Linepharma, 200 mg tabletid	SE/H/0986/001	818613	LINEPHARMA INTERNATIONAL LIMITED	EE
Miffée 200 mg tabletten	SE/H/0986/001	RVG 113293	LINEPHARMA INTERNATIONAL LIMITED	NL
MIFFEE® 200 mg tablette	SE/H/0986/001	2013120638	LINEPHARMA INTERNATIONAL LIMITED	LU
MIFFEE® 200 mg, comprimé	SE/H/0986/001	34009 583 774 8 8	LINEPHARMA INTERNATIONAL LIMITED	FR
MIFFEE® 200 mg, comprimé	SE/H/0986/001	34009 926767822	LINEPHARMA INTERNATIONAL LIMITED	FR
MIFFEE® 200 mg, comprimé	SE/H/0986/001	2013120638	LINEPHARMA INTERNATIONAL LIMITED	LU
Мифегин 200 mg таблетки	NL/H/2937/002	20120578	EXELGYN SA	BG
Мифегин 200 mg таблетки	NL/H/2937/002	20120578	EXELGYN SA	BG
Мифегин 200 mg таблетки	NL/H/2937/002	20120578	EXELGYN SA	BG
Мифегин 200 mg таблетки	NL/H/2937/002	20120578	EXELGYN SA	BG