



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2024
EMA/115648/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: mifepristone

Procedure no.: PSUSA/00002060/202305

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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 200 mg tabletter	NL/H/2937/002	14064	EXELGYN SA	FI
Mifegyne 200 mg tabletter	NL/H/2937/002	14064	EXELGYN SA	FI
Mifegyne 200 mg tabletter	NL/H/2937/002	14064	EXELGYN SA	FI
Mifegyne 200 mg tabletter	NL/H/2937/002	14064	EXELGYN SA	FI
Mifegyne 200 mg tabletės	NL/H/2937/002	LT/1/22/5096/003	EXELGYN SA	LT
Mifegyne 200 mg tabletės	NL/H/2937/002	LT/1/22/5096/001	EXELGYN SA	LT
Mifegyne 200 mg tabletės	NL/H/2937/002	LT/1/22/5096/004	EXELGYN SA	LT
Mifegyne 200 mg tabletės	NL/H/2937/002	LT/1/22/5096/002	EXELGYN SA	LT
Mifegyne 200 mg töflur	NL/H/2937/002	IS/1/22/117/01	EXELGYN SA	IS
Mifegyne 200 mg töflur	NL/H/2937/002	IS/1/22/117/01	EXELGYN SA	IS

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 200 mg töflur	NL/H/2937/002	IS/1/22/117/01	EXELGYN SA	IS
Mifegyne 200 mg töflur	NL/H/2937/002	IS/1/22/117/01	EXELGYN SA	IS
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
Mifegyne 200 mg comprimate	NL/H/2937/002	10129/2017/01	EXELGYN SA	RO
Mifegyne 200 mg comprimate	NL/H/2937/002	10129/2017/02	EXELGYN SA	RO
Mifegyne 200 mg comprimate	NL/H/2937/002	10129/2017/03	EXELGYN SA	RO
Mifegyne 200 mg comprimate	NL/H/2937/002	10129/2017/04	EXELGYN SA	RO
Mifegyne 600 mg comprimate	NL/H/2937/001	12599/2019/01	EXELGYN SA	RO

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 600 mg comprimate	NL/H/2937/001	12599/2019/04	EXELGYN SA	RO
Mifegyne 600 mg comprimate	NL/H/2937/001	12599/2019/03	EXELGYN SA	RO
Mifegyne 600 mg comprimate	NL/H/2937/001	12599/2019/02	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
Мифегин 200 mg таблетки	NL/H/2937/002	20120578	EXELGYN SA	BG
Mifegyne 200 mg δισκία	NL/H/2937/002	022983	EXELGYN SA	CY
Mifegyne 200 mg δισκία	NL/H/2937/002	022983	EXELGYN SA	CY

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 200 mg δισκία	NL/H/2937/002	022983	EXELGYN SA	CY
Mifegyne 200 mg δισκία	NL/H/2937/002	022983	EXELGYN SA	CY
Mifegyne 200 mg δισκία	NL/H/2937/002	2362/26-06-2020	EXELGYN SA	GR
Mifegyne 200 mg δισκία	NL/H/2937/002	2362/26-06-2020	EXELGYN SA	GR
Mifegyne 200 mg δισκία	NL/H/2937/002	2362/26-06-2020	EXELGYN SA	GR
Mifegyne 200 mg δισκία	NL/H/2937/002	2362/26-06-2020	EXELGYN SA	GR
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

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 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 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	62728	EXELGYN SA	ES
Mifegyne 200 mg comprimidos	NL/H/2937/002	62728	EXELGYN SA	ES
Mifegyne 600 mg comprimidos	NL/H/2937/001	84219	EXELGYN SA	ES
Mifegyne 600 mg comprimidos	NL/H/2937/001	84219	EXELGYN SA	ES

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 600 mg comprimidos	NL/H/2937/001	84219	EXELGYN SA	ES
Mifegyne 600 mg comprimidos	NL/H/2937/001	84219	EXELGYN SA	ES
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 600 mg Tabletten	NL/H/2937/001	138602	EXELGYN SA	AT
Mifegyne 600 mg Tabletten	NL/H/2937/001	138602	EXELGYN SA	AT
Mifegyne 600 mg Tabletten	NL/H/2937/001	138602	EXELGYN SA	AT
Mifegyne 600 mg Tabletten	NL/H/2937/001	138602	EXELGYN SA	AT

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 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 600 mg tablety	NL/H/2937/001	54/315/18-C	EXELGYN SA	CZ
Mifegyne 600 mg tablety	NL/H/2937/001	54/315/18-C	EXELGYN SA	CZ
Mifegyne 600 mg tablety	NL/H/2937/001	54/315/18-C	EXELGYN SA	CZ
Mifegyne 600 mg tablety	NL/H/2937/001	54/315/18-C	EXELGYN SA	CZ
Mifegyne, tabletter	NL/H/2937/002	30741	EXELGYN SA	DK
Mifegyne, tabletter	NL/H/2937/002	30741	EXELGYN SA	DK

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, tabletter	NL/H/2937/002	30741	EXELGYN SA	DK
Mifegyne, tabletter	NL/H/2937/002	30741	EXELGYN SA	DK
MIFEGYNE 200 mg, comprimé	NL/H/2937/002	34009 365 134 7 1	EXELGYN SA	FR
MIFEGYNE 200 mg, comprimé	NL/H/2937/002	34009 369 125 2 6	EXELGYN SA	FR
MIFEGYNE 200 mg, comprimé	NL/H/2937/002	34009 582 105 5 6	EXELGYN SA	FR
MIFEGYNE 200 mg, comprimé	NL/H/2937/002	34009 582 106 1 7	EXELGYN SA	FR
Mifegyne 600 mg, comprimé	NL/H/2937/001	34009 300 421 6 8	EXELGYN SA	FR
Mifegyne 600 mg, comprimé	NL/H/2937/001	34009 300 421 9 9	EXELGYN SA	FR
Mifegyne 600 mg, comprimé	NL/H/2937/001	34009 300 421 8 2	EXELGYN SA	FR
Mifegyne 600 mg, comprimé	NL/H/2937/001	34009 300 421 7 5	EXELGYN SA	FR

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 200 mg tablets	NL/H/2937/002	PA22946/001/001	EXELGYN SA	IE
Mifegyne 200 mg tablets	NL/H/2937/002	PA22946/001/001	EXELGYN SA	IE
Mifegyne 200 mg tablets	NL/H/2937/002	PA22946/001/001	EXELGYN SA	IE
Mifegyne 200 mg tablets	NL/H/2937/002	PA22946/001/001	EXELGYN SA	IE
Mifegyne 600 mg Tablets	NL/H/2937/001	PA22946/001/002	EXELGYN SA	IE
Mifegyne 600 mg Tablets	NL/H/2937/001	PA22946/001/002	EXELGYN SA	IE
Mifegyne 600 mg Tablets	NL/H/2937/001	PA22946/001/002	EXELGYN SA	IE
Mifegyne 600 mg Tablets	NL/H/2937/001	PA22946/001/002	EXELGYN SA	IE
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

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 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 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 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 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

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 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 200 mg tabletter	NL/H/2937/002	11642	EXELGYN SA	SE
Mifegyne 200 mg tabletter	NL/H/2937/002	11642	EXELGYN SA	SE
Mifegyne 200 mg tabletter	NL/H/2937/002	11642	EXELGYN SA	SE
Mifegyne 200 mg tabletter	NL/H/2937/002	11642	EXELGYN SA	SE
Mifegyne 200 mg tablete	NL/H/2937/002	H/13/01022/004	EXELGYN SA	SI
Mifegyne 200 mg tablete	NL/H/2937/002	H/13/01022/001	EXELGYN SA	SI

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 200 mg tablete	NL/H/2937/002	H/13/01022/002	EXELGYN SA	SI
Mifegyne 200 mg tablete	NL/H/2937/002	H/13/01022/003	EXELGYN SA	SI
Mifegyne 200 mg tablets	NL/H/2937/002	PL 16152/0006	EXELGYN SA	XI
Mifegyne 200 mg tablets	NL/H/2937/002	PL 16152/0006	EXELGYN SA	XI
Mifegyne 200 mg tablets	NL/H/2937/002	PL 16152/0006	EXELGYN SA	XI
Mifegyne 200 mg tablets	NL/H/2937/002	PL 16152/0006	EXELGYN SA	XI
Mifegyne 200 mg tablete	NL/H/2937/002	HR-H-135441123-01	EXELGYN SA	HR
Mifegyne 200 mg tablete	NL/H/2937/002	HR-H-135441123-02	EXELGYN SA	HR
Mifegyne 200 mg tablete	NL/H/2937/002	HR-H-135441123-03	EXELGYN SA	HR
Mifegyne 200 mg tablete	NL/H/2937/002	HR-H-135441123-04	EXELGYN SA	HR

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 200 mg comprimidos	NL/H/2937/002	5178256	EXELGYN SA	PT
Mifegyne 200 mg comprimidos	NL/H/2937/002	5178264	EXELGYN SA	PT
Mifegyne 200 mg comprimidos	NL/H/2937/002	5403209	EXELGYN SA	PT
Mifegyne 200 mg comprimidos	NL/H/2937/002	5403217	EXELGYN SA	PT
Mifegyne 200 mg tablettes	NL/H/2937/002	02-0229	EXELGYN SA	LV
Mifegyne 200 mg tablettes	NL/H/2937/002	02-0229	EXELGYN SA	LV
Mifegyne 200 mg tablettes	NL/H/2937/002	02-0229	EXELGYN SA	LV
Mifegyne 200 mg tablettes	NL/H/2937/002	02-0229	EXELGYN SA	LV
Mifegyne 200 mg compresse	NL/H/2937/002	038704019	EXELGYN SA	IT
Mifegyne 200 mg compresse	NL/H/2937/002	038704021	EXELGYN SA	IT

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 600 mg compresse.	NL/H/2937/001	038704033	EXELGYN SA	IT
Mifegyne 600 mg, compresse	NL/H/2937/001	038704060	EXELGYN SA	IT
Mifegyne 600 mg, compresse	NL/H/2937/001	038704058	EXELGYN SA	IT
Mifegyne 600 mg compresse.	NL/H/2937/001	038704045	EXELGYN SA	IT
Mifegyne 600 mg comprimés	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg comprimés	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg comprimés	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg comprimés	NL/H/2937/001	BE550720	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

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 200 mg comprimés	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 200 mg comprimés	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 600 mg comprimés	NL/H/2937/001	2021070135	EXELGYN SA	LU
Mifegyne 600 mg comprimés	NL/H/2937/001	2021070135	EXELGYN SA	LU
Mifegyne 600 mg comprimés	NL/H/2937/001	2021070135	EXELGYN SA	LU
Mifegyne 600 mg comprimés	NL/H/2937/001	2021070135	EXELGYN SA	LU
MIFEGYNE 200 mg comprimés	NL/H/2937/002	2000110052	EXELGYN SA	LU
Mifegyne 600 mg tabletten	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg tabletten	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg tabletten	NL/H/2937/001	BE550720	EXELGYN SA	BE

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 600 mg tabletten	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg Tabletten	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg Tabletten	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg Tabletten	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 600 mg Tabletten	NL/H/2937/001	BE550720	EXELGYN SA	BE
Mifegyne 200 mg tabletten	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 200 mg tabletten	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 200 mg tabletten	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifegyne 200 mg tabletten	NL/H/2937/002	BE207487	EXELGYN SA	BE
Mifepristone Linepharma 200 mg tablets	SE/H/0986/001	PL 43680/0001	LINEPHARMA INTERNATIONAL LIMITED	XI

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
MIFFEE 200 mg, comprimé	SE/H/0986/001	34009 267 678 2 2	AMRING S.A.S.	FR
MIFFEE 200 mg, comprimé	SE/H/0986/001	34009 583 774 8 8	AMRING S.A.S.	FR
Mifepristone Linepharma 200 mg töflur	SE/H/0986/001	IS/1/10/096/01	AMRING S.A.S.	IS
Mifepristona Linepharma 200 mg comprimidos	SE/H/0986/001	77617	AMRING S.A.S.	ES
Mifepristone Linepharma 200 mg tabletter	SE/H/0986/001	43888	AMRING S.A.S.	SE
Mifepristona Linepharma 200 mg comprimidos	SE/H/0986/001	77617	AMRING S.A.S.	ES
Mifepristone Linepharma 200 mg töflur	SE/H/0986/001	IS/1/10/096/01	AMRING S.A.S.	IS
Mifepristone Linepharma 200 mg tabletter	SE/H/0986/001	43888	AMRING S.A.S.	SE
Mifepristone Linepharma 200 mg tablets	SE/H/0986/001	PL 43680/0001	LINEPHARMA INTERNATIONAL LIMITED	XI