



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2021
EMA/706074/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure No.: PSUSA/00010354/202005

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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
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Mispregmol 400 mikrogramů tablety	NL/H/2355/001	54/246/13-C	NORDIC GROUP B.V.	CZ
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE
Topogyne 400 mikrogram tabletter	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE

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
tablette				
Topogyne 400 mikrogramm tablette	NL/H/2355/001	46903	NORDIC GROUP B.V.	SE
MisoOne 400 microgrammes, comprimé sécable	NL/H/2355/001	34009 273 833 6 6	NORDIC GROUP B.V.	FR
MisoOne 400 microgrammes, comprimé sécable	NL/H/2355/001	34009 274 265 1 3	NORDIC GROUP B.V.	FR
MisoOne 400 microgrammes, comprimé sécable	NL/H/2355/001	34009 584 964 5 5	NORDIC GROUP B.V.	FR
MisoOne 400 microgrammes, comprimé sécable	NL/H/2355/001	34009 584 965 1 6	NORDIC GROUP B.V.	FR
MisoOne 400 microgrammes, comprimé sécable	NL/H/2355/001	34009 584 967 4 5	NORDIC GROUP B.V.	FR
MisoOne 400 microgrammes, comprimé sécable	NL/H/2355/001	34009 273 834 2 7	NORDIC GROUP B.V.	FR
MisoOne 400 microgrammes, comprimé sécable	NL/H/2355/001	34009 274 266 8 1	NORDIC GROUP B.V.	FR
MisoOne 400 microgrammes, comprimé sécable	NL/H/2355/001	34009 584 966 8 4	NORDIC GROUP B.V.	FR
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926015	NORDIC GROUP B.V.	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926078	NORDIC GROUP B.V.	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926039	NORDIC GROUP B.V.	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926027	NORDIC GROUP B.V.	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
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926041	NORDIC GROUP B.V.	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926080	NORDIC GROUP B.V.	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926054	NORDIC GROUP B.V.	IT
Misoone 400 microgrammi, compresse	NL/H/2355/001	041926066	NORDIC GROUP B.V.	IT
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	NORDIC GROUP B.V.	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	NORDIC GROUP B.V.	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	NORDIC GROUP B.V.	AT
Topogyne 400 Mikrogramm	NL/H/2355/001	1-31715	NORDIC GROUP B.V.	AT

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Tabletten				
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	NORDIC GROUP B.V.	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	NORDIC GROUP B.V.	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	NORDIC GROUP B.V.	AT
Topogyne 400 Mikrogramm Tabletten	NL/H/2355/001	1-31715	NORDIC GROUP B.V.	AT
MisoOne, tabletter	NL/H/2355/001	49597	NORDIC GROUP B.V.	DK
MisoOne, tabletter	NL/H/2355/001	49597	NORDIC GROUP B.V.	DK
MisoOne, tabletter	NL/H/2355/001	49597	NORDIC GROUP B.V.	DK
MisoOne, tabletter	NL/H/2355/001	49597	NORDIC GROUP B.V.	DK
MisoOne, tabletter	NL/H/2355/001	49597	NORDIC GROUP B.V.	DK
MisoOne, tabletter	NL/H/2355/001	49597	NORDIC GROUP B.V.	DK
MisoOne, tabletter	NL/H/2355/001	49597	NORDIC GROUP B.V.	DK
MisoOne, tabletter	NL/H/2355/001	49597	NORDIC GROUP B.V.	DK
Misoone 400 mikrogrammaa, tabletit	NL/H/2355/001	30188	NORDIC GROUP B.V.	FI
Misoone 400 mikrogrammaa, tabletit	NL/H/2355/001	30188	NORDIC GROUP B.V.	FI
Misoone 400 mikrogrammaa, tabletit	NL/H/2355/001	30188	NORDIC GROUP B.V.	FI
Misoone 400 mikrogrammaa, tabletit	NL/H/2355/001	30188	NORDIC GROUP B.V.	FI
Misoone 400 mikrogrammaa, tabletit	NL/H/2355/001	30188	NORDIC GROUP B.V.	FI

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
Misoone 400 mikrogrammaa, tabletit	NL/H/2355/001	30188	NORDIC GROUP B.V.	FI
Misoone 400 mikrogrammaa, tabletit	NL/H/2355/001	30188	NORDIC GROUP B.V.	FI
Misoone 400 mikrogrammaa, tabletit	NL/H/2355/001	30188	NORDIC GROUP B.V.	FI
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.00	NORDIC GROUP B.V.	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.00	NORDIC GROUP B.V.	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.00	NORDIC GROUP B.V.	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.00	NORDIC GROUP B.V.	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.00	NORDIC GROUP B.V.	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.00	NORDIC GROUP B.V.	DE
Misoone 400 mikrogram, tabletter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.00	NORDIC GROUP B.V.	DE
MisoOne 400 Mikrogramm Tabletten	NL/H/2355/001	86194.00.00	NORDIC GROUP B.V.	DE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433011	NORDIC GROUP B.V.	BE
Misopregmol 400 mikrograma	NL/H/2355/001	HR-H-148237306-02	NORDIC GROUP B.V.	HR

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tablete				
Mispregmol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-03	NORDIC GROUP B.V.	HR
Mispregmol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-04	NORDIC GROUP B.V.	HR
Mispregmol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-04	NORDIC GROUP B.V.	HR
Mispregmol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-03	NORDIC GROUP B.V.	HR
Mispregmol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-02	NORDIC GROUP B.V.	HR
Mispregmol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-01	NORDIC GROUP B.V.	HR
Mispregmol 400 mikrograma tablete	NL/H/2355/001	HR-H-148237306-01	NORDIC GROUP B.V.	HR
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433002	NORDIC GROUP B.V.	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433002	NORDIC GROUP B.V.	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433002	NORDIC GROUP B.V.	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433011	NORDIC GROUP B.V.	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433011	NORDIC GROUP B.V.	BE
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433002	NORDIC GROUP B.V.	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
Topogyne 400 microgrammes comprimés	NL/H/2355/001	2013060197	NORDIC GROUP B.V.	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001	2013060197	NORDIC GROUP B.V.	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001	2013060197	NORDIC GROUP B.V.	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001	2013060197	NORDIC GROUP B.V.	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001	2013060197	NORDIC GROUP B.V.	LU
Topogyne 400 microgrammes comprimés	NL/H/2355/001	2013060197	NORDIC GROUP B.V.	LU
Misoone 400 mikrogram, tableter	NL/H/2355/001	11-8648	NORDIC GROUP B.V.	NO
Topogyne 400 mikrogramov tablete	NL/H/2355/001	H/13/01541/003	NORDIC GROUP B.V.	SI
Topogyne 400 mikrogramov tablete	NL/H/2355/001	H/13/01541/004	NORDIC GROUP B.V.	SI
Topogyne 400 mikrogramov tablete	NL/H/2355/001	H/13/01541/002	NORDIC GROUP B.V.	SI
Topogyne 400 mikrogramov tablete	NL/H/2355/001	H/13/01541/001	NORDIC GROUP B.V.	SI
Topogyne 400 microgramas comprimidos	NL/H/2355/001	NL/H/2355/01/DC	NORDIC GROUP B.V.	PT
Topogyne 400 microgramas comprimidos	NL/H/2355/001	NL/H/2355/01/DC	NORDIC GROUP B.V.	PT
Topogyne 400 microgramas	NL/H/2355/001	5751110	NORDIC GROUP B.V.	PT

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
comprimidos				
Topogyne 400 microgramas comprimidos	NL/H/2355/001	5751102	NORDIC GROUP B.V.	PT
Topogyne 400 microgramas comprimidos	NL/H/2355/001	NL/H/2355/01/DC	NORDIC GROUP B.V.	PT
Topogyne 400 microgramas comprimidos	NL/H/2355/001	5751136	NORDIC GROUP B.V.	PT
Topogyne 400 microgramas comprimidos	NL/H/2355/001	5751128	NORDIC GROUP B.V.	PT
Topogyne 400 microgrammes comprimés	NL/H/2355/001	BE433011	NORDIC GROUP B.V.	BE
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	NORDIC GROUP B.V.	NL
Misoone 400 mikrogrami tabletes	NL/H/2355/001	13-0015	NORDIC GROUP B.V.	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001	13-0015	NORDIC GROUP B.V.	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001	13-0015	NORDIC GROUP B.V.	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001	13-0015	NORDIC GROUP B.V.	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001	13-0015	NORDIC GROUP B.V.	LV
MisoOne 400 microgramos comprimidos	NL/H/2355/001	77146	NORDIC GROUP B.V.	ES
MisoOne 400 microgramos comprimidos	NL/H/2355/001	77146	NORDIC GROUP B.V.	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
Misoone 400 mikrogrami tabletes	NL/H/2355/001	13-0015	NORDIC GROUP B.V.	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001	13-0015	NORDIC GROUP B.V.	LV
Misoone 400 mikrogrami tabletes	NL/H/2355/001	13-0015	NORDIC GROUP B.V.	LV
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	NORDIC GROUP B.V.	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	NORDIC GROUP B.V.	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	NORDIC GROUP B.V.	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	NORDIC GROUP B.V.	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	NORDIC GROUP B.V.	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	NORDIC GROUP B.V.	NL
MisoOne 400 microgram, tabletten	NL/H/2355/001	RVG 110664	NORDIC GROUP B.V.	NL
MisoOne 400 microgramos comprimidos	NL/H/2355/001	77146	NORDIC GROUP B.V.	ES
MisoOne 400 microgramos comprimidos	NL/H/2355/001	77146	NORDIC GROUP B.V.	ES
Topogyne 400 microgramas comprimidos	NL/H/2355/001	NL/H/2355/01/DC	NORDIC GROUP B.V.	PT
MisoOne 400 μικρογραμμάρια,	NL/H/2355/001	15571/12-02-2019	NORDIC GROUP B.V.	GR

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
δισκία				
MisoOne 400 μικρογραμμάρια, δισκία	NL/H/2355/001	15571/12-02-2019	NORDIC GROUP B.V.	GR
MisoOne 400 μικρογραμμάρια, δισκία	NL/H/2355/001	15571/12-02-2019	NORDIC GROUP B.V.	GR
MisoOne 400 μικρογραμμάρια, δισκία	NL/H/2355/001	15571/12-02-2019	NORDIC GROUP B.V.	GR
MisoOne 400 μικρογραμμάρια, δισκία	NL/H/2355/001	15571/12-02-2019	NORDIC GROUP B.V.	GR
MisoOne 400 μικρογραμμάρια, δισκία	NL/H/2355/001	15571/12-02-2019	NORDIC GROUP B.V.	GR
MisoOne 400 μικρογραμμάρια, δισκία	NL/H/2355/001	15571/12-02-2019	NORDIC GROUP B.V.	GR
MisoOne 400 μικρογραμμάρια, δισκία	NL/H/2355/001	15571/12-02-2019	NORDIC GROUP B.V.	GR
Topogyne 400 microgram tablets	NL/H/2355/001	PL 40621/0034	NORDIC GROUP B.V.	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 40621/0034	NORDIC GROUP B.V.	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 40621/0034	NORDIC GROUP B.V.	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 40621/0034	NORDIC GROUP B.V.	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 40621/0034	NORDIC GROUP B.V.	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 40621/0034	NORDIC GROUP B.V.	UK

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
Topogyne 400 microgram tablets	NL/H/2355/001	PL 40621/0034	NORDIC GROUP B.V.	UK
Topogyne 400 microgram tablets	NL/H/2355/001	PL 40621/0034	NORDIC GROUP B.V.	UK
MisoOne 400 microgram tablets	NL/H/2355/001	PA2252/003/001	NORDIC GROUP B.V.	IE
MisoOne 400 microgram tablets	NL/H/2355/001	PA2252/003/001	NORDIC GROUP B.V.	IE
MisoOne 400 microgram tablets	NL/H/2355/001	PA2252/003/001	NORDIC GROUP B.V.	IE
MisoOne 400 microgram tablets	NL/H/2355/001	PA2252/003/001	NORDIC GROUP B.V.	IE
MisoOne 400 microgram tablets	NL/H/2355/001	PA2252/003/001	NORDIC GROUP B.V.	IE
MisoOne 400 microgram tablets	NL/H/2355/001	PA2252/003/001	NORDIC GROUP B.V.	IE
MisoOne 400 microgram tablets	NL/H/2355/001	PA2252/003/001	NORDIC GROUP B.V.	IE
MisoOne 400 microgram tablets	NL/H/2355/001	PA2252/003/001	NORDIC GROUP B.V.	IE
Topogyne 400 micrograme comprimate	NL/H/2355/001	11234/2018/01	EXELGYN SA	RO
Topogyne 400 micrograme comprimate	NL/H/2355/001	11234/2018/02	EXELGYN SA	RO
Topogyne 400 micrograme comprimate	NL/H/2355/001	11234/2018/03	EXELGYN SA	RO
Topogyne 400 micrograme comprimate	NL/H/2355/001	11234/2018/04	EXELGYN SA	RO
Topogyne 400 micrograme comprimate	NL/H/2355/001	11234/2018/05	EXELGYN SA	RO
Topogyne 400 micrograme comprimate	NL/H/2355/001	11234/2018/06	EXELGYN SA	RO
Topogyne 400 micrograme comprimate	NL/H/2355/001	11234/2018/07	EXELGYN SA	RO
Topogyne 400 micrograme	NL/H/2355/001	11234/2018/08	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
comprimat				
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
Топогин 400 микрограма таблетки	NL/H/2355/001	20130303	EXELGYN SA	BG
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	NORDIC GROUP B.V.	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	NORDIC GROUP B.V.	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	NORDIC GROUP B.V.	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	NORDIC GROUP B.V.	NL
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	NORDIC GROUP B.V.	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
Misoprostol Exelgyn 200 microgram, Tabletten	not available	RVG 113032	NORDIC GROUP B.V.	NL
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
Topogyne, 400 mikrogrammi tabletid	NL/H/2355/001	801412	EXELGYN SA	EE
GYMISO 200 microgrammes, comprimé	not available	34009 3624994 3	AMRING S.A.S.	FR