



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 December 2016
EMA/858449/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): ethinylestradiol / levonorgestrel

Procedure No.: PSUSA/00001309/201604



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
ADEPAL, comprimé enrobé	not available	34009 318 406 4 0	PFIZER HOLDING FRANCE (S.C.A.)	FR
ADEPAL, comprimé enrobé	not available	34009 318 408 7 9	PFIZER HOLDING FRANCE (S.C.A.)	FR
Egogyn 0,150 mg + 0,030 mg comprimé rivestito	not available	023647011	BAYER PHARMA AG	IT
Eleonor 20 0,1 mg/0,02 mg omhulde tabletten	DE/H/0876/001	BE314395	SANDOZ N.V.	BE
Femigoa® Überzogene Tabletten	not available	6175107.00.00	PFIZER PHARMA GMBH	DE
Gravistat 125	not available	17/658/92-C	BAYER PHARMA AG	CZ
Gravistat 125 fem, 125 Mikrogramm / 50 Mikrogramm, überzogene Tabletten	not available	41346.00.00	JENAPHARM GMBH & CO KG	DE
Leios® Überzogene Tabletten Wirkstoffe: Ethinylestradiol 20 µg und Levonorgestrel 100 µg	not available	6175656.00.00	PFIZER PHARMA GMBH	DE
Loette	DK/H/1898/001	30121	PFIZER APS	DK
Loette – Filmtabletten 100 Mikrogramm/20Mikrogramm	not available	1-23211	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
LOETTE 0,100 mg + 0,02 mg comprimé rivestito	not available	033161023	PFIZER ITALIA S.R.L.	IT
LOETTE 0,100 mg + 0,02 mg comprimé rivestito	not available	033161011	PFIZER ITALIA S.R.L.	IT
LOETTE 100/20 microgramos comprimidos recubiertos con película	DK/H/1898/001	65.067	WYETH FARMA, S.A	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
Loette 28 tabletter, filmdrasjerte	not available	99-2727	PFIZER AS	NO
Loette 28, fillovertrukne tabletter	DK/H/1898/002	30875	PFIZER APS	DK
LOETTE DIARIO 100/20 microgramos comprimidos recubiertos con película	DK/H/1898/002	66.628	WYETH FARMA, S.A	ES
LOETTE potahované tablety 100 mikrogramů / 20 mikrogramů	not available	17/492/99-C	PFIZER, SPOL. S R.O.	CZ
Logynon Tablets	not available	PA 1410/5/1	BAYER LTD	IE
Logynon® coated tablets	not available	PL 00010/0540	BAYER PLC	UK
Logynon® ED	not available	PL 00010/0541	BAYER PLC	UK
Lovette, omhulde tabletten	not available	RVG 21187	PFIZER B.V.	NL
Lowette 0,100 mg/0,020 mg comprimés pelliculés	not available	BE196786	PFIZER S.A. (BELGIUM)	BE
Lowette 0,100 mg/0,020 mg comprimés pelliculés	not available	0617/06109086	PFIZER S.A. (BELGIUM)	LU
Lowette 0,100 mg/0,020 mg filmomhulde tabletten	not available	BE196786	PFIZER S.A. (BELGIUM)	BE
Lowette 0,100 mg/0,020 mg Filmtabletten	not available	BE196786	PFIZER S.A. (BELGIUM)	BE
Lowette 0,100 mg/0,020 mg Filmtabletten	not available	0617/06109086	PFIZER S.A. (BELGIUM)	LU
Microginon 0,03 mg + 0,15 mg comprimidos revestidos	not available	8412106	BAYER PORTUGAL LDA	PT
Microginon 0,03 mg + 0,15 mg comprimidos revestidos	not available	8412114	BAYER PORTUGAL LDA	PT
Microgyn 150 míkrog/30 míkrog, húðaðar töflur	not available	MTNR. 731684	BAYER PHARMA AG	IS

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Microgyn, overtrukne tabletter	not available	07877	BAYER PHARMA AG	DK
Microgynon 0,03 mg/ 0,15 mg drajeuri	not available	4211/2004/01	BAYER PHARMA AG	RO
Microgynon 0,03 mg/0,15 mg obložene tablete	not available	H/93/01017/001	BAYER PHARMA AG	SI
Microgynon 0,03 mg/0,150 mg obalené tablety	not available	17/0349/92-CS	BAYER PHARMA AG	SK
Microgynon 0,15 mg/0,03 mg comprimidos recubiertos	not available	52.612	BAYER HISPANIA SL	ES
Microgynon 0.125 mg + 0.05 mg comprese rivestite	not available	023646019	BAYER PHARMA AG	IT
Microgynon 150 mikrogram/30 mikrogram, tabletter, drasjerte	not available	6030	BAYER PHARMA AG	NO
Microgynon 20, 100 microgram/20 microgram omhulde tabletten	NL/H/2868/001	RVG 30863	BAYER BV	NL
Microgynon 20, 100 Mikrogramm/20 Mikrogramm überzogene Tabletten	NL/H/2868/001	BE 279404	BAYER SA NV	BE
Microgynon 20, 100 Mikrogramm/20 Mikrogramm überzogene Tabletten	NL/H/2868/001	0442/09110627	BAYER SA NV	LU
Microgynon 20®, 100 microgram/20 microgram omhulde tabletten	NL/H/2868/001	BE 279404	BAYER SA NV	BE
Microgynon 20®,100 microgrammes/20 microgrammes comprimés enrobés	NL/H/2868/001	BE 279404	BAYER SA NV	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
Microgynon 20®, 100 microgrammes/20 microgrammes comprimés enrobés	NL/H/2868/001	0442/09110627	BAYER SA NV	LU
Microgynon 21, 30 µg + 150 µg, tabletki powlekane	not available	R/0600	BAYER PHARMA AG	PL
Microgynon 28, 150 Mikrogramm / 30 Mikrogramm, überzogene Tabletten	not available	6929523.00.00	JENAPHARM GMBH & CO KG	DE
Microgynon 30 – Dragees	not available	1-15.618	BAYER AUSTRIA GMBH	AT
Microgynon 30 0,15 mg / 0,03 mg, comprimés enrobés	not available	BE091235	BAYER SA NV	BE
Microgynon 30 0,15 mg / 0,03 mg, comprimés enrobés	not available	2009010081	BAYER SA NV	LU
Microgynon 30 0,15 mg / 0,03 mg, überzogene Tabletten	not available	BE091235	BAYER SA NV	BE
Microgynon 30 0,15 mg / 0,03 mg, überzogene Tabletten	not available	2009010081	BAYER SA NV	LU
Microgynon 30 0,15mg / 0,03 mg, omhulde tabletten	not available	BE091235	BAYER SA NV	BE
Microgynon 30, 0,15 mg/0,03 mg omhulde tabletten	not available	RVG 08204	BAYER BV	NL
Microgynon 50 0,125 mg / 0,05 mg, comprimés enrobés	not available	BE091244	BAYER SA NV	BE
Microgynon 50 0,125 mg / 0,05 mg, comprimés enrobés	not available	1986080501	BAYER SA NV	LU
Microgynon 50 0,125 mg / 0,05 mg, überzogene Tabletten	not available	BE091244	BAYER SA NV	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
Microgynon 50 0,125 mg / 0,05 mg, überzogene Tabletten	not available	1986080501	BAYER SA NV	LU
Microgynon 50 0,125mg / 0,05mg, omhulde tabletten	not available	BE091244	BAYER SA NV	BE
Microgynon 50, 0,125 mg/0,05 mg omhulde tabletten	not available	RVG 08205	BAYER BV	NL
Microgynon dragerade tabletter	not available	6838	BAYER OY	FI
Microgynon Obalené tablety	not available	17/349/92-C	BAYER PHARMA AG	CZ
Microgynon päällystetyt tabletit	not available	6838	BAYER OY	FI
Microgynon, 150 Mikrogramm / 30 Mikrogramm, überzogene Tabletten	not available	6929552.00.00	JENAPHARM GMBH & CO KG	DE
Microgynon® 30	not available	PL 00010/0545	BAYER PLC	UK
MICROGYNON® 30 ED	not available	PL 00010/0546	BAYER PLC	UK
Microlite 100/20 microgram tablets	not available	PA 1410/7/1	BAYER LTD	IE
MINIDRIL, comprimé enrobé	not available	34009 318 240 9 1	PFIZER HOLDING FRANCE (S.C.A.)	FR
MINIDRIL, comprimé enrobé	not available	34009 318 239 0 2	PFIZER HOLDING FRANCE (S.C.A.)	FR
Minisiston 0,03 mg/0,125 mg obalené tablety	not available	17/0224/95-S	BAYER PHARMA AG	SK
Minisiston 20 fem, 100 Mikrogramm / 20 Mikrogramm, überzogene Tabletten	not available	6928653.00.00	JENAPHARM GMBH & CO KG	DE
MINISISTON Obalené tablety	not available	17/942/94-C	BAYER PHARMA AG	CZ
Minisiston, 125 Mikrogramm / 30 Mikrogramm, überzogene Tabletten	not available	3000385.00.00	JENAPHARM GMBH & CO KG	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
Miranova 0,02 mg + 0,1 mg comprimidos revestidos	not available	3182284	BAYER PORTUGAL LDA	PT
Miranova 0,02 mg + 0,1 mg comprimidos revestidos	not available	3182383	BAYER PORTUGAL LDA	PT
Miranova 0,1 mg + 0,02 mg compresse rivestite	not available	033779012	BAYER SPA	IT
Miranova überzogene Tabletten	NL/H/2867/001	60360.00.00	JENAPHARM GMBH & CO KG	DE
Miranova, 100 microgram/20 microgram omhulde tabletten	NL/H/2867/001	RVG 30862	BAYER BV	NL
MonoStep, 125 Mikrogramm / 30 Mikrogramm, überzogene Tabletten	not available	6929405.00.00	JENAPHARM GMBH & CO KG	DE
Neovletta 28 dragerade tabletter	not available	18540	BAYER PHARMA AG	SE
Neovletta dragerade tabletter	not available	9120	BAYER PHARMA AG	SE
NovaStep überzogene Tabletten	not available	6929084.00.00	JENAPHARM GMBH & CO KG	DE
OPTIDRIL 30 microgrammes /150 microgrammes, comprimé pelliculé	not available	NL41824-3400926752514	LABORATOIRES MAJORELLE	FR
OPTIDRIL 30 microgrammes /150 microgrammes, comprimé pelliculé	not available	NL41824-3400926752682	LABORATOIRES MAJORELLE	FR
OPTILOVA 20 microgrammes / 100 microgrammes, comprimé pelliculé	not available	NL 41633-3400922178967	LABORATOIRES MAJORELLE	FR
OPTILOVA 20 microgrammes / 100 microgrammes, comprimé pelliculé	not available	NL 41633-3400922179049	LABORATOIRES MAJORELLE	FR
OPTILOVA 20 microgrammes / 100 microgrammes, comprimé pelliculé	not available	NL 41633-3400958229657	LABORATOIRES MAJORELLE	FR
OVOPLEX 150/30 comprimidos recubiertos	not available	52.574	WYETH FARMA, S.A	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
Ovranette 150 micrograms/30 micrograms coated tablets	not available	PA 0822/094/001	PFIZER HEALTHCARE IRELAND	IE
Ovranette 150 micrograms/30 micrograms coated tablets	not available	PL 00057/1283	PFIZER LIMITED	UK
Rigevidon (21+7) 150 mikrogramm/30 mikrogramm + 76,05 mg bevont tabletta	not available	OGYI-T-6052/01	GEDEON RICHTER PLC.	HU
Rigevidon (21+7) 150 mikrogramm / 30 mikrogramm + 76,05 mg bevont tabletta	not available	OGYI-T-6052/02	GEDEON RICHTER PLC.	HU
Stediril 30, 150 mikrogramów (µg) + 30 mikrogramów (µg), tabletki drażowane	not available	R/0725	PFIZER EUROPE MA EEIG	PL
Stediril 30, omhulde tabletten	not available	RVG 08191	PFIZER B.V.	NL
Stediril-30 0,150 mg/0,030 mg comprimés enrobés	not available	BE091217	PFIZER S.A. (BELGIUM)	BE
Stediril-30 0,150 mg/0,030 mg comprimés enrobés	not available	0617/06119099	PFIZER S.A. (BELGIUM)	LU
Stediril-30 0,150 mg/0,030 mg omhulde tabletten	not available	BE091217	PFIZER S.A. (BELGIUM)	BE
Stediril-30 0,150 mg/0,030 mg Überzogene Tabletten	not available	BE091217	PFIZER S.A. (BELGIUM)	BE
Stediril-m 150 mikrogramov/30 mikrogramov obložene tablete	not available	5363-I-1684/13	PFIZER EUROPE MA EEIG	SI
Triagynon comprimidos recubiertos	not available	55.994	BAYER HISPANIA SL	ES
TRICICLOR comprimidos recubiertos	not available	55.989	WYETH FARMA, S.A	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
Trigoa® Dragees	not available	33599.00.00	PFIZER PHARMA GMBH	DE
Trigynon omhulde tabletten	not available	RVG 08663	BAYER BV	NL
Trigynon, comprimés enrobés	not available	BE117092	BAYER SA NV	BE
Trigynon, comprimés enrobés	not available	1986050987	BAYER SA NV	LU
Trigynon, omhulde tabletten	not available	BE117092	BAYER SA NV	BE
Trigynon, überzogene Tabletten	not available	BE117092	BAYER SA NV	BE
Trigynon, überzogene Tabletten	not available	1986050987	BAYER SA NV	LU
Trikvilar dragerade tabletter	not available	8112	BAYER OY	FI
Trikvilar päällystetyt tabletit	not available	8112	BAYER OY	FI
Trinordiol (0,03 mg + 0,05 mg) + (0,04 mg + 0,075 mg) + (0,03 mg + 0,125 mg) comprimido revestido	not available	8525519	LABORATÓRIOS PFIZER, LDA.	PT
Trinordiol (0,03 mg + 0,05 mg) + (0,04 mg + 0,075 mg) + (0,03 mg + 0,125 mg) comprimido revestido	not available	8525501	LABORATÓRIOS PFIZER, LDA.	PT
Trinordiol comprimés enrobés	not available	BE116907	PFIZER S.A. (BELGIUM)	BE
Trinordiol comprimés enrobés	not available	0617/06119100	PFIZER S.A. (BELGIUM)	LU
Trinordiol omhulde tabletten	not available	BE116907	PFIZER S.A. (BELGIUM)	BE
Trinordiol Tablets	not available	PA 0822/100/101	PFIZER HEALTHCARE IRELAND	IE
Trinordiol Überzogene Tabletten	not available	BE116907	PFIZER S.A. (BELGIUM)	BE
Trinordiol Überzogene Tabletten	not available	0617/06119100	PFIZER S.A. (BELGIUM)	LU
TRINORDIOL, comprimé enrobé	not available	34009 328 070 9 3	PFIZER HOLDING FRANCE (S.C.A.)	FR

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TRINORDIOL, comprimé enrobé	not available	34009 328 071 5 4	PFIZER HOLDING FRANCE (S.C.A.)	FR
Trinordiol, dragees	not available	RVG 08514	PFIZER B.V.	NL
Trionetta 28 dragerade tabletter	not available	9651	BAYER PHARMA AG	SE
Trionetta dragerade tabletter	not available	9650	BAYER PHARMA AG	SE
Triquilar Obalené tablety	not available	17/280/92-C	BAYER PHARMA AG	CZ
Triquilar obalené tablety	not available	17/0280/92-CS	BAYER PHARMA AG	SK
Triquilar obložene tablete	not available	UP/I-530-09/10-02/377	BAYER DOO	HR
Triquilar überzogene Tabletten	not available	6929167.00.00	JENAPHARM GMBH & CO KG	DE
Triquilar, 30 µg + 50 µg (jasnobrązowe); 40 µg + 75 µg (białe); 30 µg + 125 µg (w kolorze ochry), tabletki powlekane	not available	R/2227	BAYER PHARMA AG	PL
Trisiston überzogene Tabletten	not available	3000412.00.00	JENAPHARM GMBH & CO KG	DE