



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 December 2019  
EMA/40774/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: ethinylestradiol / levonorgestrel

Procedure no.: PSUSA/00001309/201904

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Ovoplex 0,15 mg/0,03 mg comprimidos recubiertos	not available	52.574	WYETH FARMA, S.A	ES
Stediril-30 0,150 mg/0,030 mg Überzogene Tabletten	not available	BE091217	PFIZER S.A. (BELGIUM)	BE
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 omhulde tabletten	not available	BE091217	PFIZER S.A. (BELGIUM)	BE
MINIDRIL, comprimé enrobé	not available	34009 318 240 9 1	PFIZER HOLDING FRANCE	FR
MINIDRIL, comprimé enrobé	not available	34009 318 239 0 2	PFIZER HOLDING FRANCE	FR
Stediril 30, 150 mikrogramów (µg) + 30 mikrogramów (µg), tabletki drażowane	not available	R/0725	PFIZER EUROPE MA EEIG	PL
Ovranette 150 micrograms/30 micrograms coated tablets	not available	PL 00057/1283	PFIZER LIMITED	UK
Trigoa® Dragees	not available	33599.00.00	PFIZER PHARMA PFE GMBH	DE
Logynon® coated tablets	not available	PL 00010/0540	BAYER PLC	UK

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Trisiston überzogene Tabletten	not available	3000412.00.00	JENAPHARM GMBH & CO KG	DE
Loette® – Filmtabletten 100 Mikrogramm/20Mikrogramm	not available	1-23211	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Trinordiol Überzogene Tabletten	not available	BE116907	PFIZER S.A. (BELGIUM)	BE
Trinordiol omhulde tabletten	not available	BE116907	PFIZER S.A. (BELGIUM)	BE
Trinordiol comprimés enrobés	not available	BE116907	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 comprimés pelliculés	not available	BE196786	PFIZER S.A. (BELGIUM)	BE
Lowette 0,100 mg/0,020 mg filmomhulde tabletten	not available	BE196786	PFIZER S.A. (BELGIUM)	BE
LOETTE 0,1 mg/0,02 mg potahované tablety	not available	17/492/99-C	PFIZER, SPOL. S R.O.	CZ
Leios® 100 Mikrogramm/ 20 Mikrogramm überzogene Tabletten	not available	6175656.00.00	PFIZER PHARMA PFE GMBH	DE

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Stediril-30 0,150 mg/0,030 mg comprimés enrobés	not available	2006119099	PFIZER S.A. (BELGIUM)	LU
Stediril-30 0,150 mg/0,030 mg Überzogene Tabletten	not available	2006119099	PFIZER S.A. (BELGIUM)	LU
Rigevidon (21+7) 150 mikrogramm / 30 mikrogramm + 76,05 mg bevont tableta	not available	OGYI-T-6052/01	GEDEON RICHTER PLC.	HU
Rigevidon (21+7) 150 mikrogramm / 30 mikrogramm + 76,05 mg bevont tableta	not available	OGYI-T-6052/02	GEDEON RICHTER PLC.	HU
Ovranette 150 micrograms/30 micrograms coated tablets	not available	PA 822/94/1	PFIZER HEALTHCARE IRELAND	IE
Microgynon® 30	not available	PL 00010/0545	BAYER PLC	UK
OPTILOVA 20 microgrammes / 100 microgrammes, comprimé pelliculé	not available	NL 41633	LABORATOIRES MAJORELLE	FR
Stediril 30, omhulde tabletten	not available	RVG 08191	PFIZER B.V.	NL
LEVONORGESTREL/ETHINY LESTRADIOL RICHTER 125 microgrammes/30 microgrammes, comprimé enrobé	DE/H/3953/001	34009 301 040 2 6	GEDEON RICHTER PLC.	FR

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LEVONORGESTREL/ETHINY LESTRADIOL RICHTER 125 microgrammes/30 microgrammes, comprimé enrobé	DE/H/3953/001	34009 301 040 3 3	GEDEON RICHTER PLC.	FR
LEVONORGESTREL/ETHINY LESTRADIOL RICHTER 125 microgrammes/30 microgrammes, comprimé enrobé	DE/H/3953/001	34009 550 365 3 1	GEDEON RICHTER PLC.	FR
LEVONORGESTREL/ETHINY LESTRADIOL RICHTER 125 microgrammes/30 microgrammes, comprimé enrobé	DE/H/3953/001	34009 550 365 4 8	GEDEON RICHTER PLC.	FR
Loette, filmovertrukne tabletter	DK/H/1898/001	30121	PFIZER APS	DK
LOETTE 100/20 microgramos comprimidos recubiertos con película	DK/H/1898/001	65.067	WYETH FARMA, S.A	ES
LOETTE DIARIO 100/20 microgramos comprimidos recubiertos con película	DK/H/1898/002	66.628	WYETH FARMA, S.A	ES
Loette 28, filmovertrukne tabletter	DK/H/1898/002	30875	PFIZER APS	DK
Trinordiol Überzogene Tabletten	not available	2006119100	PFIZER S.A. (BELGIUM)	LU
Trinordiol comprimés enrobés	not available	2006119100	PFIZER S.A. (BELGIUM)	LU

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ADEPAL, comprimé enrobé	not available	34009 318 406 4 0	PFIZER HOLDING FRANCE	FR
ADEPAL, comprimé enrobé	not available	34009 318 408 7 9	PFIZER HOLDING FRANCE	FR
OPTIDRIL 30 microgrammes /150 microgrammes, comprimé pelliculé	not available	NL41824-3400926752682	LABORATOIRES MAJORELLE	FR
TRINORDIOL, comprimé enrobé	not available	34009 300 810 5 1	PFIZER HOLDING FRANCE	FR
TRINORDIOL, comprimé enrobé	not available	34009 300 810 6 8	PFIZER HOLDING FRANCE	FR
TRINORDIOL, comprimé enrobé	not available	34009 328 070 9 3	PFIZER HOLDING FRANCE	FR
TRINORDIOL, comprimé enrobé	not available	34009 328 071 5 4	PFIZER HOLDING FRANCE	FR
Miranova, 100 microgram/20 microgram omhulde tabletten	NL/H/2867/001	RVG 30862	BAYER BV	NL
Miranova überzogene Tabletten	NL/H/2867/001	60360.00.00	JENAPHARM GMBH & CO KG	DE
Triclor comprimidos recubiertos	not available	55.989	WYETH FARMA, S.A	ES

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Lovette, omhulde tabletten	not available	RVG 21187	PFIZER B.V.	NL
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	0442/09110627	BAYER SA NV	LU
Microgynon 20, 100 microgram/20 microgram omhulde tabletten	NL/H/2868/001	RVG 30863	BAYER BV	NL
Logynon® ED	not available	00010/0541	BAYER PLC	UK
Microgynon dragerade tabletter	not available	6838	BAYER OY	FI
Trikvilar dragerade tabletter	not available	8112	BAYER OY	FI
Microgyn 150 míkrog/30 míkrog, húðaðar töflur	not available	MTNR 731684	BAYER AB	IS
Microgynon 150 mikrogram/30 mikrogram, tabletter, drasjerte	not available	6030	BAYER AB	NO
Microgynon 30 0,15 mg / 0,03 mg, überzogene Tabletten	not available	BE091235	BAYER SA NV	BE

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Trigynon, überzogene Tabletten	not available	BE117092	BAYER SA NV	BE
Microgynon 50 0,125 mg / 0,05 mg, überzogene Tabletten	not available	BE091244	BAYER SA NV	BE
Trigynon, überzogene Tabletten	not available	1986050987	BAYER SA NV	LU
Microgynon 50 0,125 mg / 0,05 mg, überzogene Tabletten	not available	1986080501	BAYER SA NV	LU
Microgynon 30 0,15 mg / 0,03 mg, überzogene Tabletten	not available	2009010081	BAYER SA NV	LU
Triquilar, 30 µg + 50 µg (jasnobrazowe); 40 µg + 75 µg (białe); 30 µg + 125 µg (w kolorze ochry), tabletki powlekane	not available	R/2227	BAYER AG	PL
Microgynon 30 0,15 mg / 0,03 mg, comprimés enrobés	not available	2009010081	BAYER SA NV	LU
Trigynon, comprimés enrobés	not available	1986050987	BAYER SA NV	LU
Microgynon, 150 Mikrogramm / 30 Mikrogramm, überzogene Tabletten	not available	6929552.00.00	JENAPHARM GMBH & CO KG	DE
Miranova 0,1 mg + 0,02 mg compresse rivestite	not available	033779012	BAYER SPA	IT



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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 omhulde tabletten	not available	RVG 08205	BAYER BV	NL
Gravistat 125 fem, 125 Mikrogramm / 50 Mikrogramm, überzogene Tabletten	not available	41346.00.00	JENAPHARM GMBH & CO KG	DE
Microgynon 28, 150 Mikrogramm / 30 Mikrogramm, überzogene Tabletten	not available	6929523.00.00	JENAPHARM GMBH & CO KG	DE
NovaStep überzogene Tabletten	not available	6929084.00.00	JENAPHARM GMBH & CO KG	DE
Trionetta 28 dragerade tabletter	not available	9651	BAYER AB	SE
Microginon 0,03 mg + 0,15 mg comprimidos revestidos	not available	8412106	BAYER PORTUGAL LDA	PT
Triquilar überzogene Tabletten	not available	6929167.00.00	JENAPHARM GMBH & CO KG	DE
Trigynon omhulde tabletten	not available	RVG 08663	BAYER BV	NL
Neovletta dragerade tabletter	not available	9120	BAYER AB	SE

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Triquilar obalené tablety	not available	17/0280/92-CS	BAYER AG	SK
Trionetta dragerade tabletter	not available	9650	BAYER AB	SE
Neovletta 28 dragerade tabletter	not available	18540	BAYER AB	SE
Microgynon 21, 30 µg + 150 µg, tabletki powlekane	not available	R/0600	BAYER AG	PL
Microgynon 50 0,125 mg / 0,05 mg, comprimés enrobés	not available	1986080501	BAYER SA NV	LU
Microgynon päällystetyt tabletit	not available	6838	BAYER OY	FI
Trikvilar päällystetyt tabletit	not available	8112	BAYER OY	FI
Minisiston, 125 Mikrogramm / 30 Mikrogramm, überzogene Tabletten	not available	3000385.00.00	JENAPHARM GMBH & CO KG	DE
MonoStep, 125 Mikrogramm / 30 Mikrogramm, überzogene Tabletten	not available	6929405.00.00	JENAPHARM GMBH & CO KG	DE
Minisiston 20 fem, 100 Mikrogramm / 20 Mikrogramm, überzogene Tabletten	not available	6928653.00.00	JENAPHARM GMBH & CO KG	DE

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Microgynon 0,15 mg/0,03 mg obalené tablety	not available	17/349/92-C	BAYER AG	CZ
Minisiston 0,125 mg/0,030 mg obalené tablety	not available	17/942/94-C	BAYER AG	CZ
Triquilar obalené tablety	not available	17/280/92-C	BAYER AG	CZ
Microginon 0,03 mg + 0,15 mg comprimidos revestidos	not available	8412114	BAYER PORTUGAL LDA	PT
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
Microgynon 0.125 mg + 0.05 mg compresse rivestite	not available	023646019	BAYER AG	IT
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, omhulde tabletten	not available	BE091235	BAYER SA NV	BE
Trigynon, omhulde tabletten	not available	BE117092	BAYER SA NV	BE
Trigynon, comprimés enrobés	not available	BE117092	BAYER SA NV	BE

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Microgynon 50 0,125 mg / 0,05 mg, omhulde tabletten	not available	BE091244	BAYER SA NV	BE
Microgynon 50 0,125 mg / 0,05 mg, comprimés enrobés	not available	BE091244	BAYER SA NV	BE
Microgynon 30 – Dragees	not available	1-15618	BAYER AUSTRIA GMBH	AT
Egogyn 0,150 mg + 0,030 mg compresse rivestite	not available	023647011	BAYER AG	IT
Microlite 100/20 microgram Tablets	not available	PA 1410/7/1	BAYER LTD	IE
Logynon Tablets	not available	PA 1410/5/1	BAYER LTD	IE
Triquilar obložene tablete	not available	HR-H-762679692-01	BAYER DOO	HR
Microgynon 0,03 mg/0,15 mg drajeuri	not available	11195/2018/01	BAYER AG	RO
Femigoa® 150 Mikrogramm/ 30 Mikrogramm überzogene Tabletten	not available	6175107.00.00	PFIZER PHARMA PFE GMBH	DE
LOETTE 0,100 mg + 0,02 mg compresse rivestite	not available	033161023	PFIZER ITALIA S.R.L.	IT

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LOETTE 0,100 mg + 0,02 mg compresse rivestite	not available	033161011	PFIZER ITALIA S.R.L.	IT
Stediril-m 150 mikrogramov/30 mikrogramov obložene tablete	not available	H/92/01458/001	PFIZER EUROPE MA EEIG	SI
Triagynon comprimidos recubiertos	not available	55.994	BAYER HISPANIA SL	ES
Eleonor 20 0,1 mg/0,02 mg omhulde tabletten	DE/H/0876/001	BE314395	SANDOZ N.V.	BE
Trinordiol Tablets	not available	PA 822/100/001	PFIZER HEALTHCARE IRELAND	IE
Lowette 0,100 mg/0,020 mg Filmtabletten	not available	2006109086	PFIZER S.A. (BELGIUM)	LU
Lowette 0,100 mg/0,020 mg comprimés pelliculés	not available	2006109086	PFIZER S.A. (BELGIUM)	LU
Trinordiol, dragees	not available	RVG 08514	PFIZER B.V.	NL
Microgyn, overtrukne tabletter	not available	07877	BAYER AB	DK
Microgynon 0,15 mg/0,03 mg comprimidos recubiertos	not available	52.612	BAYER HISPANIA SL	ES

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Loette 28 filmdrasjerte tabletter	not available	99-2727	PFIZER AS	NO
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
MICROGYNON® 30 ED	not available	PL 00010/0546	BAYER PLC	UK