



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2018
EMA/235814/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ethinylestradiol / norethisterone

Procedure no.: PSUSA/00001312/201708



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
TRIELLA, comprimé	not available	34009 334 161 2 6	JANSSEN-CILAG	FR
TRIELLA, comprimé	not available	34009 325 491 3 9	JANSSEN-CILAG	FR
Ovysmen 1,000 mg/0,035 mg Tabletten	not available	0162/11071234	JANSSEN-CILAG NV	LU
Ovysmen 1,000 mg/0,035 mg Tabletten	not available	BE111027	JANSSEN-CILAG NV	BE
Trinovum Tabletten	not available	0162/08019623	JANSSEN-CILAG NV	LU
Trinovum Tabletten	not available	BE132885	JANSSEN-CILAG NV	BE
Trinovum, tabletten	not available	BE132885	JANSSEN-CILAG NV	BE
Ovysmen 1,000 mg/0,035 mg tabletten	not available	BE111027	JANSSEN-CILAG NV	BE
Ovysmen 1,000 mg/0,035 mg comprimés	not available	BE111027	JANSSEN-CILAG NV	BE
Trinovum, comprimés	not available	BE132885	JANSSEN-CILAG NV	BE
TRINOVUM	not available	17/207/91-C	JANSSEN-CILAG S.R.O	CZ
Trinovum töflur	not available	853791	JANSSEN-CILAG AB	IS
Orthonett Novum tabletter	not available	9484	JANSSEN-CILAG AB	SE
Trinovum tabletter	not available	10381	JANSSEN-CILAG AB	SE
TRIELLA, comprimé	not available	34009 325 493 6 8	JANSSEN-CILAG	FR
Trinovum 28 töflur	not available	920100	JANSSEN-CILAG AB	IS
Trinovum 28 tabletter	not available	10594	JANSSEN-CILAG AB	SE
Ovysmen 1,000 mg/0,035 mg comprimés	not available	0162/11071234	JANSSEN-CILAG NV	LU
Trinovum, comprimés	not available	0162/08019623	JANSSEN-CILAG NV	LU
Eve 30 Filmtabletten	not available	6728776.00.00	GEDEON RICHTER PLC.	DE
Eve® 20 0,02 mg/0,5 mg Filmtabletten	not available	6728747.00.00	GEDEON RICHTER PLC.	DE
Synphase	not available	PL 00057/1053	PFIZER LIMITED	UK
Norimin 1 mg/0.035 mg tablets	not available	PL 00057/1020	PFIZER LIMITED	UK
Synfase tabletter	not available	7493	PFIZER AS	NO
Conceplan® M 0,03 mg/0,5 mg Filmtabletten	not available	6728693.00.00	PFIZER PHARMA PFE GMBH	DE
Synphasec®, Filmtabletten	not available	6915.00.00	PFIZER PHARMA PFE GMBH	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
BREVINOR 0.5 milligram (mg)/35 micrograms (μ g) Tablets	not available	PL 00057/0935	PFIZER LIMITED	UK
Loestrin 20	not available	PL 27827/0023	GALEN LIMITED	UK
Loestrin 30	not available	PL 27827/0024	GALEN LIMITED	UK