

27 September 2017
EMA/483088/2013 correction 9*
Patient Health Protection

List of Cyproterone acetate-Ethinylestradiol containing medicinal products in the European Union

Name of the product	Marketing Authorisation Holder	Country where product is authorised
Cyprotomin 2 mg/0,035 mg Filmtabletten **	Dermapharma GmbH	Austria
Femogyn 2 mg/0,035 mg überzogene Tabletten **	Dermapharm AG	Austria
Xyllia - Dragées	Sandoz GmbH	Austria
Gratiella 35	3 DDD Pharma N.V.	Belgium
Melleva	Medico Uno Worldwide Ltd.	Bulgaria
Dianova Mite	Alternova A/S	Denmark
Zyrona	Orifarm Generics A/S	Denmark
Femina	Nycomed Sefa AS	Estonia
CYPROTERONE/ETHINYLESTRADIOL BAYER 35 µg	Bayer Santé	France
CYPROPHARM 2 mg/0,035 mg	Laboratoires Majorelle	France
CYPROTERONE/ETHINYLESTRADIOL DCI PHARMA 2 mg/0,035 mg	DCI Pharma	France
CYPROTERONE/ETHINYLESTRADIOL EG 2 mg/0,035 mg	EG LABO - LABORATOIRES EUROGENERICS	France
CYPROTERONE/ETHINYLESTRADIOL RANBAXY 2 mg/0,035 mg	Ranbaxy Pharmacie Generiques	France
CYPROTERONE/ETHINYLESTRADIOL RATIOPHARM 2 mg/0,035 mg	Teva Sante	France
CYPROTERONE/ETHINYLESTRADIOL SANDOZ 2 mg/0,035 mg	SANDOZ	France
CYPROTERONE/ETHINYLESTRADIOL ZENTIVA 2 mg/0,035 mg	Sanofi Aventis France	France
CYPROTERONE/ETHINYLESTRADIOL ZYDUS 2 mg/0,035 mg	ZYDUS France	France
ELLEACNELLE 2 mg/0,035 mg	CHEMICAL FARMA	France
HOLGYEME 2 mg/0,035 mg	EFFIK	France
LUMALIA 2 mg/0,035 mg	Pierre Fabre Dermatologie	France
Cyproderm ***	Dermapharm AG	Germany
Micypra 2,00/0,035 mg Filmtabletten	Mithra Pharmaceuticals	Germany
Femina	Nycomed Sefa AS	Lithuania
Cypretil	Ratiopharm GmbH	Lithuania
Lumalia ****	Pierre Fabre Dermatologie	Luxembourg
Acnocrin 2000/35 Tablets	Sandoz d.d	Malta
Zyrona	Orifarm Generics A/S	Norway
Aenemine/Cyprodiol ***	Acis Arzneimittel GmbH V/Sun-Farm Sp. z.o.o	Poland
OC-35	Polfarmex S.A.	Poland
Syndi-35	SymPhar Sp. z o.o.	Poland
Ciproterona + Ethinylestradiol Inventis	Generis Farmaceutica, S.A.	Portugal
MELLEVA 2mg/0,035mg	Ladeepharmaceutical Limited	Romania
DIANE DIARIO 2 mg/0.035 mg comprimidos recubiertos	BAYER HISPANIA, S.L.	Spain
DIANE 2 mg/0.035 mg comprimidos recubiertos	BAYER HISPANIA, S.L.	Spain
DIANE 35 comprimidos recubiertos	Berlifarma - Especialidades Farmaceuticas, Lda.	Spain
ACETATO DE CIPROTERONA/ETINILESTRADIOL GINESERVICE 2 mg/0.035 mg comprimidos recubiertos EFG	Laboratorios EFFIK, S.A.	Spain
GYNEPLEN 0.035 mg/2 mg comprimidos recubiertos	Laboratorios EFFIK, S.A.	Spain
Zyrona	Orifarm Generics A/S	Sweden
Cyproteronacetaat/ethinylestradiol Actavis 2/0,035 mg, filmomhulde tabletten 2 mg/0,035 mg	Actavis B.V.	The Netherlands
Cyproteronacetaat/ethinylestradiol Apotex 2/0,035 mg, omhulde tabletten	Apotex Europe B.V.	The Netherlands
Cyproteronacetaat/Ethinylestradiol CF 2/0,035 mg, omhulde tablet	Centrafarm B.V.	The Netherlands
Cyproteronacetaat/Ethinylestradiol Mylan 2 mg/0,035 mg, omhulde tabletten	Mylan B.V.	The Netherlands
Cyproteronacetaat/Ethinylestradiol Mylan 2 mg/0,035 mg, omhulde tabletten	Mylan B.V.	The Netherlands
Cyproteronacetaat/ethinylestradiol ratiopharm 2 mg/0,035 mg, omhulde tabletten	Ratiopharm Nederland B.V.	The Netherlands
Cyproteronacetaat/Ethinylestradiol Sandoz 2/0,035, omhulde tabletten	Sandoz B.V.	The Netherlands

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Cyproteronacetaat/Ethinylestradiol 2 mg/0,035 mg, omhulde tabletten	Mylan B.V.	The Netherlands
Camilette Co-Cyprindiol 2000/35 Tablets	Chatfield Pharmaceuticals Limited	United Kingdom
Cyproterone Acetate 2.0mg Ethinylestradiol 0.035mg Tablets	Sandoz Limited	United Kingdom
Co-Cyprindiol Tablets 2mg/0.035mg	Generics (UK) Limited	United Kingdom
Generics UK Cyproterone Acetate and Ethinylestradiol Tablets	Generics (UK) Limited	United Kingdom
Fannin UK Co-Cyprindiol 2000/35 Tablets	Fannin (UK) Limited	United Kingdom
Dialider Tablets	Farmalider SA	United Kingdom

* This annex was previously amended on 26 July 2017.

**The marketing authorisation of this product has been withdrawn.

***Following the fulfilment of specific obligations, this product is no longer under additional monitoring.

****Lumalia has been removed from this annex following the withdrawal of its marketing authorisation in Luxembourg.