



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2013
EMA/84655/2013
Patient Health Protection

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for cypoterone acetate/ethinylestradiol containing medicinal products

Article 107i of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-107i/1357



Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Gynial GmbH Gablenzgasse 11/III 1150 Wien Austria	Alisma 2mg/35µg Filmtablette	2 mg/0,035mg	film-coated tablet	oral use
Austria	Ratiopharm Arzneimittel Vertriebs-GmbH Albert-Schweitzer-Gasse 3 1140 Wien Austria	Bellgyn "ratiopharm" 2 mg/ 0,035 mg - überzogene Tabletten	2 mg/0,035mg	coated tablet	oral use
Austria	Acis Arzneimittel GmbH Lil- Dagover-Ring 7 82031 Grünwald Germany	Cyproteron/Ethinylestr adiol acis 2 mg/0,035 mg Filmtabletten	2 mg/0,035mg	coated tablet	oral use
Austria	Bayer Austria GmbH Herbststrasse 6-10 1160 Wien Austria	Diane mite - Dragees	2 mg/0,035mg	coated tablet	oral use
Austria	Dermapharm AG Lil-Dagover-Ring 7 82031 Grünwald Germany	Femogyn 2 mg/0,035 mg überzogene Tabletten	2 mg/0,035mg	coated tablet	oral use
Austria	Pelpharma Handels GmbH Stammhausstraße 31 1140 Wien Austria	Midane - Dragees	2 mg/0,035mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Bayer Austria GmbH Herbststrasse 6-10 1160 Wien Austria	Minerva - Dragees	2 mg/0,035mg	coated tablet	oral use
Austria	Sandoz GmbH Biochemiestrass 10 6250 Kundl Austria	Xylia - Dragées	2 mg/0,035mg	coated tablet	oral use
Belgium	Mithra Pharmaceuticals S.A. Rue Saint Georges 5 4000 Liège Belgium	Chloe	2 mg/0,035mg	Film-coated tablet	oral use
Belgium	Sandoz N.V. Telecom Gardens Medialaan 40 1800 Vilvoorde Belgium	Claudia-35	2 mg/0,035mg	coated tablet	oral use
Belgium	Mithra Pharmaceuticals S.A. Rue Saint Georges 5 4000 Liège Belgium	Daphne	2 mg/0,035mg	coated tablet	oral use
Belgium	Bayer N.V. Jan Emiel Mommaertsiaan 14 1831 Machelen Belgium	Diane-35	2 mg/0,035mg	coated tablet	oral use
Belgium	Mylan BVBA/SPRL Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Elisamylan	2 mg/0,035mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	3 DDD Pharma N.V. Diestersteenweg 349 3510 Hasselt Belgium	Gratiella 35	2 mg/0,035mg	coated tablet	oral use
Bulgaria	Bayer Pharma AG Muellerstrasse 178+Berlin D-13353 Germany	Diane 35	2 mg/0,035mg	coated tablets	oral use
Bulgaria	Medico Uno Worldwide Ltd.,2 Grigori Afxentiou Street + Larnaca 6023 Cyprus	Melleva	2 mg/0,035mg	film-coated tablets	oral use
Bulgaria	Zentiva k.s. 130 U kabelovny+Prague 10237 Czech Republic	Chloe	2 mg/0,035mg	film-coated tablets	oral use
Czech Republic	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Dolní Měcholupy Czech Republic	CHLOE	2 mg/0,035mg	film-coated tablets	oral use
Czech Republic	Heaton a.s. Na Pankráci 14 14000 Praha 4 Czech Republic	VREYA	2 mg/0,035mg	film-coated tablets	oral use
Czech Republic	Bayer Pharma AG Müllerstrasse 178 13353 Berlin Germany	MINERVA	2 mg/0,035mg	coated tablets	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Bayer Pharma AG Müllerstrasse 178 13353 Berlin Germany	DIANE-35	2 mg/0,035mg	coated tablets	oral use
Denmark	Mithra Pharmaceuticals SA, Rue Saint Georges 5 BE-4000 Liege Belgium	Chloe	2 mg/0,035mg	Filmcoated tablets	Oral use
Denmark	Ratiopharm GmbH, Graf- Arco-Strasse 3 DE-89079 Ulm Germany	Cyproteronacetat/ ethinylestradiol Ratiopharm	2 mg/0,035mg	Filmcoated tablets	Oral use
Denmark	Bayer Schering Pharma AG, Müllerstrasse 170-178 DE-13342 Berlin Germany	Diane Mite	2 mg/0,035mg	Filmcoated tablets	Oral use
Denmark	Alternova A/S, Lodshusvej 11, DK-4230 Skælskør Denmark	Dianova Mite	2 mg/0,035mg	Filmcoated tablets	Oral use
Denmark	Sandoz A/S, Edvard Thomsens Vej 14, DK-2300 København S Denmark	Feminil mite	2 mg/0,035mg	Filmcoated tablets	Oral use
Denmark	Stragen Nordic A/S, Helsingørsgade 8C, DK-3400 Hillerød Denmark	Vreya	2 mg/0,035mg	Filmcoated tablets	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Denmark	Orifarm Generics A/S, Postbox 69, Energivej 15, DK-5260 Odense S., Denmark	Zyrona	2 mg/0,035mg	Filmcoated tablets	Oral use
Estonia	Bayer Pharma AG D-13342 Berlin Germany	Diane	2 mg/0,035mg	coated tablet	oral use
Estonia	Nycomed Sefa AS, Jaama 55B 63308 Põlva Estonia	Femina	2 mg/0,035mg	coated tablet	oral use
Estonia	ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germany	Cypretil	2 mg/0,035mg	coated tablet	oral use
Finland	BAYER OY Keilaranta 12 PL 73, 02151 Espoo Finland	DIANE NOVA	2 mg/0,035mg	Tablet	oral use
Finland	RATIOPHARM GMBH Keilaranta 10 PL 67, 02631 Espoo Finland	CYPRETYL	2 mg/0,035mg	Tablet	oral use
Finland	SANDOZ A/S Edvard Thomsens Vej 14 2300 Copenhagen S Denmark	FEMINIL	2 mg/0,035mg	Tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Finland	STRAGEN Hesselvej 41 Ganlose 3660 Stenlose Denmark	VREYA	2 mg/0,035mg	Tablet	oral use
France	Bayer Santé 220, avenue de la Recherche 59120 Loos France	DIANE 35 µg, coated tablet	2 mg/0,035mg	Coated tablet	Oral route
France	Bayer Santé 220, avenue de la Recherche 59120 Loos France	MINERVA 35 µg	2 mg/0,035mg	Coated tablet	Oral route
France	Bayer Santé 220, avenue de la Recherche 59120 Loos France	CYPROTERONE/ETHINYLESTRADIOL BAYER 35 µg	2 mg/0,035mg	Coated tablet	Oral route
France	Jenapharm GmbH Otto - Schott - Strasse 15 07745 Jena Germany	ARIELLE, coated tablet	2 mg/0,035mg	Coated tablet	Oral route
France	LABORATOIRES MAJORELLE 80-82 rue Gallieni 92100 BOULOGNE BILLANCOURT FRANCE	CYPROPHARM 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	DCI PHARMA 180 RUE EUGENE AVINEE 59120 LOOS FRANCE	CYPROTERONE/ETHINYLESTRADIOL DCI PHARMA 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	EG LABO - LABORATOIRES EUROGENERICS 12 rue Danjou le Quintet bâtiment A 92517 BOULOGNE BILLANCOURT CEDEX FRANCE	CYPROTERONE/ETHINYLESTRADIOL EG 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	IDD International Drug Development 5 rue Simonet 75013 Paris France	CYPROTERONE/ETHINYLESTRADIOL IDD 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	RANBAXY PHARMACIE GENERIQUES 11-15 quai de Dion Bouton 92800 PUTEAUX FRANCE	CYPROTERONE/ETHINYLESTRADIOL RANBAXY 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	TEVASANTE 110 Esplanade du Général de Gaulle 92931 PARIS LA DEFENSE , FRANCE	CYPROTERONE/ETHINYLESTRADIOL RATIOPHARM 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	SANDOZ 49 avenue Georges Pompidou 92593 LEVALLOIS PERRET CEDEX FRANCE	CYPROTERONE/ETHINYLESTRADIOL SANDOZ 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	TEVASANTE 110 Esplanade du Général de Gaulle 92931 PARIS LA DEFENSE FRANCE	CYPROTERONE/ETHINYLESTRADIOL TEVA 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	SANOFI AVENTIS FRANCE 1-13 BOULEVARD ROMAIN ROLLAND 75014 PARIS FRANCE	CYPROTERONE/ETHIN YLESTRADIOL ZENTIVA 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	ZYDUS France Parc d'Activités des Peupliers - 25 rue des Peupliers 92000 NANTERRE FRANCE	CYPROTERONE/ETHIN YLESTRADIOL ZYDUS 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	CHEMICAL FARMA 19-23 rue d'Hautpoul 75019 PARIS FRANCE	ELLEACNELLE 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	MYLAN SAS 117 allée des Parcs 69800 SAINT PRIEST FRANCE	EVEPAR 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	EFFIK bâtiment "le Newton" 9-11 rue Jeanne Braconnier 92366 MEUDON LA FORET FRANCE	HOLGYEME 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route
France	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE FRANCE	LUMALIA 2 mg/0,035 mg	2 mg/0,035mg	Coated tablet	Oral route

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	acis Arzneimittel GmbH Lil-Dagover-ring 7 82031 Grünwald Germany	Cyproethinyl acis	2 mg/0,035mg	Film-coated tablet	oral use
Germany	Almirall Hermal GmbH Scholzstr. 3 21465 Reinbek Germany	Clevia 2 mg/0,035 mg Filmtabletten	2 mg/0,035mg	Film-coated tablet	oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Jennifer 35 2 mg/0,035 mg Filmtabletten	2 mg/0,035mg	Film-coated tablet	oral use
Germany	Bayer Vital GmbH Kaiser-Wilhelm-Allee 51373 Leverkusen Germany	Diane-35 0,035mg/2mg überzogene Tablette	2 mg/0,035mg	coated tablet	oral use
Germany	Dermapharm AG Lil-Dagover-Ring 7 82031 Grünwald Germany	Cyproderm	2 mg/0,035mg	coated tablet	oral use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Bella HEXAL 35 2 mg/0,035 mg überzogene Tablette	2 mg/0,035mg	coated tablet	oral use
Germany	Mylan dura GmbH Wittichstr. 6 64295 Darmstadt Germany	Juliette	2 mg/0,035mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Attempta-ratiopharm 35 2 mg/0,035 mg überzogene Tablette	2 mg/0,035mg	coated tablet	oral use
Greece	BAYER ΕΛΛΑΣ ΑΒΕΕ SOROU 18-20 MAROUSSI GR-15125 ATHENS	GYNOFEN 35	2 mg/0,035mg	COATED TABLETS	oral
Hungary	Pliva Hungária Kereskedelmi és Szolgáltató Kft. Rákóczi út 70-72 Budapest 1074 Hungary	Bellune Pliva	2 mg/0,035 mg	coated tablet	oral
Hungary	Bayer-Schering Pharma AG Müllerstrasse 170-178 Berlin 13342 Germany	Diane	2 mg/0,035 mg	coated tablet	oral
Hungary	Bayer-Schering Pharma AG Müllerstrasse 170-178 Berlin 13342 Germany	Minerva	2 mg/0,035 mg	coated tablet	oral
Iceland	Bayer Pharma AG D13342 - Berlin Germany	Diane mite	2 mg/0,035mg	tablet	oral use
Iceland	Ratiopharm GmbH - Graf Arco Strasse 3 - 89079 Ulm – Germany	Cypretyl	2 mg/0,035mg	Coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Generics (UK) Limited trading as Mylan Station Close Potters Bar Hertfordshire EN6 1TL United Kingdom	Cyproterone Acetate/Ethinylestradiol Tablets 2mg/0.035mg	2 mg/0,035mg	Tablets	Oral
Ireland	Bayer Limited The Atrium Blackthorn Road Sandyford Dublin 18 Ireland	Dianette 2mg/35 microgram coated tablets.	2 mg/0,035mg	Coated Tablets	Oral
Italy	Bayer S.p.A. Viale Certosa, 130 - 20156 Milano (MI) Italy	DIANE	2 mg/0,035mg	Coated tablets	oral
Italy	FIDIA Farmaceutici S.p.A., Via Ponte della Fabbrica, 3/A, 35031 Abano Terme (PD) Italy	VISOFID	2 mg/0,035mg	Coated tablets	oral
Latvia	Zentiva k.s. U kabelovny 130 Dolni Mecholupy 102 37 Prague 10, Czech Republic	Chloe 35 micrograms/2 mg film-coated tablets	2 mg/0,035mg	film-coated tablets	oral use
Latvia	ratiopharm GmbH Graf-Arco-Str. 3, 89079 Ulm Germany	Cypretil 2 mg/35 micrograms coated tablets	2 mg/0,035mg	coated tablets	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Latvia	Nycomed SEFA AS Jaama 55B 63308 Polva Estonia	Femina-35 2 mg/35 micrograms coated tablets	2 mg/0,035mg	coated tablets	oral use
Latvia	Bayer Schering Pharma AG, D-13342, Berlin Germany	Diane 2000 micrograms/35 micrograms film-coated tablets	2 mg/0,035mg	film-coated tablets	oral use
Lithuania	Bayer Pharma AG, Müllerstraße 178 D-13342 Berlin Germany	Diane	2 mg/0,035mg	Coated tablet	Oral use
Lithuania	Nycomed SEFA AS Jaama 55B 63308 Põlva Estonia	Femina	2 mg/0,035mg	Coated tablet	Oral use
Lithuania	ZENTIVA, k.s. U kabelovny 130 Dolní Měcholupy 102 37, Praha 10 Czech Republic	CHLOE	2 mg/0,035mg	Film-coated tablet	Oral use
Lithuania	ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm Germany	Cypretil	2 mg/0,035mg	Coated tablet	Oral use
Luxembourg	Bayer Vital GmbH D-51368 Leverkusen Germany	Diane-35	2 mg/0,035mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Mithra Pharmaceuticals SA Rue Saint Georges, 5 B-4000 Liège Belgium	Chloe	2 mg/0,035mg	coated tablet	oral use
Luxembourg	Mithra Pharmaceuticals SA Rue Saint Georges, 5 B-4000 Liège Belgium	Daphne	2 mg/0,035mg	coated tablet	oral use
Luxembourg	Pierre Fabre Dermatologie 45, place Abel Gance F-92100 Boulogne France	Lumalia	2 mg/0,035mg	coated tablet	oral use
Malta	Stragen UK Ltd. Castle Court 41, London Road, Reigate, Surrey RH2 PRJ, United Kingdom	Clairette 2000/35 Tablets	2 mg/0,035mg	Coated tablet	Oral route
Malta	Sandoz d.d Verovskova 57, 1000 Ljubljana Slovenia	Acnocin 2000/35 Tablets	2 mg/0,035mg	Coated tablet	Oral route
Norway	Bayer Schering Pharma AG Müllerstr. 178 13353 Berlin Germany	Diane	2 mg/0,035mg	coated tablet	oral use
Norway	Sandoz Edvard Thomsens Vej 14, 2300 KØBENHAVN S, Denmark	Feminil	2 mg/0,035mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Norway	Orifarm Generics Energivej 15 - POB 69 DK-5260 Odense S Denmark	Zyrona	2 mg/0,035mg	coated tablet	oral use
Poland	acis Arzneimittel GmbH Lil-Dagover-Ring 7 82031 Grunwald Germany	Acnemine	2 mg/0,035mg	film coated tablet	oral use
Poland	Bayer Pharma AG Muellerstrasse 178 D-13342 Berlin Germany	Diane-35	2 mg/0,035mg	film coated tablet	oral use
Poland	Zentiva, k.s. U kabelovny 130 Praga 10, Dolni Mecholupy 10237 Czech Republic	Chloe	2 mg/0,035mg	film coated tablet	oral use
Poland	Pabianickie Zakłady Farmaceutyczne Polfa S.A. ul. Marszałka J. Piłsudskiego 5 95-200 Pabianice Poland	Cyprest	2 mg/0,035mg	coated tablet	oral use
Poland	Polfarmex S.A. Józefów 9 99-300 Kutno Poland	OC-35	2 mg/0,035mg	film coated tablet	oral use
Poland	SymPhar Sp. z o.o. ul. Włoska 1 00-777 Warszawa Poland	Syndi-35	2 mg/0,035mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	Sun-Farm Sp. z o.o. Człkówka 75 05-340 Kołbiel Poland	Cyprodiol	2 mg/0,035mg	coated tablet	oral use
Portugal	Berlifarma - Especialidades Farmaceuticas, Lda. Rua Quinta Pinheiro, 5, Oturela - Carnaxide 2794-003 Portugal	Diane 35	2 mg/0,035mg	Coated tablet	Oral use
Portugal	Mylan, Lda. Rua Doutor Antonio Loureiro Borges, Edificio Arquiparque 1, R/C Esq – Algés 1499-016 Portugal	Acetato Ciproterona/ Etinilestradiol 2 mg/ 0,035 mg Comprimidos	2 mg/0,035mg	Coated tablet	Oral use
Portugal	Generis Farmaceutica, S.A. Rua Joao de Deus, 19 - Amadora 2700-487 Portugal	Ciproterona + Etinilestradiol Generis	2 mg/0,035mg	Coated tablet	Oral use
Portugal	Generis Farmaceutica, S.A. Rua Joao de Deus, 19 - Amadora 2700-487 Portugal	Ciproterona + Etinilestradiol Inventis	2 mg/0,035mg	Coated tablet	Oral use
Romania	BAYER PHARMA AG Müllerstraße 178, 13353 Berlin Germany	DIANE- 35	2 mg/0,035mg	coated tablet	Oral

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Romania	LADEEPHARMA PHARMACEUTICAL Limited Lajos u. 48-66, E ép. 5. em., H-1036 Budapest Hungary	MELLEVA 2mg/0,035mg	2 mg/0,035mg	film-coated tablet	Oral
Slovak Republic	HEATON a.s. Na Pankráci 14 Praha 4 Czech Republic	Vreya	2 mg/0,035mg	coated tablet	oral use
Slovak Republic	Bayer Pharma AG Muellestrasse 170- 178 13342 Berlin Germany	Minerva	2 mg/0,035mg	coated tablet	oral use
Slovak Republic	Zentiva k.s. U kabelovny 130 102 37 Praha Czech Republic	CHLOE	2 mg/0,035mg	coated tablet	oral use
Slovak Republic	Bayer Pharma AG Muellestrasse 170- 178 13342 Berlin Germany	Diane-35	2 mg/0,035mg	coated tablet	oral use
Slovenia	Bayer Pharma AG, 13342 Berlin, Germany; Contact for Slovenia: Bayer d.o.o., Bravničarjeva 13, 1000 Ljubljana	Diane 0,035 mg/2 mg obložene tablete	2 mg/0,035mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	BAYER HISPANIA, S.L. Avda. Baix Llobregat 3 y 5 08970 Sant Joan Despi (Barcelona) Spain	DIANE 35	2 mg/0,035mg	Coated tablet	Oral use
Spain	BAYER HISPANIA, S.L. Avda. Baix Llobregat 3 y 5 08970 Sant Joan Despi (Barcelona) Spain	DIANE 35 DIARIO	2 mg/0,035mg	Coated tablet	Oral use
Spain	LABORATORIOS EFFIK, S.A. San Rafael, 3 28108 Alcobendas (Madrid) Spain	ETINILESTRADIOL/CIP ROTERONA GINESERVICE 0,035 mg/2 mg comprimidos EFG	2 mg/0,035mg	Coated tablet	Oral use
Spain	SANDOZ FARMACEUTICA, S.A. Avda. Osa Mayor, 4 28023 Aravaca (Madrid) Spain	ACETATO DE CIPROTERONA/ETINIL ESTRADIOL SANDOZ 2 mg/0,035 mg comprimidos recubiertos EFG	2 mg/0,035mg	Film coated tablet	Oral use
Spain	LABORATORIOS EFFIK, S.A. San Rafael, 3 28108 Alcobendas (Madrid) Spain	GYNEPLEN 0,035 mg/2 mg comprimidos recubiertos	2 mg/0,035mg	Coated tablet	Oral use
Spain	FARMALIDER, S.A. Aragoneses, 15 28108 Alcobendas (Madrid) Spain	DIALIDER 2/0,035 mg comprimidos recubiertos con película	2 mg/0,035mg	Film coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	TEVA PHARMA, SLU Anabel Segura 11, Edificio Albatros B, 1ª planta 28108 Alcobendas (Madrid) Spain	CYPRINETTE DIARIO 0,035 mg/2 mg comprimidos recubiertos EFG	2 mg/0,035mg	Coated tablet	Oral use
Sweden	Bayer Pharma AG DE-13342 Berlin Germany	Diane®	2 mg/0,035mg	Tablet	Oral
Sweden	Orifarm Generics A/S, Energivej 15 POB 69 DK- 5260 Odense S Danmark	Zyrona	2 mg/0,035mg	Coated tablet	Oral
The Netherlands	Actavis B.V. Baarnsche Dijk 1 3741 LN Baarn The Netherlands	Cyproteronacetaat/ethinyloestradiol Actavis 2/0,035 mg, filmomhulde tabletten 2 mg/0,035 mg	2 mg/0,035mg	Film coated tablet	Oral
The Netherlands	Apotex Europe B.V. Darwinweg 20 2333 CR Leiden The Netherlands	Cyproteronacetaat/ethinyloestradiol Apotex 2/0,035 mg, omhulde tabletten	2 mg/0,035mg	Film coated tablet	Oral
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC Etten-Leur The Netherlands	Cyproteronacetaat/Ethinyloestradiol CF 2/0,035 mg, omhulde tablet	2 mg/0,035mg	Film coated tablet	Oral
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB BUNSCHOTEN The Netherlands	Cyproteronacetaat/Ethinyloestradiol Mylan 2 mg/0,035 mg, omhulde tabletten	2 mg/0,035mg	Film coated tablet	Oral

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB BUNSCHOTEN The Netherlands	Cyproteronacetaat/Ethinylestradiol Mylan 2 mg/0,035 mg, omhulde tabletten	2 mg/0,035mg	Film coated tablet	Oral
The Netherlands	ratiopharm Nederland B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Cyproteronacetaat/ethinylestradiol ratiopharm 2 mg/0,035 mg, omhulde tabletten	2 mg/0,035mg	Film coated tablet	Oral
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH Almere The Netherlands	Cyproteronacetaat/Ethinylestradiol Sandoz 2/0,035, omhulde tabletten	2 mg/0,035mg	Film coated tablet	oral
The Netherlands	Mylan B.V. Dieselweg 25 3752 LB BUNSCHOTEN The Netherlands	Cyproteronacetaat/Ethinylestradiol 2 mg/0,035 mg, omhulde tabletten	2 mg/0,035mg	Film coated tablet	oral
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Cyproteronacetaat/Ethinylestradiol 2/0,035 PCH, omhulde tabletten 2 mg/0,035 mg	2 mg/0,035mg	Film coated tablet	oral
The Netherlands	Stragen Nordic A/S Helsingørsgade 8C DK-3400 Hillerød Denmark	Ethinylestradiol 0,035 mg /Cyproteronacetaat 2 mg, omhulde tabletten	2 mg/0,035mg	Film coated tablet	oral
The Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht The Netherlands	Diane-35, omhulde tabletten	2 mg/0,035mg	Film coated tablet	oral

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Bayer plc, Bayer House, strawberry Hill, Newbury, Berkshire RG14 1JA UK	Dianette Tablets	2 mg/0,035mg	coated tablet	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG UK	Co-Cyprindiol Tablets 2000/35	2 mg/0,035mg	coated tablet	oral use
United Kingdom	Stragen UK Limited, Castle Court, 41 London Road, Reigate, Surrey RH2 9RJ UK	Clairette Tablets 2000/35	2 mg/0,035mg	Coated tablets	Oral use
United Kingdom	Chatfield Pharmaceuticals Limited, Kramer Mews, London SW5 9JL UK	Camilette Co-Cyprindiol 2000/35 Tablets	2 mg/0,035mg	Tablet	oral use
United Kingdom	Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR UK	Sandoz Co-Cyprindiol Tablets 2000/35	2 mg/0,035mg	coated tablet	oral use
United Kingdom	Generics (UK) Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL UK	Co-Cyprindiol Tablets 2mg/0.035mg	2 mg/0,035mg	coated tablet	oral use
United Kingdom	Generics (UK) Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL UK	Generics UK Cyproterone Acetate and Ethinylestradiol Tablets	2 mg/0,035mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Ranbaxy (UK) Limited, Building 4, Chiswick Park, 566 Chiswick High Road, London W4 5YE UK	Co-Cyprindiol 2000/35 Tablets	2 mg/0,035mg	coated tablet	oral use
United Kingdom	Strandhaven Limited, 600 High Road, Seven Kings, Ilford, Essex IG3 8BS UK	Strandhaven Co-Cyprindiol 2000/35 Tablets	2 mg/0,035mg	coated tablet	oral use
United Kingdom	Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough, Kent NN8 6GT UK	Fannin UK Co-Cyprindiol 2000/35 Tablets	2 mg/0,035mg	film-coated tablet	oral use
United Kingdom	Farmalider SA, Calle Aragoneses 15, Alcobendas, Madrid E-28108 Spain	Dialider Tablets	2 mg/0,035mg	film-coated tablet	oral use
United Kingdom	Cipla (EU) Limited, Millbrow House, Millbrow Road, Esher, Surrey KT10 9NW UK	Co-Cyprindiol 2000/35 Tablets	2 mg/0,035mg	film-coated tablet	oral use