



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for cyproterone-containing medicinal products

Referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1488

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Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Austria	Bayer Austria GmbH	Androcur Depot	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Austria	Bayer Austria GmbH	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Austria	Bayer Austria GmbH	Climen 28-Tage	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Austria	Bayer Austria GmbH	Diane Mite	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
Austria	Bayer Austria GmbH	Minerva	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Austria	Bayer Austria GmbH	Andro-Diane	Cyproterone Acetate 10mg Tablet	Tablet	Oral Use
Austria	Bayer Austria GmbH	Androcur	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Austria	Bayer Austria GmbH	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Austria	Gynial GmbH	Alisma	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Film-Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Austria	Pelpharma Handels Gmbh	Midane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
Austria	Teva B.V	Bellgyn	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Belgium	Bayer Sa Nv	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Belgium	Bayer Sa Nv	Diane-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Belgium	Bayer Sa Nv	Androcur	Cyproterone Acetate 10mg Tablet	Tablet	Oral Use
Belgium	Bayer Sa Nv	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Belgium	Ceres Pharma Nv	Daphne	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Belgium	Ceres Pharma Nv	Daphne Continu	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Belgium	Mylan Bvba/Sprl	Elisamylan 35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Belgium	Mylan Bvba/Sprl	Elisamylan 35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0mg Tablet	Coated Tablet	Oral Use
Belgium	Sandoz N.V.	Claudia-35	Cyproterone 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Bulgaria	Bayer Ag	Андрокур Депо	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Bulgaria	Bayer Ag	Диане 35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Bulgaria	Bayer Ag	Климен	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Bulgaria	Bayer Ag	Андрокур	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Croatia	Bayer Doo	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Croatia	Bayer Doo	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Croatia	Mibe Pharmaceuticals D.O.O.	Axira 35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Film-Coated Tablet	Oral Use
Croatia	Pliva Hrvatska D.O.O.	Bellune 35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Czech Republic	Bayer Ag	Androcur Depot	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Czech Republic	Bayer Ag	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Czech Republic	Bayer Ag	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Czech Republic	Bayer Ag	Minerva	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Czech Republic	Bayer Ag	Androcur	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Czech Republic	Bayer Ag	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Czech Republic	Heaton K.S.	Vreya	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Film-Coated Tablet	Oral Use
Czech Republic	Italchimici S.P.A.	Cysaxal	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Czech Republic	Italchimici S.P.A.	Cysaxal	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Denmark	Bayer Ab	Androcur Depot	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Denmark	Bayer Ab	Diane Mite	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Denmark	Orifarm Generics A/S	Zyrona	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
Denmark	Sandoz A/S	Feminil Mite	Cyproterone 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Denmark	Stragen Nordic A/S	Vreya	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Estonia	Ratiopharm Gmbh	Cypretil	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Gastroenteral Use Oral Use
Estonia	Bayer Ag	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Estonia	Bayer Ag	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Finland	Ratiopharm Gmbh	Cypretyl	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Gastroenteral Use Oral Use
Finland	Bayer Oy	Diane Nova	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Finland	Bayer Oy	Femilar	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 1mg Tablet Cyproterone Acetate 2mg Tablet, Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Finland	Bayer Oy	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Finland	Stragen Nordic A/S	Vreya	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
France	Arrow Generiques	Acetate De Cyproterone Arrow	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
France	Arrow Generiques	Acetate De Cyproterone Arrow	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
France	Bayer Healthcare	Climene	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
France	Bayer Healthcare	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
France	Bayer Healthcare	Minerva	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
France	Bayer Healthcare	Androcur	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
France	Bayer Healthcare	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
France	Bayer Healthcare	Cyproterone Biogaran	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
France	Bayer Healthcare	Cyproterone Biogaran	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
France	Eg Labo Laboratoires Eurogenerics	Acetate De Cyproterone Eg	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
France	Eg Labo Laboratoires Eurogenerics	Acetate De Cyproterone Eg	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
France	Harefield Pharma Associates Ltd	Acetate De Cyproterone/Ethinyles radiol Harefield	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
France	Harefield Pharma Associates Ltd	Acetate De Cyproterone/Ethinyles radiol Harefield Pharma Associates	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
France	Harefield Pharma Associates Ltd	Cypromix	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
France	Laboratoires Besins International	Erapyl	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
France	Mylan S.A.S	Evepar	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
France	Mylan S.A.S	Cyproterone Mylan	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
France	Mylan S.A.S	Cyproterone Mylan S.A.S	Cyproterone 50mg Tablet	Tablet	Oral Use
France	Sandoz	Acetate De Cyproterone Sandoz	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
France	Sandoz	Acetate De Cyproterone Sandoz	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
France	Teva Santé	Acetate De Cyproterone Teva	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
France	Teva Santé	Acetate De Cyproterone Teva	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
France	Zentiva France	Cyproterone Zentiva	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
France	Zentiva France	Cyproterone Zentiva	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Germany	Jenapharm Gmbh & Co Kg	Androcur-Depot	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Germany	Apontis Pharma Gmbh & Co. Kg	Morea Sanol	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Germany	Aristo Pharma Gmbh (Art 57)	Jennifer 35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Betapharm Arzneimittel Gmbh	Cyproteronacetat Beta	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Germany	Betapharm Arzneimittel Gmbh	Cyproteronacetat Beta	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Germany	Dermapharm Ag	Cyproderm	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Film-Coated Tablet	Oral Use
Germany	Hexal Ag	Bella	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Germany	Jenapharm Gmbh & Co Kg	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Germany	Jenapharm Gmbh & Co Kg	Diane-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Germany	Jenapharm Gmbh & Co Kg	Androcur	Cyproterone Acetate 10mg Tablet	Tablet	Oral Use
Germany	Jenapharm Gmbh & Co Kg	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Germany	Mithra Pharmaceuticals Sa	Micypra	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Film-Coated Tablet	Oral Use
Germany	Mylan Dura Gmbh	Juliette	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Germany	Ratiopharm Gmbh	Attempta	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Film-Coated Tablet	Oral Use
Germany	Tad Pharma Gmbh	Cyproteron Tad	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Germany	Tad Pharma Gmbh	Cyproteron Tad	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Germany	Teva Gmbh	Cyproteronacetat Gry Teva	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Greece	Bayer Hellas Sa	Androcur	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Greece	Bayer Hellas Sa	Gynofen 35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Greece	Bayer Hellas Sa	Androcur	Cyproterone Acetate 10mg Tablet	Tablet	Oral Use
Greece	Bayer Hellas Sa	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Hungary	Aramis Pharma Kft	Cypromix	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Hungary	Bayer Ag	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Hungary	Bayer Ag	Minerva	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Hungary	Bayer Ag	Androcur	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Hungary	Italchimici S.P.A.	Cysaxal	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Hungary	Italchimici S.P.A.	Cysaxal	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Iceland	Ratiopharm Gmbh	Cypretyl	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Gastroenteral Use Oral Use
Iceland	Bayer Ab	Diane Mite	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Iceland	Mylan Ab	Cyproteron Mylan	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Ireland	Bayer Ltd	Dianette	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Ireland	Bayer Ltd	Androcur	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Italy	Bayer Spa	Androcur	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Italy	Bayer Spa	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Italy	Bayer Spa	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Italy	Bayer Spa	Androcur	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Italy	Bayer Spa	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Italy	Fidia Farmaceutici S.P.A	Visofid	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Latvia	Bayer Ag	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Latvia	Bayer Ag	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Lithuania	Bayer Ag	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Lithuania	Bayer Ag	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Luxembourg	Bayer Sa Nv	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Luxembourg	Bayer Sa Nv	Diane-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Luxembourg	Bayer Sa Nv	Androcur	Cyproterone Acetate 10mg Tablet	Tablet	Oral Use
Luxembourg	Bayer Sa Nv	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Luxembourg	Ceres Pharma Nv	Daphne	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Malta	Bayer Plc	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Malta	Wockhardt Uk Ltd	Cyproterone Acetate Wockhardt Uk	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Netherlands	Bayer Bv	Androcur Depot	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Netherlands	Bayer Bv	Diane-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Netherlands	Bayer Bv	Androcur	Cyproterone Acetate 10mg Tablet	Tablet	Oral Use
Netherlands	Bayer Bv	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Netherlands	Italchimici S.P.A.	Cysaxal	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Netherlands	Italchimici S.P.A.	Cysaxal	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Netherlands	Mylan B.V.	Cyproteronacetaat/Ethinylestradiol Mylan	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Netherlands	Pharmachemie B.V	Cyproteronacetaat Pch	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Netherlands	Stragen Nordic A/S	Ethinylestradiol/Cyproteronacetaat Stragen	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Netherlands	Teva Nederland B.V.	Cyproteronacetaat/Ethinylestradiol Teva	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Norway	Bayer Ab	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Norway	Bayer Ab	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Norway	Orifarm Generics A/S	Zyrona	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Poland	Bayer Ag	Diane-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Poland	Bayer Ag	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Poland	Polfarmex S.A.	Oc-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Film-Coated Tablet	Oral Use
Poland	Sun-Farm Sp. Z.O.O.	Cyprodiol	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Film-Coated Tablet	Oral Use
Poland	Symphar Sp. Z O.O.	Syndi-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
Portugal	Bayer Portugal Lda	Androcur Depot	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Portugal	Bayer Portugal Lda	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Portugal	Bayer Portugal Lda	Diane 35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Portugal	Bayer Portugal Lda	Androcur	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Portugal	Bayer Portugal Lda	Androcur	Cyproterone Acetate 10mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Portugal	Generis Farmacêutica, S.A.	Ciproterona + Etinilestradiol Generis	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Portugal	Generis Farmacêutica, S.A.	Ciproterona Generis	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Portugal	Generis Farmacêutica, S.A.	Ciproterona Generis	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Portugal	Mylan, Lda	Acetato De Ciproterona/Etinilestradiol Mylan	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Romania	Bayer Ag	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Romania	Bayer Ag	Diane-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Romania	Bayer Ag	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Slovakia	Bayer Ag	Androcur-Depot	Cyproterone Acetate 300mg/3ml	Solution For Injection	Intramuscular Use
Slovakia	Bayer Ag	Diane-35	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Slovakia	Bayer Ag	Minerva	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Slovakia	Bayer Ag	Androcur - 50	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Slovakia	Heaton K.S.	Vreya	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Slovenia	Bayer D.O.O	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Slovenia	Bayer D.O.O	Androcur	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
Slovenia	Bayer D.O.O	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Spain	Bayer Hispania SI	Climen	Cyproterone Acetate 1mg Tablet, Estradiol Valerate 2mg Tablet Estradiol Valerate 2mg Tablet	Coated Tablet	Oral Use
Spain	Bayer Hispania SI	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Spain	Bayer Hispania SI	Diane Diario	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet Lactose Monohydrate 48.25mg Tablet	Coated Tablet	Oral Use
Spain	Bayer Hispania SI	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Spain	Laboratorios Effik S.A.	Gineservice	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Spain	Laboratorios Effik S.A.	Gyneplen	Cyproterone Acetate 0mg Tablet, Ethinylestradiol 0mg Tablet Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Film-Coated Tablet	Oral Use
Spain	Sandoz Farmacéutica, S.A.	Acetato De Ciproterona/Ethinylestradiol Sandoz	Cyproterone 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Sweden	Bayer Ab	Diane	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
Sweden	Bayer Ab	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Sweden	Mylan Ab	Cyproteron Mylan	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
Sweden	Orifarm Generics A/S	Zyrona	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
United Kingdom	Bayer Plc	Dianette	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
United Kingdom	Bayer Plc	Androcur	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
United Kingdom	Bayer Plc	Cyprostat	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
United Kingdom	Bayer Plc	Cyprostat	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use

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United Kingdom	Chelonia Healthcare Limited	Camilette	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
United Kingdom	Chelonia Healthcare Limited	Co-Cyprindiol	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
United Kingdom	Cipla (Eu) Limited	Co-Cyprindiol	Cyproterone Acetate 2000µg Tablet, Ethinylestradiol 35µg Tablet	Film-Coated Tablet	Oral Use
United Kingdom	Cipla (Eu) Limited	Cyproterone Acetate Cipla (Eu)	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
United Kingdom	Cipla (Eu) Limited	Cyproterone Acetate Cipla (Eu)	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
United Kingdom	Fannin (Uk) Limited	Co-Cyprindiol	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Film-Coated Tablet	Oral Use
United Kingdom	Fannin (Uk) Limited	Cyproterone Acetate Fannin (Uk)	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use
United Kingdom	Fannin (Uk) Limited	Cyproterone Acetate Fannin (Uk)	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
United Kingdom	Generics [uk] Limited	Cyproterone Acetate/Ethinylestradiol Generics	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
United Kingdom	Generics [uk] Limited	Cyproterone Acetate Generics UK	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
United Kingdom	Morningside Healthcare Ltd	Co-Cyprindiol	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Film-Coated Tablet	Oral Use

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United Kingdom	Morningside Healthcare Ltd	Teragezza	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Film-Coated Tablet	Oral Use
United Kingdom	Sandoz Ltd	Acnocin	Cyproterone 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
United Kingdom	Sandoz Ltd	Cyproterone Acetate Sandoz Ltd	Cyproterone 2mg Tablet, Ethinylestradiol 0.035mg Tablet	Coated Tablet	Oral Use
United Kingdom	Stragen Uk Ltd.	Clairette	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
United Kingdom	Stragen Uk Ltd.	Cyproterone Acetate Stragen	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
United Kingdom	Strandhaven Limited T/A Somex Pharma	Co-Cyprindiol	Cyproterone Acetate 2mg Tablet, Ethinylestradiol 35µg Tablet	Coated Tablet	Oral Use
United Kingdom	Wockhardt Uk Ltd	Cyproterone Acetate Wockhardt Uk	Cyproterone Acetate 50mg Tablet	Tablet	Oral Use
United Kingdom	Wockhardt Uk Ltd	Cyproterone Acetate Wockhardt Uk Ltd	Cyproterone Acetate 100mg Tablet	Tablet	Oral Use