



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2016
EMA/68246/2017
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: cyproterone/ethinylestradiol

Procedure no.: EMEA/H/N/PSR/J/0003
EMEA/H/N/PSR/J/0005
EMEA/H/N/PSR/J/0006



Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Diane Mite	N/A	1-18338	Bayer Austria GmbH	Austria
Minerva	N/A	1-21646	Bayer Austria GmbH	Austria
Diane-35	N/A	BE114572	Bayer SA NV, Belgium	Belgium
Diane 35	N/A	20000493	Bayer Pharma AG, Germany	Bulgaria
Diane-35 coated tablets	N/A	HR-H-931753518	Bayer doo, Croatia	Croatia
Diane-35	N/A	17/154/84-C	Bayer Pharma AG, Germany	Czech Republic
Minerva	N/A	17/173/02-C	Bayer Pharma AG, Germany	Czech Republic
Diane Mite	N/A	12301	Bayer Pharma AG, Germany	Denmark
Diane	N/A	269299	Bayer Pharma AG, Germany	Estonia
Diane Nova	N/A	9376	Bayer Oy, Finland	Finland
Diane 35	N/A	NL 14337	Bayer HealthCare, France	France
Minerva 35	N/A	NL 21987	Bayer HealthCare, France	France
Diane-35	N/A	347.01.00	Jenapharm GmbH & Co KG, Germany	Germany
Gynofen 35	N/A	39943/16-9-2009	Bayer Hellas SA, Greece	Greece
Diane	N/A	OGYI-T-1499/01 OGYI-T-1499/02	Bayer Pharma AG, Germany	Hungary
Minerva	N/A	OGYI-T-8687/01 OGYI-T-8687/02	Bayer Pharma AG, Germany	Hungary
Diane mite	N/A	MTnr. 860163(IS)	Bayer Pharma AG, Germany	Iceland
Dianette	N/A	PA 1410/003/001	Bayer Ltd, Ireland	Ireland
Diane	N/A	023777030	Bayer SpA, Italy	Italy
Diane	N/A	94-0169	Bayer Pharma AG, Germany	Latvia
Diane	N/A	LT/1/94/0413/001	Bayer Pharma AG, Germany	Lithuania
Diane-35	N/A	1987110963	Bayer SA NV, Belgium	Luxembourg
Diane-35	N/A	RVG 11903	Bayer BV, Netherlands	Netherlands
Diane	N/A	6611	Bayer Pharma AG, Germany	Norway
Diane-35	N/A	R/2222	Bayer Pharma AG, Germany	Poland
Diane 35	N/A	8507020 8507038	Berlifarma Especialidades Farmaceuticas Lda, Portugal	Portugal
Diane-35 0,035mg/2,0 mg drajeuri	N/A	5995/2013/01	Bayer Pharma AG, Germany	Romania
Minerva	N/A	17/0135/04-S	Bayer Pharma AG, Germany	Slovakia
Diane-35	N/A	17/0154/84-C/S	Bayer Pharma AG, Germany	Slovakia

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Diane	N/A	5363-I-1489/13	Bayer Pharma AG, Germany	Slovenia
Diane 35	N/A	55.698	Bayer Hispania SL, Spain	Spain
Diane	N/A	14800	Bayer Pharma AG, Germany	Sweden
Dianette tablets	N/A	PL 00010/0526	Bayer Plc, United Kingdom	United Kingdom
Cyprest	N/A	12302	Pabianickie Zakłady Farmaceutyczne Polfa S.A.	Poland
Cypromix coated tablets	N/A	OGYI-T: 20128/01-02	Aramis Pharma Kft	Hungary
Jennifer 35 2 mg/0,035 mg Filmtabletten	N/A	59938.00.00	Aristo Pharma GmbH	Germany
Co-cyprindiol 2000/35 Tablets	N/A		Cipla EU Ltd,	United Kingdom
Cyproderm	N/A	84200.00.00	Dermapharm AG	Germany
Cyprodiol	N/A	20903	SUN-FARM Sp. z o.o.	Poland
Alisma 2mg/35µg Filmtabletten	N/A	1-29268	Drehm Pharma GmbH / Gynial GmbH	Austria
Visofid	N/A	035368012	Fidia Farmaceutici S.p.A	Italy
Ciproterona + Etinilestradiol Generis	N/A	5078480 5078589	Generis Farmacêutica S.A.	Portugal
Vreya	NL/H/0623/001	17/088/06-C	Heaton k.s.	Czech republic
Vreya	NL/H/0623/001	17/0123/06-S	Heaton k.s.	Slovakia
CLAUDIA-35, 2mg/0,035mg omhulde tabletten	N/A	BE265255 BE265264	Sandoz N.V	Belgium
Feminil mite	N/A	33578	Sandoz A/S	Denmark
Feminil 2 mg/35 mikrog tabletti, päällystetty	N/A	20814	Sandoz A/S	Finland
Bella® HEXAL® 35 2mg/0,035mg überzogene Tabletten	N/A	59718.00.00	Hexal AG	Germany
Feminil 2 mg/35 mikrogram tabletter, drasjerte	N/A	05-3301	Sandoz	Norway
Acetato de Ciproterona/Etinilestradiol Sandoz 2 mg/ 0,035 mg comprimidos recubiertos EFG	N/A	68629	Sandoz Farmaceutica	Spain
Acnecin 2000/35 Tablets	N/A	PL 04416/0465	Sandoz Ltd.	United Kingdom

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Cyproterone Acetate 2.00 mg Ethinylestradiol 0.035 mg Coated Tablets	N/A	PL 04416/1040	Hexal AG	United Kingdom
Daphne	N/A	BE263751	Mithra Pharmaceuticals N.V	Belgium
Ergalea 2,00/0,035 mg Filmtabletten	N/A	59939.00.00	Mithra Pharmaceuticals GmbH	Germany
Daphne	N/A		Mithra Pharmaceuticals	Luxembourg
ElisaMylan 35, 2mg/0,035 mg	N/A	BE239181	Mylan	Belgium
Evepar 2mg/0.035mg, comprimé enrobé	N/A	NL 21995	Mylan	France
Juliette	N/A	45792.00.00	Mylan	Germany
Acetato de Ciproterona/Etinilestradiol 2 mg/0.035 mg, comprimidos	N/A	2994085 2994184 2994283 2994382 2994481 2994580 2994689 2994788 2994887 2994986 2995082 2995181	Mylan	Portugal
Cyproterone Acetate/Ethinylestradiol Tablets 2 mg/0.035 mg	N/A	PL 04569/0306	Mylan	United Kingdom
Midane-Dragees	N/A	1-25324	Pelpharma Handels GmbH	Austria
Bellgyn "ratiopharm" 2mg/0,035mg - überzogene Tabletten	N/A	1-25318	ratiopharm Arzneimittel Vertriebs-GmbH,	Austria
BELLUNE 35 obložene tablete	N/A	UP-I-530-09/11-02/639	Pliva Hrvatska d.o.o.,	Croatia
Cypretyl	N/A	36594	Teva Denmark A/S	Denmark
CYPROTERONE/ETHINYLESTRADIOL TEVA 2 mg/0,035 mg, comprimé enrobé	N/A	34009 378 844 8 8 34009 378 845 4 9	Teva Santé,	France

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Attempta-ratiopharm® 35 2 mg/0,035 mg überzogene Tablette	N/A	60439.00.00	ratiopharm GmbH, Germany	Germany
Cypretil	N/A	646709	ratiopharm GmbH, Germany	Estonia
Cypretyl	N/A	24542	ratiopharm GmbH, Germany	Finland
Cypretyl húðuð tafla	N/A	IS/1/12/094/01	ratiopharm GmbH, Germany	Iceland
Cyproteronacetaat /Ethinylestradiol 2/0,035 PCH, omhulde tabletten 2 mg/0,035 mg	N/A	RVG 33581	Pharmachemie B.V.,	Netherlands
Co-cyprindiol 2000/35 Coated Tablets	N/A	PL 00289/1604	Teva UK Limited, United Kingdom	United Kingdom
Vreya	NL/H/0623/001	38427	Stragen Nordic A/S	Denmark
Vreya 0.035 mg/2 mg	NL/H/0623/001	21514	Stragen Nordic A/S	Finland
Ethinylestradiol 0.035mg/cyproteronacetaat 2mg	NL/H/0623/001	RVG 29728	Stragen Nordic A/S	Netherlands
Clairette 2000/35	N/A	PL 21844/0009	Stragen UK Ltd	United Kingdom
Co-cyprindiol 2000/35 Coated Tablets	N/A	15764/0011	Strandhaven Limited	United Kingdom
Morea sanol 2 mg/0,035 mg überzogene Tabletten	N/A	64006.00.00	UCB Innere Medizin GmbH & Co. KG	Germany