



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2021
EMA/32642/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: cyproterone / ethinylestradiol

Procedure no.: PSUSA/00000906/202005

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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
Diane-35, 2 mg + 0,035 mg, tabletki powlekane	not available	R/2222	BAYER AG	PL
Diane 2000 mikrogramu /35 mikrogramu apvalkotās tabletes	not available	94-0169	BAYER AG	LV
Diane 2 mg/0,035 mg comprimidos recubiertos	not available	55.698	BAYER HISPANIA SL	ES
Diane-35, 0,035 mg/2mg überzogene Tabletten	not available	347.01.00	JENAPHARM GMBH & CO KG	DE
Diane Mite, overtrukne tabletter	not available	12301	BAYER AB	DK
Diane 2 mg + 0,035 mg compresse rivestite	not available	023777030	BAYER SPA	IT
Diane 35, 2 mg + 0,035 mg, comprimidos revestidos	not available	8507038	BAYER PORTUGAL LDA	PT
Diane 35, 2 mg + 0,035 mg, comprimidos revestidos	not available	8507020	BAYER PORTUGAL LDA	PT
Dianette ®	not available	PL 00010/0526	BAYER PLC	UK

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
Diane 2000 mikrogramų/35 mikrogramai dengtos tabletės	not available	LT/1/94/0413/001	BAYER AG	LT
Dianette 2mg/35 microgram coated tablets	not available	PA 1410/003/001	BAYER LTD	IE
Diane 2 mg/0,035 mg obalené tablety	not available	17/154/84-C	BAYER AG	CZ
Diane® Nova dragerade tabletter	not available	9376	BAYER OY	FI
Diane® Nova tabletti, päällystetty	not available	9376	BAYER OY	FI
Diane-35, 2 mg/0,035 mg überzogene Tabletten	not available	1987110963	BAYER SA NV	LU
Diane-35, 2 mg / 0,035 mg comprimés enrobés	not available	1987110963	BAYER SA NV	LU
MINERVA 35 microgrammes, comprimé enrobé	not available	34009 345 067 2 7	BAYER HEALTHCARE	FR
MINERVA 35 microgrammes, comprimé enrobé	not available	34009 345 068 9 5	BAYER HEALTHCARE	FR

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
Diane tablett, drasjert	not available	6611	BAYER AB	NO
Diane-35, 2 mg/0,035 mg überzogene Tabletten	not available	BE114572	BAYER SA NV	BE
Diane-35, 2 mg / 0,035 mg omhulde tabletten	not available	BE114572	BAYER SA NV	BE
Diane-35, 2 mg / 0,035 mg comprimés enrobés	not available	BE114572	BAYER SA NV	BE
Cyproterone Acetate 2.00 mg Ethinylestradiol 0.035 mg Coated Tablets	DE/H/5662/001	PL 04416/1040	SANDOZ LTD	UK
Diane bevont tablettá	not available	OGYI-T-1499/01	BAYER AG	HU
Diane bevont tablettá	not available	OGYI-T-1499/02	BAYER AG	HU
Diane-35, omhulde tabletten 2,0 mg / 0,035 mg	not available	RVG 11903	BAYER BV	NL
Diane 2 mg/35 mikrogram, tablett	not available	14800	BAYER AB	SE

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
Co-cyprindiol 2000 micrograms /35 micrograms film-coated tablets	not available	PL 36390/0027	CIPLA (EU) LIMITED	UK
Diane-35 0,035 mg/2,0 mg drajeuri	not available	12690/2019/01	BAYER AG	RO
Diane 2 mg/0,035 mg obložene tablete	not available	H/93/00462/001	BAYER D.O.O	SI
Diane mite filmuhúðaðar töflur	not available	MTNR 860163 (IS).	BAYER AB	IS
Minerva - Dragees	not available	1-21646	BAYER AUSTRIA GMBH	AT
Diane, 2000 µg/35 µg kaetud tabletid	not available	269299	BAYER AG	EE
Gynofen 35®	not available	39943/16-9-2009	BAYER HELLAS SA	GR
Diane mite - Dragees	not available	1-18338	BAYER AUSTRIA GMBH	AT
Диане 35 0,035 mg/2,0 mg обвити таблетки	not available	20000493	BAYER AG	BG

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
Diane Diario 2 mg/0,035 mg comprimidos recubiertos	not available	62.946	BAYER HISPANIA SL	ES
Minerva 2 mg/0,035 mg obalené tablety	not available	17/173/02-C	BAYER AG	CZ
Diane-35 obložene tablete	not available	HR-H-931753518-01	BAYER DOO	HR
DIANE 35 microgrammes, comprimé enrobé	not available	34009 329 697 5 3	BAYER HEALTHCARE	FR
DIANE 35 microgrammes, comprimé enrobé	not available	34009 329 698 1 4	BAYER HEALTHCARE	FR
DIANE 35 microgrammes, comprimé enrobé	not available	34009 329 699 8 2	BAYER HEALTHCARE	FR