



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2024
EMA/110565/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: cyproterone / ethinylestradiol

Procedure no.: PSUSA/00000906/202305

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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 mite - Dragees	not available	1-18338	BAYER AUSTRIA GMBH	AT
Minerva - Dragees	not available	1-21646	BAYER AUSTRIA GMBH	AT
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
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
Minerva 2 mg/0,035 mg obalené tablety	not available	17/173/02-C	BAYER AG	CZ
Diane 2 mg/0,035 mg obalené tablety	not available	17/154/84-C	BAYER AG	CZ
Diane-35, 0,035 mg/2mg überzogene Tabletten	not available	347.01.00	JENAPHARM GMBH & CO KG	DE
Diane, 2000 mg/35 mg kaetud tabletid	not available	269299	BAYER AG	EE
Diane Diario 2 mg/0,035 mg comprimidos recubiertos	not available	62.946	BAYER HISPANIA SL	ES
Diane® Nova dragerade tabletter	not available	9376	BAYER OY	FI

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® Nova tabletti, päällystetty	not available	9376	BAYER OY	FI
MINERVA 35 microgramme s, comprimé enrobé	not available	34009 345 067 2 7	BAYER HEALTHCARE	FR
MINERVA 35 microgramme s, comprimé enrobé	not available	34009 345 068 9 5	BAYER HEALTHCARE	FR
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

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 obložene tablete	not available	HR-H-931753518	BAYER DOO	HR
Dianette 2mg/35 microgram coated tablets	not available	PA1410/003/001	BAYER LTD	IE
Diane 2 mg + 0,035 mg compresse rivestite	not available	023777030	BAYER SPA	IT
Diane 2000 mikrogramų/35 mikrogramai dengtos tabletės	not available	LT/1/94/0413/001	BAYER AG	LT
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

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 mikrogramu /35 mikrogramu apvalkotās tabletes	not available	94-0169	BAYER AG	LV
Diane-35, 2 mg + 0,035 mg, tabletki powlekane	not available	R/2222	BAYER AG	PL
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
Diane-35 0,035 mg/2,0 mg drajeuri	not available	12690/2019/01	BAYER AG	RO
Co-cyprindiol 2000 micrograms/35 micrograms film-coated tablets	not available	PL 20416/0691	CRESCENT PHARMA LIMITED	XI

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 20416/0691	CRESCENT PHARMA LIMITED	XI
Cyproterone Acetate 2.00 mg Ethinylestradiol 0.035 mg Coated Tablets	DE/H/5662/001	PL 04416/1040	SANDOZ LTD	XI
Dianette®	not available	PL 00010/0526	BAYER PLC	XI