



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2024
EMA/111641/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: chlormadinone acetate (CMA), ethinylestradiol (EE)

Procedure no.: EMEA/H/N/PSR/J/0042



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
Madinance 2,0 mg/0,03 mg Filmtabletten		88770.00.00	acis Arzneimittel GmbH	Germany
Bonita AL 0,03 mg/2 mg Filmtabletten	DE/H/2375/001	77885.00.00	ALIUD PHARMA GmbH	Germany
Clormetin 2 mg/0,03 mg potahované tablety	LV/H/0187/001	17/464/10-C	Aristo Pharma GmbH	Czech Republic
Lilia 0,03 mg/ 2 mg Filmtabletten	N/A	78366.00.00	Aristo Pharma GmbH	Germany
Madinette 0,03 mg/2 mg Filmtabletten	DE/H/2193/001/D C	1-29161	Dermapharm GmbH	Austria
Minette 2 mg/0,03 mg Filmtabletten	DE/H/1466/001 CMS:AT	73092.00.00	DR. KADE/BESINS Pharma GmbH	Germany
Balanca	DE/H/0516/001/M R	1-26296	Gedeon Richter Plc.	Austria
Balanca	DE/H/0516/001/M R	50920.00.00	Gedeon Richter Plc.	Germany
Balianca	DE/H/0516/001/M R	66904	Gedeon Richter Plc.	Spain
Balianca diario	DE/H/0516/002/D C	71968	Gedeon Richter Plc.	Spain
Belara	DE/H/0505/001/M R	1-26297	Gedeon Richter Plc.	Austria
Belara	National	HR-H- 368848654- 01, HR-H- 368848654-02	Gedeon Richter Plc.	Croatia

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Belara	National	17/101/02-C	Gedeon Richter Plc.	Czech Republic
Belara	DE/H/0505/001/M R	3400936950085, 3400936950146, no	Gedeon Richter Plc.	France
Belara	DE/H/0505/001/M R	50919.00.00	Gedeon Richter Plc.	Germany
Belara	National	36579.00.00	Gedeon Richter Plc.	Germany
Belara	National	OGYI-T-8786/01, OGYI-T-8786/02	Gedeon Richter Plc.	Hungary
Belara	DE/H/0505/001/M R	036875019, 036875021, 036875033, 036875072	Gedeon Richter Plc.	Italy
Belara	National	03-0382	Gedeon Richter Plc.	Latvia
Belara	National	LT/1/02/3084/001, LT/1/02/3084/002	Gedeon Richter Plc.	Lithuania
Belara	DE/H/0505/001/M R	5503487, 5503586, no	Gedeon Richter Plc.	Portugal
Belara	National	17/0201/02-S	Gedeon Richter Plc.	Slovak Republic
Belara	DE/H/0505/001/M R	H/09/00255/001, H/09/00255/002, H/09/00255/003, H/09/00255/004	Gedeon Richter Plc.	Slovenia

Belara	DE/H/0505/001/M R	66905	Gedeon Richter Plc.	Spain
Belara 21+7	DE/H/3586/001/D C	20140161	Gedeon Richter Plc.	Bulgaria

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Belara 21+7	DE/H/0505/003/D C	71081.00.00	Gedeon Richter Plc.	Germany
Belara diario	DE/H/0505/003/D C	71898	Gedeon Richter Plc.	Spain
Belaracontinú	DE/H/0505/003/D C	3400939936970, 3400939937052, 3400939937113, no	Gedeon Richter Plc.	France
Bellina	DE/H/0505/001/M R	BE352554	Gedeon Richter Plc.	Belgium
Bellina	DE/H/0505/001/M R	0530542, 0530556, 0530573, 0704476	Gedeon Richter Plc.	Luxembourg
Chariva	National	56592.00.00	Gedeon Richter Plc.	Germany
Chariva	DE/H/3587/001/D C	5606504, 5606512, 5606520	Gedeon Richter Plc.	Portugal
Chariva 21+7	DE/H/0516/002/D C	71082.00.00	Gedeon Richter Plc.	Germany
Ethinylestradiol/Chlormad inonacetat Richter	DE/H/3587/001/D C	87492.00.00	Gedeon Richter Plc.	Germany
Ethinylestradiol/Chlormad inonacetat Richter 21+7	DE/H/3586/001/D C	87491.00.00	Gedeon Richter Plc.	Germany
Libeli	DE/H/0516/001/M R	5503685, 5503784, no	Gedeon Richter Plc.	Portugal
Lybella	DE/H/0516/001/M R	036876011, 036876023, 036876035	Gedeon Richter Plc.	Italy

Neo-Eunomin	National	4807.00.00	Gedeon Richter Plc.	Germany
Belara	DE/H/3587/001/D C	21993	Gedeon Richter Polska SP. Z o.o.	Poland

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Belara	National	750/2008/01, 750/2008/02	Gedeon Richter Romania S.A.	Romania
Belara Continu	National	12587/2019/01, 12587/2019/02	Gedeon Richter Romania S.A.	Romania
Bilinda 0,03mg/2mg Filmtabletten	n.a.	1-30167	Gynial GmbH	Austria
Bilinda Gynial 0,03mg/2mg Filmtabletten	n.a.	138538	Gynial GmbH	Austria
FLAYA	N/A	17/ 365/12-C	HEATON k.s.	Czech Republic
MONA HEXAL® 2 mg/0,03 mg Filmtabletten	DE/H/1427/001	72712.00.00	HEXAL AG	Germany
Solera 2mg/0,03mg Filmtabletten	DE/H/1831/001/D C	74480.00.00	Hormosan Pharma GmbH	Germany
Clarissa	NA	10/H/0127/001	ITF Farmahealth , Produtos Farmacêuticos, Lda	Portugal
Enriqa	DE/H/1573/001 (DCP)	72663.00.00	Jenapharm	Germany
Delia	DE/H/1466/001	1-29421	Kwizda Pharma GmbH	Austria
Etinilestradiol/Clormadino na STADA 0,03 mg/2 mg comprimidos recubiertos con película EFG	DE/H/2375/001	75.288	Laboratorio STADA, S.L.	Spain

Bellissima	na	60076.00.00	MEDA Pharma GmbH & Co KG	Germany
Bellissima	na	2009110002	MEDA Pharma GmbH & Co KG	Luxemburg

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Bellissima 21+7	na	78368.00.00	MEDA Pharma GmbH & Co KG	Germany
Madinette 30	DE/H/2193/001/D C	73107.00.00	mibe GmbH Arzneimittel	Germany
Lisette 0,03 mg/2 mg Filmtabletten	DE/H/1606/001/D C	73096.00.00	Mylan Germany GmbH	Germany
Angiletta 2 mg/0,03 mg Filmtabletten	DE/H/1830/001/D C	74479.00.00	PUREN Pharma GmbH & Co. KG	Germany
EVE	IT/H/0838/001	039566017 039566029 039566031 039566043	SANDOZ S.P.A.	Italy
Belissa 0,03 mg/2 mg filmom obalené tablety	DE/H/2375/001	17/0458/12-S	STADA Arzneimittel AG	Slovakia
Bonissa 0,03 mg/2 mg potahované tablety	DE/H/2375/001	17/809/11-C	STADA Arzneimittel AG	Czech Republic
Pink Luna 0,03 mg/2 mg Filmtabletten	DE/H/2374/001	77884.00.00	STADApHarm GmbH	Germany
Madinette	DE/H/2193/001/D C	17197	Sun-Farm Sp. z.o.o.	Poland
Chloee 0,03 mg/2 mg Filmtabletten	DE/H/2349/001	77617.00.00	ZENTIVA PHARMA GmbH	Germany