



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2017
EMA/583978/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: chlormadinone acetate / ethinylestradiol

Procedure no.: PSUSA/00000679/201611



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
Belara 0,03 mg/2 mg apvalkotās tabletes	not available	03-0382	GEDEON RICHTER PLC.	LV
BELARA 0,03 mg/2 mg, comprimé pelliculé	DE/H/0505/001	369 500-8	GEDEON RICHTER PLC.	FR
BELARA 0,03 mg/2 mg, comprimé pelliculé	DE/H/0505/001	369 501-4	GEDEON RICHTER PLC.	FR
BELARA compresse rivestite con film	DE/H/0505/001	036875072	GEDEON RICHTER PLC.	IT
LYBELLA compresse rivestite con film	DE/H/0516/001	036876011	GEDEON RICHTER PLC.	IT
LYBELLA compresse rivestite con film	DE/H/0516/001	036876023	GEDEON RICHTER PLC.	IT
LYBELLA compresse rivestite con film	DE/H/0516/001	036876035	GEDEON RICHTER PLC.	IT
BELARACONTINU 0,03 mg/2 mg, comprimé pelliculé	DE/H/0505/003	34009 399 369 7 0	GEDEON RICHTER PLC.	FR
BELARACONTINU 0,03 mg/2 mg, comprimé pelliculé	DE/H/0505/003	34009 399 370 5 2	GEDEON RICHTER PLC.	FR
BELARACONTINU 0,03 mg/2 mg, comprimé pelliculé	DE/H/0505/003	34009 399 371 1 3	GEDEON RICHTER PLC.	FR
Libeli, 2 mg + 0,03 mg comprimidos revestidos por película	DE/H/0516/001	5503784	GEDEON RICHTER PLC.	PT
BALANCACONTINU 0,03 mg/2 mg, comprimé pelliculé	DE/H/0516/002	34009 395 688 0 5	GEDEON RICHTER PLC.	FR
BALANCACONTINU 0,03 mg/2 mg, comprimé pelliculé	DE/H/0516/002	34009 395 689 7 3	GEDEON RICHTER PLC.	FR
BALANCACONTINU 0,03 mg/2 mg, comprimé pelliculé	DE/H/0516/002	34009 395 690 5 5	GEDEON RICHTER PLC.	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
Balianca diario 2 mg/0,03 mg comprimidos recubiertos con película	DE/H/0516/002	71968	GEDEON RICHTER PLC.	ES
Belara 0,03 mg/2 mg filmisko obložene tablete	DE/H/0505/001	H/09/00255/001	GEDEON RICHTER PLC.	SI
Belara 0,03 mg/2 mg filmisko obložene tablete	DE/H/0505/001	H/09/00255/002	GEDEON RICHTER PLC.	SI
Belara 0,03 mg/2 mg filmisko obložene tablete	DE/H/0505/001	H/09/00255/003	GEDEON RICHTER PLC.	SI
Belara 0,03 mg/2 mg filmisko obložene tablete	DE/H/0505/001	H/09/00255/004	GEDEON RICHTER PLC.	SI
Belara 0,03 mg/2 mg filmom obložene tablete	not available	UP/I-530-09/11-02/216	GEDEON RICHTER PLC.	HR
Neo-Eunomin® 0,05 mg/2 mg Filmtabletten	NULL	4807.00.00	GEDEON RICHTER PLC.	DE
BELLINA 0,03mg/ 2 mg, comprimés pelliculés	DE/H/0505/001	0530556	GEDEON RICHTER PLC.	LU
BELLINA 0,03mg/ 2 mg, comprimés pelliculés	DE/H/0505/001	0530573	GEDEON RICHTER PLC.	LU
BELLINA 0,03mg/ 2 mg, comprimés pelliculés	DE/H/0505/001	0704476	GEDEON RICHTER PLC.	LU
Balanca® 0,03 mg/2 mg - Filmtabletten	DE/H/0516/001	1-26296	GEDEON RICHTER PLC.	AT
Belara 0,03 mg/2 mg filmtabletta	not available	OGYI-T-8786/02	GEDEON RICHTER PLC.	HU
Belara 0,03 mg/2 mg filmtabletta	not available	OGYI-T-8786/01	GEDEON RICHTER PLC.	HU
Belara® 0,03 mg/2 mg - Filmtabletten	DE/H/0505/001	1-26297	GEDEON RICHTER PLC.	AT
BELARA compresse rivestite con film	DE/H/0505/001	036875021	GEDEON RICHTER PLC.	IT
Belara 0,03 mg/2 mg, Filmtabletten	not available	36579.00.00	GEDEON RICHTER PLC.	DE

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Belara 0,03 mg/2 mg Filmtabletten	DE/H/0505/001	50919.00.00	GEDEON RICHTER PLC.	DE
Balanca 0,03 mg/2 mg Filmtabletten	DE/H/0516/001	50920.00.00	GEDEON RICHTER PLC.	DE
Chariva 0,03 mg/2 mg Filmtabletten	not available	56592.00.00	GEDEON RICHTER PLC.	DE
Libeli, 2 mg + 0,03 mg comprimidos revestidos por película	DE/H/0516/001	5503685	GEDEON RICHTER PLC.	PT
BALIANCA 2 mg / 0,03 mg comprimidos recubiertos con película	DE/H/0516/001	66.904	GEDEON RICHTER PLC.	ES
BELARA compresse rivestite con film	DE/H/0505/001	036875019	GEDEON RICHTER PLC.	IT
BELARA, 0,03 mg/2 mg potahované tablety	not available	17/101/02-C	GEDEON RICHTER PLC.	CZ
Belara diario 2 mg / 0,03 mg comprimidos recubiertos con película	DE/H/0505/003	71898	GEDEON RICHTER PLC.	ES
Neo-Eunomin® 0,05 mg/1 mg Filmtabletten	NULL	4807.00.00	GEDEON RICHTER PLC.	DE
Belara 2 mg / 0,03 mg comprimidos recubiertos con película	DE/H/0505/001	66.905	GEDEON RICHTER PLC.	ES
BELARA compresse rivestite con film	DE/H/0505/001	036875033	GEDEON RICHTER PLC.	IT
BELARA compresse rivestite con film	DE/H/0505/001	036875045	GEDEON RICHTER PLC.	IT
BELLINA 0,03mg/ 2 mg, comprimés pelliculés	DE/H/0505/001	0530542	GEDEON RICHTER PLC.	LU
Belara, comprimate filmate	not available	750/2008/01	GEDEON RICHTER ROMÂNIA S.A.	RO
Belara, comprimate filmate	not available	750/2008/02	GEDEON RICHTER ROMÂNIA S.A.	RO

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Belara, comprimate filmate	not available	750/2008/03	GEDEON RICHTER ROMÂNIA S.A.	RO
Belara, comprimate filmate	not available	750/2008/04	GEDEON RICHTER ROMÂNIA S.A.	RO
BELLINA 0,03mg/ 2 mg, comprimés pelliculés	DE/H/0505/001	BE352554	GEDEON RICHTER PLC.	BE
Bellina 0,03 mg/2 mg Filmtabletten	DE/H/0505/001	BE352554	GEDEON RICHTER PLC.	BE
BELLINA 0,03 mg / 2 mg filmomhulde tabletten	DE/H/0505/001	BE352554	GEDEON RICHTER PLC.	BE
Belara 21+7 0,03 mg/2 mg, Filmtabletten	DE/H/0505/003	71081.00.00	GEDEON RICHTER PLC.	DE
Chariva 21+7 0,03 mg/2 mg, Filmtabletten	DE/H/0516/002	71082.00.00	GEDEON RICHTER PLC.	DE
Belara 0,03 mg / 2 mg filmom obalené tablety	not available	17/0201/02-S	GEDEON RICHTER PLC.	SK
Belara 0,03 mg/2 mg plėvele dengtos tabletės	not available	LT/1/02/3084/001	GEDEON RICHTER PLC.	LT
Belara 0,03 mg/2 mg plėvele dengtos tabletės	not available	LT/1/02/3084/002	GEDEON RICHTER PLC.	LT
Belara 2mg + 0.03 mg comprimidos revestidos por película	DE/H/0505/001	5503586	GEDEON RICHTER PLC.	PT
Belara 2mg + 0.03 mg comprimidos revestidos por película	DE/H/0505/001	5503487	GEDEON RICHTER PLC.	PT