



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2016
EMA/761543/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: bilastine

Procedure no.: PSUSA/00003163/201603



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
Bilaxten 20 mg comprimidos	DE/H/2301/001	73.027	FAES FARMA, S.A.	ES
ILEXEL 20 MG	DE/H/2301/001	BE401387	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
INORIAL 20 mg, comprimé	DE/H/2301/001	34009 499 139 3 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 20 mg, comprimé	DE/H/2301/001	34009 499 138 7 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 20 mg, comprimé	DE/H/2301/001	34009 578 992 0 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Antires® 20 mg Tabletten	DE/H/2301/001	73800.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
INORIAL 20 mg, comprimé	DE/H/2301/001	34009 578 991 4 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Bilaxten, 20 mg, tabletki	DE/H/2301/001	17821	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Bilargen® 20 mg δισκία	DE/H/2301/001	64838/12	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
INORIAL 20 mg, comprimé	DE/H/2301/001	34009 499 140 1 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341508	LABORATÓRIOS VITÓRIA, SA	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341516	LABORATÓRIOS VITÓRIA, SA	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341524	LABORATÓRIOS VITÓRIA, SA	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341532	LABORATÓRIOS VITÓRIA, SA	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341474	LABORATÓRIOS VITÓRIA, SA	PT
Bellozal 20 mg	DE/H/2300/001	BE381211	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Revitelle 20 mg tabletter	DE/H/2300/001	27335	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Borenar 20 mg comprimate	DE/H/2300/001	8562/2016/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 20 mg comprimate	DE/H/2300/001	8562/2016/04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 20 mg comprimate	DE/H/2300/001	8562/2016/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO

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
Borenar 20 mg comprimé	DE/H/2300/001	8562/2016/05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 20 mg comprimé	DE/H/2300/001	8562/2016/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Bellozal 20 mg comprimés	DE/H/2300/001	2011011460	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Opexa, 20 mg tabletid	DE/H/2300/001	715910	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
BILASKA 20 mg, comprimé	DE/H/2300/001	34009 578 990 8 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé	DE/H/2300/001	34009 499 136 4 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé	DE/H/2300/001	34009 499 135 8 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Xados 20 mg tablety	DE/H/2300/001	24/001/11-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Фортекал 20 mg таблетки	DE/H/2300/001	20100738	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Nasitop® 20 mg Tabletten	DE/H/2300/001	1-30199	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Revitelle 20 mg tabletti	DE/H/2300/001	27335	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
BILASKA 20 mg, comprimé	DE/H/2300/001	34009 499 137 0 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Clatra, 20 mg, tabletki	DE/H/2300/001	17820	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Lergonix 20 mg comprimidos	DE/H/2300/001	5346747	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Bilador 20 mg tablete	DE/H/2300/001	5363-I-1187/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilaxten® 20 mg Tabletten	DE/H/2300/001	73799.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Opexa 20 mg tabletes	DE/H/2300/001	10-0602	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Olisir 20 mg compresse	DE/H/2300/001	041044052	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT

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
Lendin 20 mg tableta	DE/H/2300/001	OGYI-T-21640/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 20 mg tableta	DE/H/2300/001	OGYI-T-21640/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 20 mg tableta	DE/H/2300/001	OGYI-T-21640/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Opexa 20 mg tabletés	DE/H/2300/001	LT/1/10/2241/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletés	DE/H/2300/001	LT/1/10/2241/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletés	DE/H/2300/001	LT/1/10/2241/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletés	DE/H/2300/001	LT/1/10/2241/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletés	DE/H/2300/001	LT/1/10/2241/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Olisir 20 mg compresse	DE/H/2300/001	041044037	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT

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
Olisir 20 mg compresse	DE/H/2300/001	041044025	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Olisir 20 mg compresse	DE/H/2300/001	041044013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Olisir 20 mg compresse	DE/H/2300/001	041044049	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Bilaz® 20 mg δισκία	DE/H/2300/001	44881	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Gosall 20 mg tablets	DE/H/2300/001	MA204/00501	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Bilador 20 mg tablete	DE/H/2300/001	5363-I-1186/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Ilaxten 20 mg tablets	DE/H/2300/001	PL 16239/0034	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
Lergonix 20 mg comprimidos	DE/H/2300/001	5346762	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 20 mg comprimidos	DE/H/2300/001	5346754	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT

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
Lergonix 20 mg comprimidos	DE/H/2300/001	5346770	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Bilador 20 mg tablete	DE/H/2300/001	5363-I-1183/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilaxten 20 mg tableter	DE/H/2300/001	42287	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
Lergonix 20 mg comprimidos	DE/H/2300/001	5346739	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Zilas 20 mg tableter	DE/H/2300/001	09-6621	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
Bilador 20 mg tablete	DE/H/2300/001	5363-I-1184/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Drynol 20 mg Tablets	DE/H/2300/001	PA 865/18/1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
Bilador 20 mg tablete	DE/H/2300/001	5363-I-1185/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilaxten 20 mg töflur	DE/H/2300/001	IS/1/10/002/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS

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
Omarit 20 mg, tablety	DE/H/2300/001	24/0912/10-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
Ibis 20 mg comprimidos	DE/H/2300/001	73.029	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
BILASKA 20 mg, comprimé	DE/H/2300/001	34009 578 988 3 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Bilaz® 20 mg δισκία	DE/H/2300/001	21475	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
Nixar 20 mg tablete	not available	UP/I-530-09/12-01/61	BERLIN-CHEMIE MENARINI HRVATSKA D.O.O.	HR
Bitosen® 20 mg Tabletten	DE/H/2302/001	73801.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Ayrinal 20 mg compresse	DE/H/2302/001	040854010	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 20 mg compresse	DE/H/2302/001	040854022	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 20 mg compresse	DE/H/2302/001	040854034	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT

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
Ayrinal 20 mg compresse	DE/H/2302/001	040854046	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 20 mg compresse	DE/H/2302/001	040854059	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Obalix 20 mg comprimidos	DE/H/2302/001	73.028	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Rhinolibre® 20 mg Tabletten	DE/H/2301/001	1-30201	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Robilas 20 mg compresse	DE/H/2301/001	041045055	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 20 mg compresse	DE/H/2301/001	041045028	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 20 mg compresse	DE/H/2301/001	041045030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 20 mg compresse	DE/H/2301/001	041045016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 20 mg compresse	DE/H/2301/001	041045042	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT