



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2024
EMA/487378/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): bilastine

Procedure No. PSUSA/00003163/202403



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 Schmelztabletten	DE/H/2300/004	141659	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Nasitop 10 mg Schmelztabletten	DE/H/2300/002	137893	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Olisir® 6 mg/ml Augentropfen, Lösung	DE/H/2300/005	141629	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Olisir® 20 mg Tabletten	DE/H/2300/001	1-30199	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Nasitop 2,5 mg/ml Lösung zum Einnehmen	DE/H/2300/003	137894	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Bellozal 20 mg orodispergeerbare tabletten	DE/H/2300/004	BE661446	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 20 mg comprimés orodispersibles	DE/H/2300/004	BE661446	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 20 mg Schmelztabletten	DE/H/2300/004	BE661446	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 10 mg comprimés orodispersibles	DE/H/2300/002	BE513946	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 10 mg Schmelztabletten	DE/H/2300/002	BE513946	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 10 mg orodispergeerbare tabletten	DE/H/2300/002	BE513946	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 6 mg/ml Augentropfen, Lösung	DE/H/2300/005	BE660446	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE

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
Bellozal 6 mg/ml oogdruppels, oplossing	DE/H/2300/005	BE660446	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 6 mg/ml collyre en solution	DE/H/2300/005	BE660446	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 20 mg tabletten	DE/H/2300/001	BE381211	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 20 mg Tabletten	DE/H/2300/001	BE381211	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 20 mg comprimés	DE/H/2300/001	BE381211	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 2,5 mg/ml Lösung zum Einnehmen	DE/H/2300/003	BE513955	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 2,5 mg/ml solution buvable	DE/H/2300/003	BE513955	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Bellozal 2,5 mg/ml drank	DE/H/2300/003	BE513955	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Фортекал 20 mg диспергиращи се в устата таблетки	DE/H/2300/004	20230132	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BG
Фортекал за деца 10 mg диспергиращи се в устата таблетки	DE/H/2300/002	20170264	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BG
Фортекал 20 mg таблетки	DE/H/2300/001	20100738	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BG
Фортекал за деца 2,5 mg/ml перорален разтвор	DE/H/2300/003	20170257	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BG
Bilaz 20 mg δισκία διασπειρόμενα στο στόμα	DE/H/2300/004	023856	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY

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
Bilaz 10 mg δισκία διασπειρόμενα στο στόμα	DE/H/2300/002	22833	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
Bilaz 6 mg/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/2300/005	023848	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
Bilaz 20 mg δισκία	DE/H/2300/001	21475	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
Bilaz 2,5 mg/ml πόσιμο διάλυμα	DE/H/2300/003	022853	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
Xados 20 mg tablety dispergovatelné v ústech	DE/H/2300/004	24/437/20-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Xados 10 mg tablety dispergovatelné v ústech	DE/H/2300/002	24/750/15-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Xados 6 mg/ml oční kapky, roztok	DE/H/2300/005	64/189/21-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Xados 20 mg tablety	DE/H/2300/001	24/001/11-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Xados 2,5 mg/ml perorální roztok	DE/H/2300/003	24/751/15-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Bitosen® 20 mg Tabletten	DE/H/2302/001	73801.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Antires® 20 mg Tabletten	DE/H/2301/001	73800.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bilaxten 20 mg Schmelztabletten	DE/H/2300/004	7000688.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bilaxten 10 mg Schmelztabletten	DE/H/2300/002	96125.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE

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
Antires 20 mg Schmelztabletten	DE/H/2301/004	7000689.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Antires 2,5 mg/ml Lösung zum Einnehmen	DE/H/2301/003	96128.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bilaxten 6 mg/ml Augentropfen, Lösung	DE/H/2300/005	7003340.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Antires 10 mg Schmelztabletten	DE/H/2301/002	96127.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Antires 6 mg/ml Augentropfen, Lösung	DE/H/2301/005	7003341.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bitosen 6 mg/ml Augentropfen, Lösung	DE/H/2302/005	7003342.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bilaxten® 20 mg Tabletten	DE/H/2300/001	73799.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bilaxten 2,5 mg/ml Lösung zum Einnehmen	DE/H/2300/003	96126.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bitosen 20 mg Schmelztabletten	DE/H/2302/004	7000690.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bitosen 2,5 mg/ml Lösung zum Einnehmen	DE/H/2302/003	96130.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Bitosen 10 mg Schmelztabletten	DE/H/2302/002	96129.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Revitelle, smeltetabletter	DE/H/2300/002	56807	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK
Revitelle, tabletter	DE/H/2300/001	44819	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK

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
Revitelle, oral opløsning	DE/H/2300/003	56808	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK
Opexa, 20 mg suus dispergeeruvad tabletid	DE/H/2300/004	1104423	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Opexa, 10 mg suus dispergeeruvad tabletid	DE/H/2300/002	951517	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Opexa 6 mg/ml silmatilgad, lahus	DE/H/2300/005	1070922	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Opexa, 20 mg tabletid	DE/H/2300/001	715910	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Opexa, 2,5 mg/ml suukaudne lahus	DE/H/2300/003	951617	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Bilaxten 2,5 mg/ml solución oral	DE/H/2301/003	82582	FAES FARMA, S.A.	ES
Ibis 20 mg comprimidos bucodispersables	DE/H/2300/004	88.728	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Bilaxten 20 mg comprimidos	DE/H/2301/001	73.027	FAES FARMA, S.A.	ES
Ibis 10 mg comprimidos bucodispersables	DE/H/2300/002	82.661	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Ibis 6 mg/ml colirio en solución.	DE/H/2300/005	88.177	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Bilaxten 20 mg comprimidos bucodispersables	DE/H/2301/004	88727	FAES FARMA, S.A.	ES
Bilaxten 6 mg/ml colirio en solución.	DE/H/2301/005	88089	FAES FARMA, S.A.	ES

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
Ibis 20 mg comprimidos	DE/H/2300/001	73.029	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Ibis 2,5 mg/ml solución oral	DE/H/2300/003	82.660	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Bilaxten 10 mg comprimidos bucodispersables	DE/H/2301/002	82581	FAES FARMA, S.A.	ES
Revitelle 20 mg tabletit, suussa hajoava	DE/H/2300/004	38628	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Revitelle 20 mg munsönderfallande tabletter	DE/H/2300/004	38628	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Revitelle 10 mg suussa hajoavat tabletit	DE/H/2300/002	33694	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Revitelle 10 mg munsönderfallande tabletter	DE/H/2300/002	33694	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Revitelle 20 mg tabletter	DE/H/2300/001	27335	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Revitelle 20 mg tabletit	DE/H/2300/001	27335	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Revitelle 2,5 mg/ml oraaliliuos	DE/H/2300/003	33695	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Revitelle 2,5 mg/ml oral lösning	DE/H/2300/003	33695	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
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

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
INORIAL 20 mg, comprimé	DE/H/2301/001	34009 578 992 0 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 20 mg, comprimé	DE/H/2301/001	34009 578 991 4 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 20 mg, comprimé	DE/H/2301/001	34009 499 140 1 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé orodispersible	DE/H/2300/004	34009 302 692 7 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé orodispersible	DE/H/2300/004	34009 302 692 8 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé orodispersible	DE/H/2300/004	DE/H/2300/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé orodispersible	DE/H/2300/004	DE/H/2300/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé orodispersible	DE/H/2300/004	DE/H/2300/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 10 mg, comprimé orodispersible	DE/H/2300/002	34009 301 404 4 4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 10 mg, comprimé orodispersible	DE/H/2300/002	34009 301 404 6 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 10 mg, comprimé orodispersible	DE/H/2300/002	34009 301 404 5 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 10 mg, comprimé orodispersible	DE/H/2300/002	34009 301 404 7 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 20 mg, comprimé orodispersible	DE/H/2301/004	34009 302 692 5 1	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
INORIAL 20 mg, comprimé orodispersible	DE/H/2301/004	34009 302 692 6 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 20 mg, comprimé orodispersible	DE/H/2301/004	DE/H/2301/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 20 mg, comprimé orodispersible	DE/H/2301/004	DE/H/2301/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 20 mg, comprimé orodispersible	DE/H/2301/004	DE/H/2301/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 2,5 mg/ml, solution buvable	DE/H/2301/003	34009 301 416 2 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 6 mg/mL collyre en solution	DE/H/2300/005	34009 302 572 5 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 10 mg, comprimé orodispersible	DE/H/2301/002	34009 301 415 6 4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 10 mg, comprimé orodispersible	DE/H/2301/002	34009 301 415 7 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 10 mg, comprimé orodispersible	DE/H/2301/002	34009 301 415 9 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 10 mg, comprimé orodispersible	DE/H/2301/002	34009 301 415 8 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
INORIAL 6 mg/mL collyre en solution	DE/H/2301/005	34009 302 572 6 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA20 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

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
BILASKA 20 mg, comprimé	DE/H/2300/001	34009 499 135 8 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé	DE/H/2300/001	34009 499 137 0 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 20 mg, comprimé	DE/H/2300/001	34009 578 988 3 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILASKA 2,5 mg/ml, solution buvable	DE/H/2300/003	34009 301 033 4 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
BILARGEN 20 mg δισκία	DE/H/2301/001	103763	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Bilaz 20 mg δισκία διασπειρόμενα στο στόμα	DE/H/2300/004	51125/30-05-2023	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Bilaz 10 mg δισκία διασπειρόμενα στο στόμα	DE/H/2300/002	92197	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Bilargen 20 mg δισκία διασπειρόμενα στο στόμα	DE/H/2301/004	39911/08-05-2023	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Bilargen 2,5 mg/ml πόσιμο διάλυμα	DE/H/2301/003	92196	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Bilaz 6 mg/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/2300/005	13148/10-02-2023	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Bilargen 10 mg δισκία διασπειρόμενα στο στόμα	DE/H/2301/002	92195	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Bilargen 6 mg/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/2301/005	13149/10-02-2023	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Bilaz 20 mg δισκία	DE/H/2300/001	44881	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR

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
Bilaz 2,5 mg/ml πόσιμο διάλυμα	DE/H/2300/003	92198	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Nixar 20 mg raspadljive tablete za usta	DE/H/2300/004	HR-H-599781528-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 20 mg raspadljive tablete za usta	DE/H/2300/004	HR-H-599781528-02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 20 mg raspadljive tablete za usta	DE/H/2300/004	HR-H-599781528-03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 20 mg raspadljive tablete za usta	DE/H/2300/004	HR-H-599781528-04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 20 mg raspadljive tablete za usta	DE/H/2300/004	HR-H-599781528-05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 20 mg tablete	not available	HR-H-535007756-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 20 mg tablete	not available	HR-H-535007756-02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 10 mg raspadljive tablete za usta	not available	HR-H-039242232-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 6 mg/ml kapi za oko, otopina	DE/H/2300/005	HR-H-264633267-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Nixar 2,5 mg/ml oralna otopina	not available	HR-H-467123118-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Lendin NEO 20 mg szájban diszpergálódó tabletta	DE/H/2300/004	OGYI-T-21640/10	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin NEO 20 mg szájban diszpergálódó tabletta	DE/H/2300/004	OGYI-T-21640/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU

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 NEO 20 mg szájban diszpergálódó tabletta	DE/H/2300/004	OGYI-T-21640/12	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin NEO 20 mg szájban diszpergálódó tabletta	DE/H/2300/004	OGYI-T-21640/13	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin NEO 20 mg szájban diszpergálódó tabletta	DE/H/2300/004	OGYI-T-21640/14	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 10 mg szájban diszpergálódó tabletta	DE/H/2300/002	OGYI-T-21640/04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 10 mg szájban diszpergálódó tabletta	DE/H/2300/002	OGYI-T-21640/07	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 10 mg szájban diszpergálódó tabletta	DE/H/2300/002	OGYI-T-21640/06	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 10 mg szájban diszpergálódó tabletta	DE/H/2300/002	OGYI-T-21640/05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 6 mg/ml oldatos szemcsepp	DE/H/2300/005	OGYI-T-21640/09	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 20 mg tabletta	DE/H/2300/001	OGYI-T-21640/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 20 mg tabletta	DE/H/2300/001	OGYI-T-21640/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 20 mg tabletta	DE/H/2300/001	OGYI-T-21640/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Lendin 2,5 mg/ml belsőleges oldat	DE/H/2300/003	OGYI-T-21640/08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Drynol 20 mg orodispersible tablets	DE/H/2300/004	PA 865/18/4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE

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
Drynol 10 mg orodispersible tablets	DE/H/2300/002	PA 865/018/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
Drynol 6 mg/mL eye drops, solution	DE/H/2300/005	PA 0865/018/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
Drynol 20 mg tablets	DE/H/2300/001	PA 865/18/1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
Drynol 2.5 mg/ml oral solution	DE/H/2300/003	PA 865/018/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
Bilaxten 10 mg munndreifitafla	DE/H/2300/002	IS/1/17/065/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
Bilaxten 20 mg tafla	DE/H/2300/001	IS/1/10/002/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
Bilaxten 2,5 mg/ml mixtúra, lausn	DE/H/2300/003	IS/1/17/065/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
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
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
ROBILAS 20 mg compresse	DE/H/2301/001	041045055	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
ROBILAS 20 mg compresse	DE/H/2301/001	041045016	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	041045028	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
ROBILAS 20 mg compresse	DE/H/2301/001	041045042	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Bysabel 20 mg compresse orodispersibili	DE/H/2300/004	041044064	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Bysabel 20 mg compresse orodispersibili	DE/H/2300/004	041044076	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Bysabel 20 mg compresse orodispersibili	DE/H/2300/004	041044088	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Bysabel 20 mg compresse orodispersibili	DE/H/2300/004	041044102	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Bysabel 20 mg compresse orodispersibili	DE/H/2300/004	041044090	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 20 mg compresse orodispersibili	DE/H/2301/004	041045117	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 20 mg compresse orodispersibili	DE/H/2301/004	041045129	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 20 mg compresse orodispersibili	DE/H/2301/004	041045131	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 20 mg compresse orodispersibili	DE/H/2301/004	041045143	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
Robilas 20 mg compresse orodispersibili	DE/H/2301/004	041045156	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
ROBILAS 2,5 mg/ml soluzione orale	DE/H/2301/003	041045105	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Bysabel 6 mg/ml collirio, soluzione.	DE/H/2300/005	041044114	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
ROBILAS 10 mg compresse orodispersibili	DE/H/2301/002	041045067	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
ROBILAS 10 mg compresse orodispersibili	DE/H/2301/002	041045093	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
ROBILAS 10 mg compresse orodispersibili	DE/H/2301/002	041045081	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
ROBILAS 10 mg compresse orodispersibili	DE/H/2301/002	041045079	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Robilas 6 mg/ml collirio, soluzione.	DE/H/2301/005	041045168	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 6 mg/ml collirio, soluzione.	DE/H/2302/005	040854162	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
BYSABEL 20 mg compresse	DE/H/2300/001	041044052	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
BYSABEL 20 mg compresse	DE/H/2300/001	041044037	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
BYSABEL 20 mg compresse	DE/H/2300/001	041044025	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
BYSABEL 20 mg compresse	DE/H/2300/001	041044013	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
BYSABEL 20 mg compresse	DE/H/2300/001	041044049	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 20 mg compresse orodispersibili	DE/H/2302/004	040854135	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 20 mg compresse orodispersibili	DE/H/2302/004	040854111	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 20 mg compresse orodispersibili	DE/H/2302/004	040854123	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 20 mg compresse orodispersibili	DE/H/2302/004	040854150	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ayrinal 20 mg compresse orodispersibili	DE/H/2302/004	040854147	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
AYRINAL 2,5 mg/ml soluzione orale	DE/H/2302/003	040854109	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
AYRINAL 10 mg compresse orodispersibili	DE/H/2302/002	040854061	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
AYRINAL 10 mg compresse orodispersibili	DE/H/2302/002	040854097	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
AYRINAL 10 mg compresse orodispersibili	DE/H/2302/002	040854085	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
AYRINAL 10 mg compresse orodispersibili	DE/H/2302/002	040854073	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Opexa 20 mg burnoje disperguojamos tabletės	DE/H/2300/004	LT/1/23/5126/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg burnoje disperguojamos tabletės	DE/H/2300/004	LT/1/23/5126/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

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
Opexa 20 mg burnoje disperguojamos tabletės	DE/H/2300/004	LT/1/23/5126/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg burnoje disperguojamos tabletės	DE/H/2300/004	LT/1/23/5126/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg burnoje disperguojamos tabletės	DE/H/2300/004	LT/1/23/5126/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 10 mg burnoje disperguojamos tabletės	DE/H/2300/002	LT/1/10/2241/006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 10 mg burnoje disperguojamos tabletės	DE/H/2300/002	LT/1/10/2241/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 10 mg burnoje disperguojamos tabletės	DE/H/2300/002	LT/1/10/2241/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 10 mg burnoje disperguojamos tabletės	DE/H/2300/002	LT/1/10/2241/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 6 mg/ml akių lašai (tirpalas)	DE/H/2300/005	LT/1/22/5016/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletės	DE/H/2300/001	LT/1/10/2241/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletės	DE/H/2300/001	LT/1/10/2241/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletės	DE/H/2300/001	LT/1/10/2241/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletės	DE/H/2300/001	LT/1/10/2241/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Opexa 20 mg tabletės	DE/H/2300/001	LT/1/10/2241/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

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
Opexa 2,5 mg/ml geriamasis tirpalas	DE/H/2300/003	LT/1/10/2241/010	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Bellozal 20 mg comprimés orodispersibles	DE/H/2300/004	2023100224	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Bellozal 10 mg comprimés orodispersibles	DE/H/2300/002	2018010003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Bellozal 6 mg/ml collyre en solution	DE/H/2300/005	2023020069	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Bellozal 20 mg comprimés	DE/H/2300/001	2011011460	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Bellozal 2,5 mg/ml solution buvable	DE/H/2300/003	2018010004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Opexa 20 mg mutē disperģējamās tabletes	DE/H/2300/004	23-0042	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Opexa 20 mg mutē disperģējamās tabletes	DE/H/2300/004	24-0066	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Opexa 10 mg mutē disperģējamās tabletes	DE/H/2300/002	17-0160	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Opexa 6 mg/ml acu pilieni, šķīdums	DE/H/2300/005	22-0145	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Opexa 20 mg tabletes	DE/H/2300/001	10-0602	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Opexa 20 mg tabletes	DE/H/2300/001	21-0176	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Opexa 20 mg tabletes	DE/H/2300/001	10-0602	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV

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
Opexa 20 mg tabletes	DE/H/2300/001	10-0602	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Opexa 20 mg tabletes	DE/H/2300/001	10-0602	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Opexa 2,5 mg/ml šķīdums iekšķīgai lietošanai	DE/H/2300/003	17-0161	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Gosall 20 mg orodispersible tablets	DE/H/2300/004	MA204/00504	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Gosall 10 mg orodispersible tablets	DE/H/2300/002	MA204/00502	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Gosall 6 mg/mL eye drops, solution	DE/H/2300/005	MA204/00505	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Gosall 20 mg tablets	DE/H/2300/001	MA204/00506	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Gosall 20 mg tablets	DE/H/2300/001	MA204/00501	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Gosall 2.5 mg/ml oral solution	DE/H/2300/003	MA204/00503	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Zilas 10 mg smeltetabletter	DE/H/2300/002	15-10893	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
Zilas 20 mg tabletter	DE/H/2300/001	09-6621	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
Zilas 2,5 mg/ml mikstur, oppløsning	DE/H/2300/003	15-10897	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
Clatra Allergy, 20 mg, tabletki	DE/H/2301/001	17821	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL

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
Clatra, 20 mg, tabletki ulegające rozpadowi w jamie ustnej	DE/H/2300/004	27998	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Clatra, 10 mg, tabletki ulegające rozpadowi w jamie ustnej	DE/H/2300/002	24195	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Bilaxten, 2,5 mg/ml, roztwór doustny	DE/H/2301/003	24211	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Clatra, 6 mg/mL, krople do oczu, roztwór	DE/H/2300/005	27528	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Bilaxten, 10 mg, tabletki ulegające rozpadowi w jamie ustnej	DE/H/2301/002	24210	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Bilaxten, 6 mg/mL, krople do oczu, roztwór	DE/H/2301/005	27897	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Clatra, 20 mg, tabletki	DE/H/2300/001	17820	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Clatra, 2,5 mg/ml, roztwór doustny	DE/H/2300/003	24196	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Bilaxten 2,5 mg/ml solução oral	DE/H/2301/003	5720271	FAES FARMA PORTUGAL, S.A.	PT
Lergonix 20 mg comprimido orodispersível	DE/H/2300/004	DE/H/2300/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 20 mg comprimido orodispersível	DE/H/2300/004	5856414	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 20 mg comprimido orodispersível	DE/H/2300/004	DE/H/2300/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 20 mg comprimido orodispersível	DE/H/2300/004	5856463	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 comprimido orodispersível	DE/H/2300/004	DE/H/2300/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341508	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341516	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341524	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341532	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 20 mg comprimidos	DE/H/2301/001	5341474	FAES FARMA PORTUGAL, S.A.	PT
Lergonix 10 mg comprimidos orodispersíveis	DE/H/2300/002	DE/H/2300/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 10 mg comprimidos orodispersíveis	DE/H/2300/002	5721162	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 10 mg comprimidos orodispersíveis	DE/H/2300/002	5721170	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 10 mg comprimidos orodispersíveis	DE/H/2300/002	5721154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 6 mg/ml colírio, solução	DE/H/2300/005	5843750	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Bilaxten 20 mg comprimido orodispersível	DE/H/2301/004	5856547	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 20 mg comprimido orodispersível	DE/H/2301/004	5856554	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 20 mg comprimido orodispersível	DE/H/2301/004	5856562	FAES FARMA PORTUGAL, 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
Bilaxten 20 mg comprimido orodispersível	DE/H/2301/004	5856570	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 20 mg comprimido orodispersível	DE/H/2301/004	5856604	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 6 mg/ml colírio, solução	DE/H/2301/005	5843834	FAES FARMA PORTUGAL, S.A.	PT
Lergonix 20 mg comprimidos	DE/H/2300/001	5346747	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
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
Lergonix 20 mg comprimidos	DE/H/2300/001	5346770	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 20 mg comprimidos	DE/H/2300/001	5346739	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 2,5 mg/ml solução oral	DE/H/2300/003	5721204	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lergonix 2,5 mg/ml solução oral	DE/H/2300/003	5760673	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Bilaxten 10 mg comprimidos orodispersíveis	DE/H/2301/002	5720313	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 10 mg comprimidos orodispersíveis	DE/H/2301/002	5720305	FAES FARMA PORTUGAL, S.A.	PT
Bilaxten 10 mg comprimidos orodispersíveis	DE/H/2301/002	5720321	FAES FARMA PORTUGAL, 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
Borenar 20 mg comprimate orodispersabile	DE/H/2300/004	14958/2023/04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 20 mg comprimate orodispersabile	DE/H/2300/004	14958/2023/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 20 mg comprimate orodispersabile	DE/H/2300/004	14958/2023/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 20 mg comprimate orodispersabile	DE/H/2300/004	14958/2023/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 20 mg comprimate orodispersabile	DE/H/2300/004	14958/2023/05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 10 mg comprimate orodispersabile	DE/H/2300/002	14744/2022/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 10 mg comprimate orodispersabile	DE/H/2300/002	14744/2022/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 10 mg comprimate orodispersabile	DE/H/2300/002	14744/2022/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 10 mg comprimate orodispersabile	DE/H/2300/002	14744/2022/04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 6 mg/ml picături oftalmice, soluție	DE/H/2300/005	14661/2022/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
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 comprimate	DE/H/2300/001	8562/2016/05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 20 mg comprimate	DE/H/2300/001	8562/2016/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 2,5 mg/ml soluție orală	DE/H/2300/003	14745/2022/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Borenar 2,5 mg/ml soluție orală	DE/H/2300/003	14745/2022/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Bilaxten 10 mg munsönderfallande tablett	DE/H/2300/002	53501	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
Bilaxten 20 mg tabletter	DE/H/2300/001	42287	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
Bilaxten, 2,5 mg/ml oral lösning	DE/H/2300/003	53509	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
Bilador 20 mg orodispersibilne tablete	DE/H/2300/004	H/11/00281/014	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg orodispersibilne tablete	DE/H/2300/004	H/11/00281/016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg orodispersibilne tablete	DE/H/2300/004	H/11/00281/013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg orodispersibilne tablete	DE/H/2300/004	H/11/00281/015	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg orodispersibilne tablete	DE/H/2300/004	H/11/00281/017	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 10 mg orodispersibilne tablete	DE/H/2300/002	H/11/00281/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

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
Bilador 10 mg orodisperzibilne tablete	DE/H/2300/002	H/11/00281/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 10 mg orodisperzibilne tablete	DE/H/2300/002	H/11/00281/006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 10 mg orodisperzibilne tablete	DE/H/2300/002	H/11/00281/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 6 mg/ml kapljice za oko, raztopina	DE/H/2300/005	H/11/00281/012	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg tablete	DE/H/2300/001	H/11/00281/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg tablete	DE/H/2300/001	H/11/00281/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg tablete	DE/H/2300/001	H/11/00281/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg tablete	DE/H/2300/001	H/11/00281/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 20 mg tablete	DE/H/2300/001	H/11/00281/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 2,5 mg/ml peroralna raztopina	DE/H/2300/003	H/11/00281/010	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Bilador 2,5 mg/ml peroralna raztopina	DE/H/2300/003	H/11/00281/011	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Omarit 20 mg orodispergovatelne tablety	DE/H/2300/004	24/0144/23-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
Omarit 10 mg orodispergovatelne tablety	DE/H/2300/002	24/0196/17-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK

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 6 mg/ml očné roztokové kvapky	DE/H/2300/005	64/0221/22-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
Omarit 20 mg, tablety	DE/H/2300/001	24/0912/10-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
Omarit 2,5 mg/ml perorálny roztok	DE/H/2300/003	24/0197/17-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
Ilaxten 10 mg orodispersible tablets	DE/H/2300/002	PL 16239/0044	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	XI
Ilaxten 20 mg tablets	DE/H/2300/001	PL 16239/0034	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	XI
Ilaxten 2.5 mg/ml oral solution	DE/H/2300/003	PL 16239/0045	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	XI