



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 November 2018
EMA/844888/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: nebivolol

Procedure no.: PSUSA/00002129/201803



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
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
Nebivolol 10 mg Tablets	UK/H/5305/001	PL 25258/0126	GLENMARK PHARMACEUTICALS EUROPE LIMITED	UK
Nebivolol 10 mg Tablets	UK/H/5305/001	PA 1462/011/001	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IE
Небилет 5 mg таблетки	not available	9900162	BERLIN-CHEMIE AG	BG
NEBILET, 5 mg tabletid	not available	258699	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Nebilet 5 mg tablety	not available	77/380/99-C	BERLIN-CHEMIE AG	CZ
Nebilet 5 mg tabletta	not available	OGYI-T-6982/03	BERLIN-CHEMIE AG	HU
Nebilet 5 mg tabletta	not available	OGYI-T-6982/02	BERLIN-CHEMIE AG	HU
Nebilet 5 mg tabletta	not available	OGYI-T-6982/01	BERLIN-CHEMIE AG	HU
Nebilet 5 mg tabletes	not available	98-0344	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
Nebilet 5 mg tabletès	not available	LT/1/97/2660/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Nebilet 5 mg tabletès	not available	LT/1/97/2660/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Nebilet 5 mg tabletès	not available	LT/1/97/2660/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Nebilet 5 mg tabletès	not available	LT/1/97/2660/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Nebilet 5 mg tabletès	not available	LT/1/97/2660/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
NEBILET 5 mg tablets	not available	MA204/00201	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Nebilet 5 mg tabletès	not available	LT/1/97/2660/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Nebilet 5 mg tabletès	not available	LT/1/97/2660/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Hypoloc 1,25 mg tabletten	not available	RVG 33453	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL

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
Nebiloc 1,25 mg tabletten	not available	RVG 33454	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Nebilet 5 mg tabletès	not available	LT/1/97/2660/006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Hypoloc 10 mg tabletten	not available	RVG 34392	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Nebilet 10 mg tabletten	not available	RVG 34388	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Nebilet, 5 mg, tabletki	not available	4040	BERLIN-CHEMIE AG	PL
Nebiloc 10 mg tabletten	not available	RVG 34390	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Nebilet 1,25 mg tabletten	not available	RVG 33452	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Lobivon 10 mg tabletten	not available	RVG 34393	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Lobivon 1,25 mg tabletten	not available	RVG 33455	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL

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
Nebilet 5 mg tablety	not available	58/0038/99-S	BERLIN-CHEMIE AG	SK
Nebilet 5 mg tablete	not available	HR-H-645496675-01	BERLIN-CHEMIE MENARINI HRVATSKA D.O.O.	HR
Nebilet 5 mg tablete	not available	HR-H-645496675-02	BERLIN-CHEMIE MENARINI HRVATSKA D.O.O.	HR
Nebilet 5 mg comprimate	not available	10707/2018/01	BERLIN-CHEMIE AG	RO
Nebilet 5 mg comprimate	not available	10707/2018/05	BERLIN-CHEMIE AG	RO
Nebilet 5 mg comprimate	not available	10707/2018/04	BERLIN-CHEMIE AG	RO
Nebilet 5 mg comprimate	not available	10707/2018/03	BERLIN-CHEMIE AG	RO
Nebilet 5 mg comprimate	not available	10707/2018/02	BERLIN-CHEMIE AG	RO
Nebilet 5 mg comprimate	not available	10707/2018/06	BERLIN-CHEMIE AG	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
Nebivolol 2.5 mg tablets	DE/H/3840/001	PL 12762/0498	MERCURY PHARMACEUTICALS LTD.	UK
Nebivolol Mercury 2,5 mg Tablelten	DE/H/3840/001	89753.00.00	MERCURY PHARMACEUTICALS LTD.	DE
Nobistar 5 mg compresse	NL/H/0349/001	035780030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Nobistar 5 mg compresse	NL/H/0349/001	035780093	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Nobistar 5 mg compresse	NL/H/0349/001	035780079	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Nobistar 5 mg compresse	NL/H/0349/001	035780067	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Nobistar 5 mg compresse	NL/H/0349/001	035780016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Nobistar 5 mg compresse	NL/H/0349/001	035780042	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Nobistar 5 mg compresse	NL/H/0349/001	035780081	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
Nobistar 5 mg compresse	NL/H/0349/001	035780055	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Nobistar 5 mg compresse	NL/H/0349/001	035780028	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lobivon 5 mg tabletten	NL/H/0349/001	RVG 27818	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
NEBILET 5 mg comprimidos	NL/H/0349/001	65.101	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
NEBILOX 5 mg, comprimé quadrisécable	NL/H/0350/001	34009 361 874 6 7	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
NEBILOX 5 mg, comprimé quadrisécable	NL/H/0350/001	34009 361 875 2 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
NEBILOX 5 mg, comprimé quadrisécable	NL/H/0350/001	34009 374 209 6 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
NEBILOX 5 mg, comprimé quadrisécable	NL/H/0350/001	34009 374 207 3 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Nebiloc 5 mg tabletten	NL/H/0350/001	RVG 27817	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL

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
Nebivolol 2.5 mg Tablets	UK/H/6133/001	PL 00289/2018	TEVA UK LIMITED	UK
Nebivolol 1.25mg Tablets	UK/H/6461/001	PL 0142/0860	ACTAVIS UK LTD.	UK
Nebivolol 2.5mg Tablets	UK/H/6461/002	PL 0142/0861	ACTAVIS UK LTD.	UK
Nebivolol 10mg Tablets	UK/H/6461/003	PL 0142/0862	ACTAVIS UK LTD.	UK
NEBILOX 5 mg compresse	NL/H/0102/001	032209013	GLAXOSMITHKLINE S.P.A.	IT
INSUCOR® 2,5 mg comprimidos	UK/H/1548/001	71283	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ES
Nebivolol 2.5 mg Tablets	UK/H/1548/001	PL-25258-0002	GLENMARK PHARMACEUTICALS EUROPE LIMITED	UK
Nebivolol Glenmark 2,5 mg, tabletten	UK/H/1548/001	RVG 101610	GLENMARK PHARMACEUTICALS EUROPE LIMITED	NL
Nebivolol 1.25mg Tablets	UK/H/6461/001	PL 0142/0860	ACTAVIS UK LTD.	UK

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
Nebivolol 2.5mg Tablets	UK/H/6461/002	PL 0142/0861	ACTAVIS UK LTD.	UK
Nebivolol 10mg Tablets	UK/H/6461/003	PL 0142/0862	ACTAVIS UK LTD.	UK
NEBILOX 5 mg compresse	NL/H/0102/001	032209013	GLAXOSMITHKLINE S.P.A.	IT
Hypoloc 5 mg tablett	NL/H/0102/001	17443	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
NOBITEN 5 mg comprimés	NL/H/0102/001	BE177703	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
NOBITEN 5 mg Tabletten	NL/H/0102/001	BE177703	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
NEBILET 5 mg, comprimidos	NL/H/0102/001	3458981	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
NEBILET 5 mg, comprimidos	NL/H/0102/001	3459187	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
NEBILET 5 mg, comprimidos	NL/H/0102/001	3459484	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
NEBILET 5 mg, comprimidos	NL/H/0102/001	3459385	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
NEBILET 5 mg, comprimidos	NL/H/0102/001	3459286	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
NEBILET 5 mg, comprimidos	NL/H/0102/001	3459088	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
LOBIVON® 5mg δισκία	NL/H/0102/001	022269	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
LOBIVON® 5mg δισκία	NL/H/0102/001	23462	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Nobiten 5 mg tabletten	NL/H/0102/001	BE177703	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Hypoloc® 5 mg - Tabletten	NL/H/0102/001	1-25075	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Hypoloc, tabletter	NL/H/0102/001	33908	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK
Hypoloc 5 mg tabletti	NL/H/0102/001	17443	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
TEMERIT 5 mg, comprimé quadrisécable	NL/H/0102/001	34009 341 698 8 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
TEMERIT 5 mg, comprimé quadrisécable	NL/H/0102/001	34009 341 697 1 7	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
TEMERIT 5 mg, comprimé quadrisécable	NL/H/0102/001	34009 374 204 4 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
TEMERIT 5 mg, comprimé quadrisécable	NL/H/0102/001	34009 374 203 8 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Nebilet® 5 mg Tabletten	NL/H/0102/001	36893.00.00	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DE
Hypoloc 5 mg töflur	NL/H/0102/001	IS/1/04/018/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
HYPOLOC 5 mg tablets	NL/H/0102/001	PA/865/10/1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
NOBITEN 5 mg comprimés	NL/H/0102/001	0951/11041087	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Nebilet 5 mg tabletten	NL/H/0102/001	RVG 18849	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL

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
Hypoloc 5 mg tabletter	NL/H/0102/001	04-2497	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
NEBILET 5 mg, comprimidos	NL/H/0102/001	2401081	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
NEBILET 5 mg, comprimidos	NL/H/0102/001	2401180	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
HYPOLOC 5 mg tablets	NL/H/0102/001	PL 16239/0019	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
LOBIVON 5 mg comprimidos	NL/H/0102/001	61.428	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Hypoloc 5 mg tabletter	NL/H/0102/001	18598	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
HYPOLOC 5 mg comprimés	NL/H/0103/001	BE177073	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
HYPOLOC 5 mg Tabletten	NL/H/0103/001	BE177073	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
HYPOLOC 5 mg, comprimidos	NL/H/0103/001	3458486	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
HYPOLOC 5 mg, comprimidos	NL/H/0103/001	3458783	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
HYPOLOC 5 mg, comprimidos	NL/H/0103/001	3458882	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
HYPOLOC 5 mg, comprimidos	NL/H/0103/001	3458585	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
HYPOLOC 5 mg, comprimidos	NL/H/0103/001	3458387	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
HYPOLOC 5 mg, comprimidos	NL/H/0103/001	3458684	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Lobivon 5 mg compresse	NL/H/0103/001	032210015	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
HYPOLOC 5mg δισκία	NL/H/0103/001	24688	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Hypoloc 5 mg tabletten	NL/H/0103/001	BE177073	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Nomexor® 5 mg - Tabletten	NL/H/0103/001	1-21520	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT

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
Nebilet 5 mg töflur	NL/H/0103/001	IS/1/04/017/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
NEBILET 5 mg tablets	NL/H/0103/001	PA/865/5/1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
HYPOLOC 5 mg comprimés	NL/H/0103/001	0951/11041088	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Hypoloc 5 mg tabletten	NL/H/0103/001	RVG 19317	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
HYPOLOC 5 mg, comprimidos	NL/H/0103/001	2401289	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
HYPOLOC 5 mg, comprimidos	NL/H/0103/001	2401388	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
SILOSTAR 5 mg comprimidos	NL/H/0103/001	61.427	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
NEBILET 5 mg tablets	NL/H/0103/001	PL 16239/0013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
Nebivolol Aurobindo 2,5 mg, tabletten	PT/H/1743/002	RVG 119975	AUROBINDO PHARMA B.V.	NL

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
Nebivolol 2.5 mg tablets	PT/H/1743/001	PL 16363/0519	MILPHARM LIMITED	UK
Nebivolol Aurobindo, 2.5 mg, Comprimido	PT/H/1743/001	PT/H/1743/001	GENERIS FARMACÊUTICA, S.A.	PT
Nebivolol Aurobindo, 2.5 mg, Comprimido	PT/H/1743/001	PT/H/1743/001	GENERIS FARMACÊUTICA, S.A.	PT
Nebivolol Aurobindo, 2.5 mg, Comprimido	PT/H/1743/001	PT/H/1743/001	GENERIS FARMACÊUTICA, S.A.	PT
Nebivolol Aurobindo, 2.5 mg, Comprimido	PT/H/1743/001	PT/H/1743/001	GENERIS FARMACÊUTICA, S.A.	PT
Nebivolol Aurobindo, 2.5 mg, Comprimido	PT/H/1743/001	PT/H/1743/001	GENERIS FARMACÊUTICA, S.A.	PT
Nebivolol Aurobindo, 2.5 mg, Comprimido	PT/H/1743/001	PT/H/1743/001	GENERIS FARMACÊUTICA, S.A.	PT
Nebivolol Aurobindo, 2.5 mg, Comprimido	PT/H/1743/001	PT/H/1743/001	GENERIS FARMACÊUTICA, S.A.	PT