



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 June 2022
EMA/PRAC/586245/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: acetylsalicylic acid / bisoprolol

Procedure no.: PSUSA/00010287/202111



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 full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Assbiclair 10 mg/100 mg Hartkapseln	MT/H/0365/004	2204939.00.00	HENNIG ARZNEIMITTEL GMBH & CO. KG	DE
Assbiclair 5 mg/100 mg Hartkapseln	MT/H/0365/003	2204938.00.00	HENNIG ARZNEIMITTEL GMBH & CO. KG	DE
Bisoblock Plus 5 mg/100 mg kemény kapszula	MT/H/0365/003	OGYI-T-22095/03	ACTAVIS GROUP PTC EHF.	HU
Bisolaz 10 mg + 100 mg cápsulas	MT/H/0365/004	5438056	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bisolaz 10 mg + 100 mg cápsulas	MT/H/0365/004	5438064	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bisolaz 10 mg + 100 mg cápsulas	MT/H/0365/004	5438072	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bisolaz 5 mg + 100 mg cápsulas	MT/H/0365/003	5438023	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bisolaz 5 mg + 100 mg cápsulas	MT/H/0365/003	5438031	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT

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Bisolaz 5 mg + 100 mg cápsulas	MT/H/0365/003	5438049	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bisoprolol and Aspirin 10mg /100mg capsules, hard	MT/H/0365/004	1258/00204	ASA PHARMA PLC	MT
Bisoprolol and Aspirin 10mg /100mg capsules, hard	MT/H/0366/004	1258/00104	ASA PHARMA PLC	MT
Bisoprolol and Aspirin 10mg /75mg capsules, hard	MT/H/0365/003	1258/00202	ASA PHARMA PLC	MT
Bisoprolol and Aspirin 10mg /75mg capsules, hard	MT/H/0366/003	1258/00102	ASA PHARMA PLC	MT
Bisoprolol and Aspirin 5mg /100mg capsules, hard	MT/H/0365/003	1258/00203	ASA PHARMA PLC	MT
Bisoprolol and Aspirin 5mg /100mg capsules, hard	MT/H/0366/003	1258/00103	ASA PHARMA PLC	MT
Bisoprolol and Aspirin 5mg /75mg capsules, hard	MT/H/0365/001	1258/00201	ASA PHARMA PLC	MT
Bisoprolol and Aspirin 5mg /75mg capsules, hard	MT/H/0366/001	1258/00101	ASA PHARMA PLC	MT

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
Bisoratio ASA, 10 mg + 75 mg, kapsulki, twarde	MT/H/0365/002	19913	ACTAVIS GROUP PTC EHF.	PL
Bisoratio ASA, 5 mg + 75 mg, kapsulki, twarde	MT/H/0365/001	19912	ACTAVIS GROUP PTC EHF.	PL
Concorasa 10 mg /100 mg kapsule, tvrde	not available	HR-H-882606137	SWIXX BIOPHARMA KFT.	HR
Concorasa 5 mg /100 mg kapsule, tvrde	not available	HR-H-627251694	SWIXX BIOPHARMA KFT.	HR
CURILEN® 10 mg/100 mg καψάκιο, σκληρό	UK/H/1495/004	61681/05-07-2021	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
CURILEN® 10 mg/75 mg Καψάκιο, σκληρό	UK/H/1495/002	61680/05-07-2021	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
CURILEN® 5 mg/100 mg καψάκιο, σκληρό	UK/H/1495/003	61681/05-07-2021	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
CURILEN® 5 mg/75 mg Καψάκιο, σκληρό	UK/H/1495/001	61680/05-07-2021	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
CURILEN® Καψάκιο, σκληρό 10 mg/100 mg	MT/H/0365/004	022991	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 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
CURILEN® Καψάκιο, σκληρό 10 mg/75 mg	MT/H/0365/002	022989	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	CY
CURILEN® Καψάκιο, σκληρό 5 mg/100 mg	MT/H/0365/003	022990	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	CY
CURILEN® Καψάκιο, σκληρό 5 mg/75 mg	MT/H/0365/001	022988	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	CY
Бетапрес 5 mg/75 mg капсули, твърди	MT/H/0366/01	20100842	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	BG