



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2019
EMA/400260/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: acetylsalicylic acid / bisoprolol

Procedure no.: PSUSA/00010287/201811

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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
Concorasa 5 mg /100 mg kapsule, tvrde	not available	HR-H-627251694	MARTI FARM D.O.O.	HR
Concorasa 10 mg / 100 mg kapsule, tvrde	not available	HR-H-882606137	MARTI FARM D.O.O.	HR
Bisoprolol and Aspirin 5mg /100mg Capsules	UK/H/3451/003	32226/0023	ASA PHARMA PLC	UK
Bisoprolol and Aspirin 10mg /100mg Capsules	UK/H/3451/004	PL 32226/0024	ASA PHARMA PLC	UK
Betapres 10 mg/75 mg tvrdé tobolky	UK/H/3451/002	41/985/10-C	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	CZ
Betapres 5 mg/75 mg tvrdé tobolky	UK/H/3451/001	41/984/10-C	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	CZ
Betapres 5 mg / 75 mg tvrdé kapsuly	UK/H/3451/001	58/0830/10-S	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	SK
Betapres 10 mg / 75 mg tvrdé kapsuly	UK/H/3451/002	58/0831/10-S	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	SK
Бетапрес 5 mg/75 mg капсули, твърди	UK/H/3451/001	20100842	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	BG
Бетапрес 10 mg/75 mg капсули, твърди	UK/H/3451/002	20100843	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	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
Bisoprolol and Aspirin 5 mg / 75 mg Capsules	UK/H/3451/001	PL 32226/0009	ASA PHARMA PLC	UK
Bisoprolol and Aspirin 10mg /75mg capsules	UK/H/3451/002	PL 32226/0010	ASA PHARMA PLC	UK
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/01	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/02	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/03	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/04	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/05	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/06	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/07	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	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
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/08	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/09	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/10	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 5 mg/75 mg capsule	UK/H/3451/001	9450/2016/11	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/01	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/02	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/03	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/04	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/05	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	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
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/06	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/07	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/08	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/09	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/10	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Betapres 10 mg/75 mg capsule	UK/H/3451/002	9451/2016/11	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	RO
Bisoprolol/ASA Sandoz 5 mg/100 mg kemény kapszula	UK/H/3451/003	OGYI-T-21712/03	SANDOZ HUNGÁRIA KFT	HU
Bisoprolol/ Acetylsalicylic acid Sandoz 10 mg/100 mg cietās kapsulas	UK/H/3451/004	15-0145	SANDOZ PHARMACEUTICALS D.D.	LV
Bisoprolol/ASA Sandoz 10 mg/100 mg kemény kapszula	UK/H/3451/004	OGYI-T-21712/04	SANDOZ HUNGÁRIA KFT	HU

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Bisoprolol/Acetylsalicylic acid Sandoz 5 mg/75 mg cietās kapsulas	UK/H/3451/001	11-0141	SANDOZ PHARMACEUTICALS D.D.	LV
Bisoprolol/Acetylsalicylic acid Sandoz 10 mg/75 mg cietās kapsulas	UK/H/3451/002	11-0140	SANDOZ PHARMACEUTICALS D.D.	LV
Bisoprolol/Acetylsalicylic acid Sandoz 5 mg/100 mg cietās kapsulas	UK/H/3451/003	15-0144	SANDOZ PHARMACEUTICALS D.D.	LV
Bibloc ASA, 5 mg + 75 mg, kapsuļki, twarde	UK/H/3451/001	18444	SANDOZ GMBH	PL
Bibloc ASA, 10 mg + 75 mg, kapsuļki, twarde	UK/H/3451/002	18445	SANDOZ GMBH	PL
Bibloc ASA, 10 mg + 100 mg, kapsuļki, twarde	UK/H/3451/004	22498	SANDOZ GMBH	PL
Bibloc ASA, 5 mg + 100 mg, kapsuļki, twarde	UK/H/3451/003	22497	SANDOZ GMBH	PL
Bisoblock Plus 10 mg/75 mg kemény kapszula	UK/H/1495/003	OGYI-T-22095/02	ACTAVIS GROUP PTC EHF.	HU
Bisoprolol and Aspirin 5mg/75mg capsules	UK/H/1495/001	PL 32226/0001	ASA PHARMA PLC	UK
Bisoprolol and Aspirin 5mg/100mg capsules	UK/H/1495/003	PL 32226/0003	ASA PHARMA PLC	UK
Bisoprolol and Aspirin 10mg/75mg capsules	UK/H/1495/002	PL 32226/0002	ASA PHARMA PLC	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
Bisoprolol and Aspirin 10mg/100mg capsules	UK/H/1495/004	PL 32226/0004	ASA PHARMA PLC	UK
Concor ASA 10 mg + 100 mg cápsulas	UK/H/1495/004	5438056	FERRER PORTUGAL, S.A.	PT
Concor ASA 10 mg + 100 mg cápsulas	UK/H/1495/004	5438064	FERRER PORTUGAL, S.A.	PT
Concor ASA 10 mg + 100 mg cápsulas	UK/H/1495/004	5438072	FERRER PORTUGAL, S.A.	PT
Concor ASA 5 mg + 100 mg cápsulas	UK/H/1495/003	5438023	FERRER PORTUGAL, S.A.	PT
Concor ASA 5 mg + 100 mg cápsulas	UK/H/1495/003	5438031	FERRER PORTUGAL, S.A.	PT
Concor ASA 5 mg + 100 mg cápsulas	UK/H/1495/003	5438049	FERRER PORTUGAL, S.A.	PT
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/001	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/002	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/003	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/004	SANDOZ PHARMACEUTICALS D.D.	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
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/005	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/006	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/007	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/008	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 5 mg/100 mg trde kapsule	MT/H/0365/003	H/12/00414/009	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/010	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/011	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/012	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/013	SANDOZ PHARMACEUTICALS D.D.	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
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/014	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/015	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/016	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/017	SANDOZ PHARMACEUTICALS D.D.	SI
Bisoprolol/acetilsalicilna kislina Sandoz 10 mg/100 mg trde kapsule	MT/H/0365/004	H/12/00414/018	SANDOZ PHARMACEUTICALS D.D.	SI
CURILEN® Καψάκιο, σκληρό 5 mg/75 mg	UK/H/1495/001	13768/12	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
CURILEN® Καψάκιο, σκληρό 10 mg/75 mg	UK/H/1495/002	1631/13	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
CURILEN® Καψάκιο, σκληρό 5 mg/100 mg	UK/H/1495/003	30100/16	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
CURILEN® Καψάκιο, σκληρό 10 mg/100 mg	UK/H/1495/004	53010/16	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 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
Bilokord ASA, 10 mg + 75 mg, kapsułki, twarde	UK/H/1495/002	19 913	ACTAVIS GROUP PTC EHF.	PL
Bilokord ASA, 5 mg + 75 mg, kapsułki, twarde	UK/H/1495/001	19 912	ACTAVIS GROUP PTC EHF.	PL