



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 April 2025
EMA/134275/2025
Human Medicines Evaluation Division

List of nationally authorised medicinal

Active substance: sotalol

Procedure no.: PSUSA/00002774/202408



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
Дароб 160 mg таблетки	not available	20030335	MYLAN EOOD	BG
Дароб 80 mg таблетки	not available	20030334	MYLAN EOOD	BG
SOTALEX 80 mg compresse	not available	023245020	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Sotacor 80 mg tabletti	not available	10878	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Sotacor 80 mg tablett	not available	10878	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Sotalex Mite 80 mg tabletta	not available	OGYI-T-4183/02	CHEPLAPHARM ARZNEIMITTEL GMBH	HU
Sotalex Mite 80 mg tabletta	not available	OGYI-T-4183/01	CHEPLAPHARM ARZNEIMITTEL GMBH	HU
Sotalol Sandoz 80 mg tabletten	not available	BE278652	SANDOZ N.V.	BE
SOTALEX 160 mg, comprimé sécable	not available	NL11287	CHEPLAPHARM ARZNEIMITTEL GMBH	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
SOTALEX 80 mg, comprimé sécable	not available	VNL10036	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
Sotalex 160 mg comprimés	not available	2005088281	CHEPLAPHARM ARZNEIMITTEL GMBH	LU
Sotalex 160 mg, Tabletten Sotalolhydrochlorid	not available	2005088281	CHEPLAPHARM ARZNEIMITTEL GMBH	LU
Darob 80 mg comprimate	not available	6672/2014/03	VIATRIS HEALTHCARE LIMITED	RO
Darob 80 mg comprimate	not available	6672/2014/02	VIATRIS HEALTHCARE LIMITED	RO
Darob 80 mg comprimate	not available	6672/2014/01	VIATRIS HEALTHCARE LIMITED	RO
Sotalol HCl Aurobindo 40 mg, tabletten	PT/H/1735/001	RVG 119823	AUROBINDO PHARMA B.V.	NL
Sotalol Aurovitas, 40 mg, tabletki	PT/H/1735/001/DC	24445	AUROVITAS PHARMA POLSKA SP. Z O.O	PL
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, 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
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT

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Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Sotalol Aurobindo 40 mg comprimidos	PT/H/1735/001	PT/H/1735/001	GENERIS FARMACÊUTICA, S.A.	PT
Darob 160 mg comprimido	not available	4543385	VIATRIS HEALTHCARE LDA.	PT
Darob 160 mg comprimido	not available	2860385	VIATRIS HEALTHCARE LDA.	PT
Sotacor 80 mg tabletter	not available	11152	CHEPLAPHARM ARZNEIMITTEL GMBH	SE
Sotalex® 160 mg Tabletten	not available	28379.01.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Sotalex® mite 80 mg Tabletten Wirkstoff: Sotalolhydrochlorid	not available	28379.00.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
RYTMOBETA 160 mg compresse	not available	029528039	VIATRIS ITALIA S.R.L.	IT
RYTMOBETA 160 mg compresse	not available	029528041	VIATRIS ITALIA S.R.L.	IT

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RYTMOBETA 80 mg compresse	not available	029528027	VIATRIS ITALIA S.R.L.	IT
RYTMOBETA 80 mg compresse	not available	029528015	VIATRIS ITALIA S.R.L.	IT
Sotapor 80 mg comprimidos.	not available	62.001	CHEPLAPHARM ARZNEIMITTEL GMBH	ES
Sotalol HCl Teva 40 mg, tabletten	not available	RVG 33884	TEVA NEDERLAND B.V.	NL
Sotalex 160 mg tabletten	not available	BE 110783	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Sotalex 160 mg comprimés	not available	BE 110783	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Sotalex 160 mg, Tabletten Sotalolhydrochlorid	not available	BE 110783	CHEPLAPHARM ARZNEIMITTEL GMBH	BE