



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2020
EMA/308920/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: sotalol

Procedure no.: PSUSA/00002774/201908



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
Darob 160 mg comprimido	not available	4543385	BGP PRODUCTS UNIPESSOAL, LDA.	PT
Darob 160 mg comprimido	not available	2860385	BGP PRODUCTS UNIPESSOAL, LDA.	PT
RYTMOBETA 160 mg compresse	not available	029528039	MYLAN ITALIA S.R.L.	IT
RYTMOBETA 160 mg compresse	not available	029528041	MYLAN ITALIA S.R.L.	IT
RYTMOBETA 80 mg compresse	not available	029528027	MYLAN ITALIA S.R.L.	IT
RYTMOBETA 80 mg compresse	not available	029528015	MYLAN ITALIA S.R.L.	IT
Beta-Cardone Tablets 40mg	not available	PL 48465/0008	ARIERA PHARMA LIMITED	UK
Beta-Cardone Tablets 80mg	not available	PL 48465/0009	ARIERA PHARMA LIMITED	UK
Beta-Cardone Tablets 200mg	not available	PL 48465/0010	ARIERA PHARMA LIMITED	UK
Дароб 160 mg таблетки	not available	20030335	MYLAN EOOD	BG
Дароб 80 mg таблетки	not available	20030334	MYLAN EOOD	BG
Sotalol HCl Teva 40 mg, tabletten	not available	RVG 33884	TEVA NEDERLAND B.V.	NL
Sotacor 80 mg Tablets	not available	PL 27041/0009	CHEPLAPHARM ARZNEIMITTEL GMBH	UK
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	24445	AUROVITAS PHARMA POLSKA SP. Z O.O	PL
Sotalol PUREN 40 mg Tabletten	PT/H/1735/001	98462.00.00	PUREN PHARMA GMBH & CO. KG	DE
Sotacor 80 mg tabletter	not available	11152	CHEPLAPHARM ARZNEIMITTEL GMBH	SE
Sotalex 160 mg	not available	2005088281	CHEPLAPHARM	LU

comprimés			ARZNEIMITTEL GMBH	
Sotalex 160 mg, Tabletten Sotalolhydrochlorid	not available	2005088281	CHEPLAPHARM ARZNEIMITTEL GMBH	LU
Sotalex® 160 mg Tabletten Wirkstoff: Sotalolhydrochlorid	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
SOTACOR 160 mg - Tabletten	not available	17.797	BRISTOL-MYERS SQUIBB GESMBH	AT
SOTACOR 80 mg - Tabletten	not available	1-19064	BRISTOL-MYERS SQUIBB GESMBH	AT
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
SOTALEX 160 mg, comprimé sécable	not available	34009 322 256 3 7	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
SOTALEX 80 mg, comprimé sécable	not available	34009 318 158 0 8	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
Darob 80 mg comprimate	not available	6672/2014/05	MYLAN HEALTHCARE GMBH	RO
Darob 80 mg comprimate	not available	6672/2014/06	MYLAN HEALTHCARE GMBH	RO
Darob 80 mg comprimate	not available	6672/2014/03	MYLAN HEALTHCARE GMBH	RO
Darob 80 mg comprimate	not available	6672/2014/04	MYLAN HEALTHCARE GMBH	RO
Darob 80 mg comprimate	not available	6672/2014/02	MYLAN HEALTHCARE GMBH	RO
Darob 80 mg comprimate	not available	6672/2014/01	MYLAN HEALTHCARE GMBH	RO

SOTALEX 80 mg comprese	not available	023245020	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Дароб 160 mg таблетки	not available	20030335	MYLAN EOOD	BG
Дароб 80 mg таблетки	not available	20030334	MYLAN EOOD	BG
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
Sotacor 80 mg tabletti	not available	10878	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Sotacor 80 mg tabletter	not available	10878	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Sotalol Sandoz 80 mg tabletten	not available	BE278652	SANDOZ N.V.	BE
Sotapor 80 mg comprimidos.	not available	62.001	CHEPLAPHARM ARZNEIMITTEL GMBH	ES