



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2024
EMA/428122/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): betahistine

Procedure No. PSUSA/00000389/202312



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
Betahistin Viatris 24 mg - Tabletten	SK/H/0230/001	1-27995	ARCANA ARZNEIMITTEL GMBH	AT
BETASERC 16 mg - Tabletten	not available	1-19125	MYLAN ÖSTERREICH GMBH	AT
BETASERC 24 mg - Tabletten	not available	1-24043	MYLAN ÖSTERREICH GMBH	AT
BETASERC 8 mg - Tabletten	not available	14785	MYLAN ÖSTERREICH GMBH	AT
Betahistine EG 24 mg comprimés	not available	BE440447	EUROGENERICS N.V./S.A.	BE
Betahistine EG 24 mg tabletten	not available	BE440447	EUROGENERICS N.V./S.A.	BE
Betahistine EG 24 mg Tabletten	not available	BE440447	EUROGENERICS N.V./S.A.	BE
Betahistine Viatris 24 mg tabletten	SK/H/0230/001	BE353245	VIATRIS GX	BE
Betaserc 16 mg comprimés	not available	BE150726	VIATRIS HEALTHCARE	BE
Betaserc 16 mg Tabletten	not available	BE150726	VIATRIS HEALTHCARE	BE
Betaserc 16 mg tabletten	not available	BE150726	VIATRIS HEALTHCARE	BE
Betaserc 8 mg comprimés	not available	BE071766	VIATRIS HEALTHCARE	BE
Betaserc 8 mg Tabletten	not available	BE071766	VIATRIS HEALTHCARE	BE
Betaserc 8 mg tabletten	not available	BE071766	VIATRIS HEALTHCARE	BE
Бетасерк 16 mg таблетки	not available	20000360	MYLAN EOOD	BG
Бетасерк 24 mg таблетки	not available	20030511	MYLAN EOOD	BG
Бетасерк 24 mg таблетки, диспергиращи се в устата	FI/H/0827/001	20150037	MYLAN EOOD	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
Betaserc® 16, δισκία 16 mg	not available	18754	VIATRIS HEALTHCARE LTD	CY
Betaserc® 24 mg δισκία διασπειρόμενα στο στόμα	FI/H/0827/001	022394	VIATRIS HEALTHCARE LTD	CY
Betaserc 16 mg tablety	not available	83/309/00-C	VIATRIS HEALTHCARE LTD	CZ
Betaserc 24 mg tablety	not available	83/368/03-C	VIATRIS HEALTHCARE LTD	CZ
Betaserc 8 mg tablety	not available	83/123/89-C	VIATRIS HEALTHCARE LTD	CZ
Vasomotal 24 mg Tabletten	not available	7598.02.00	VIATRIS HEALTHCARE GMBH	DE
Vasomotal® 16 mg Tabletten	not available	7598.01.00	VIATRIS HEALTHCARE GMBH	DE
Vasomotal® Tropfen 8 mg/ml	not available	7598.00.01	VIATRIS HEALTHCARE GMBH	DE
Betahistin "Orifarm Generics", tabletter	DK/H/2171/003	50239	ORIFARM GENERICS A/S	DK
Betaserc, tabletter 16 mg	not available	12603	VIATRIS APS	DK
Betaserc, tabletter 8 mg	not available	06099	VIATRIS APS	DK
Betaserc 16 mg tabletid	not available	118895	VIATRIS SIA	EE
Betaserc 24 mg tabletid	not available	435004	MYLAN HEALTHCARE SIA	EE
Betaserc 8 mg tabletid	not available	118795	VIATRIS SIA	EE
Betaserc, 24 mg suus disperseeruvad tabletid	FI/H/0827/001	862914	VIATRIS HEALTHCARE LTD	EE
Serc 16 mg comprimidos	not available	64130	NEURAXPHARM SPAIN, S.L.U.	ES
Serc 16 mg comprimidos	not available	64130	NEURAXPHARM SPAIN, S.L.U.	ES
Serc 24 mg comprimidos	not available	78.431	NEURAXPHARM SPAIN, S.L.U.	ES
Serc 8 mg comprimidos	not available	55296	NEURAXPHARM SPAIN, S.L.U.	ES
Serc 8 mg comprimidos	not available	55296	NEURAXPHARM SPAIN, S.L.U.	ES
Serc 8 mg/ml solución oral	not available	57257	NEURAXPHARM SPAIN, S.L.U.	ES

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
Serc 8 mg/ml solución oral	not available	57257	NEURAXPHARM SPAIN, S.L.U.	ES
Betaserc 16 mg tablett	not available	10683	VIATRIS OY	FI
Betaserc 16 mg tabletti	not available	10683	VIATRIS OY	FI
Betaserc 24 mg munsönderfallande tabletter	FI/H/0827/001	31663	VIATRIS OY	FI
Betaserc 24 mg suussa hajoavat tabletit	FI/H/0827/001	31663	VIATRIS OY	FI
Betaserc 24 mg tabletter	not available	18447	VIATRIS OY	FI
Betaserc 24 mg tabletti	not available	18447	VIATRIS OY	FI
Betaserc 8 mg tabletter	not available	9987	VIATRIS OY	FI
Betaserc 8 mg tabletti	not available	9987	VIATRIS OY	FI
BETAHISTINE ARROW 16 mg, comprimé sécable	not available	NL45434	ARROW GENERIQUES	FR
BETAHISTINE ARROW 24 mg, comprimé	not available	NL 34370	ARROW GENERIQUES	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 383 389 3 5	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 383 390 1 7	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 383 391 8 5	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 383 392 4 6	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 571 968 7 5	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 571 969 3 6	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 571 970 1 8	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 571 971 8 6	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 571 972 4 7	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 571 973 0 8	SANDOZ	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
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 571 974 7 6	SANDOZ	FR
BETAHISTINE SANDOZ 24 mg, comprimé	not available	34009 571 975 3 7	SANDOZ	FR
BETAHISTINE VIATRIS 24 mg, comprimé	not available	34009 418 985 6 3	VIATRIS SANTE	FR
BETAHISTINE VIATRIS 24 mg, comprimé	not available	34009 563 250 3 0	VIATRIS SANTE	FR
BETAHISTINE VIATRIS 24 mg, comprimé	not available	34009 563 252 6 9	VIATRIS SANTE	FR
BETAHISTINE VIATRIS 24 mg, comprimé	not available	34009 355 648 8 7	VIATRIS SANTE	FR
BETAHISTINE VIATRIS 8 mg, comprimé	not available	34009 355 715 7 1	VIATRIS SANTE	FR
BETAHISTINE VIATRIS 8 mg, comprimé	not available	34009 348 893 0 1	VIATRIS SANTE	FR
BETAHISTINE VIATRIS 8 mg, comprimé	not available	34009 348 894 7 9	VIATRIS SANTE	FR
BETAHISTINE VIATRIS 8 mg, comprimé	not available	34009 348 892 4 0	VIATRIS SANTE	FR
BETASERC 24 mg, comprimé	not available	34009 355 647 1 9	VIATRIS MEDICAL	FR
BETASERC 24 mg, comprimé	not available	34009 563 248 9 7	VIATRIS MEDICAL	FR
BETASERC 24 mg, comprimé	not available	34009 563 249 5 8	VIATRIS MEDICAL	FR
BETASERC 24 mg, comprimé	not available	34009 355 646 5 8	VIATRIS MEDICAL	FR
EXTOVYL, gélule	not available	322 509-9	LABORATOIRES JUVISE PHARMACEUTICALS	FR
EXTOVYL, gélule	not available	322 510-7	LABORATOIRES JUVISE PHARMACEUTICALS	FR
EXTOVYL, gélule	not available	322 508-2	LABORATOIRES JUVISE PHARMACEUTICALS	FR
LECTIL 16 mg, comprimé sécable	not available	34009 351 806 8 1	BOUCHARA RECORDATI	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
LECTIL 16 mg, comprimé sécable	not available	34009 351 807 4 2	BOUCHARA RECORDATI	FR
LECTIL 16 mg, comprimé sécable	not available	34009 351 808 0 3	BOUCHARA RECORDATI	FR
LECTIL 16 mg, comprimé sécable	not available	34009 352 082 3 1	BOUCHARA RECORDATI	FR
LECTIL 16 mg, comprimé sécable	not available	34009 351 809 7 1	BOUCHARA RECORDATI	FR
LECTIL 24 mg, comprimé	not available	34009 361 018 2 1	BOUCHARA RECORDATI	FR
LECTIL 24 mg, comprimé	not available	34009 361 019 9 9	BOUCHARA RECORDATI	FR
LECTIL 24 mg, comprimé	not available	34009 564 679 3 8	BOUCHARA RECORDATI	FR
LECTIL 24 mg, comprimé	not available	34009 564 680 1 0	BOUCHARA RECORDATI	FR
SERC 8 mg, comprimé	not available	34009 355 714 0 3	VIATRIS MEDICAL	FR
SERC 8 mg, comprimé	not available	34009 315 356 6 9	VIATRIS MEDICAL	FR
SERC 8 mg, comprimé	not available	34009 355 397 5 5	VIATRIS MEDICAL	FR
SERC 8 mg, comprimé	not available	34009 315 354 3 0	VIATRIS MEDICAL	FR
SERC 8 mg, comprimé	not available	34009 315 351 4 0	VIATRIS MEDICAL	FR
ANTIVOM 16 mg δισκία	not available	127643/21-12-2021	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
ANTIVOM 24 mg δισκία	not available	127643/21-12-2021	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
ANTIVOM 8 mg δισκία	not available	127643/21-12-2021	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
ANTIVOM 8 mg/ml πόσιμες σταγόνες, διάλυμα	not available	127643/21-12-2021	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
ANTIVOM® 24 mg δισκία διασπειρόμενα στο στόμα	not available	93336/26.07.2019	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
BETASERC 16 mg δισκία	not available	41613/07/06-06-2008	VIATRIS HEALTHCARE LTD	GR
Betaserc 24 mg δισκία διασπειρόμενα στο στόμα	FI/H/0827/001	25113/25-02-2020	VIATRIS HEALTHCARE LTD	GR
BETASERC 8 mg δισκία	not available	41610/07/06-06-2008	VIATRIS HEALTHCARE LTD	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
BETAVERT, disci 24mg	NL/H/1781/001	43445/24-6-2015	FARMASYN S.A.	GR
RIBRAIN ®	not available	42767/07/23-04-2008	GALENICA SA	GR
RIBRAIN ®	not available	74468/14-11-2007	GALENICA SA	GR
Betaserc 16 mg tablete	not available	HR-H-070232989	VIATRIS HRVATSKA D.O.O.	HR
Betaserc 24 mg tablete	not available	HR-H-722180471	VIATRIS HRVATSKA D.O.O.	HR
Betaserc 16 mg tabletta	not available	OGYI-T-10004/05	VIATRIS HEALTHCARE LTD	HU
Betaserc 24 mg tabletta	not available	OGYI-T-10004/01	VIATRIS HEALTHCARE LTD	HU
Betaserc 8 mg tabletta	not available	OGYI-T-10004/04	VIATRIS HEALTHCARE LTD	HU
Serc 16mg Tablets	not available	PA 2010/16/2	VIATRIS HEALTHCARE LTD	IE
Serc 8mg Tablets	not available	PA 2010/16/1	VIATRIS HEALTHCARE LTD	IE
FORTAMID 16 mg compresse	not available	035876010	FARMACEUTICI FORMENTI S.P.A.	IT
FORTAMID 16 mg compresse	not available	035876022	FARMACEUTICI FORMENTI S.P.A.	IT
Microser 12,5 mg/ml gocce orali soluzione	not available	022628046	GRÜNENTHAL ITALIA S.R.L.	IT
Microser 16 mg compresse	not available	022628061	GRÜNENTHAL ITALIA S.R.L.	IT
Microser 16 mg compresse	not available	022628059	GRÜNENTHAL ITALIA S.R.L.	IT
Microser 24 mg compresse	not available	022628097	GRÜNENTHAL ITALIA S.R.L.	IT
Microser 24 mg compresse	not available	022628109	GRÜNENTHAL ITALIA S.R.L.	IT
Microser 8 mg compresse	not available	022628022	GRÜNENTHAL ITALIA S.R.L.	IT
Microser 8 mg compresse	not available	022628034	GRÜNENTHAL ITALIA S.R.L.	IT
Microser 8 mg compresse	not available	022628010	GRÜNENTHAL ITALIA S.R.L.	IT
VERTISERC 16 mg compresse	not available	027232038	VIATRIS ITALIA S.R.L.	IT
VERTISERC 16 mg compresse	not available	027232026	VIATRIS ITALIA S.R.L.	IT
VERTISERC 24 mg compresse	not available	027232040	VIATRIS ITALIA S.R.L.	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
VERTISERC 8 mg compresse	not available	027232014	VIATRIS ITALIA S.R.L.	IT
VERTISERC 8 mg/ml gocce orali, soluzione	not available	027232053	VIATRIS ITALIA S.R.L.	IT
Betaserc 16 mg tabletės	not available	LT/1/95/0848/002	VIATRIS SIA	LT
Betaserc 24 mg burnoje disperguojamos tabletės	FI/H/0827/001	LT/1/95/0848/006	VIATRIS HEALTHCARE LTD	LT
Betaserc 24 mg burnoje disperguojamos tabletės	FI/H/0827/001	LT/1/95/0848/007	VIATRIS HEALTHCARE LTD	LT
Betaserc 24 mg burnoje disperguojamos tabletės	FI/H/0827/001	LT/1/95/0848/008	VIATRIS HEALTHCARE LTD	LT
Betaserc 24 mg burnoje disperguojamos tabletės	FI/H/0827/001	LT/1/95/0848/009	VIATRIS HEALTHCARE LTD	LT
Betaserc 24 mg burnoje disperguojamos tabletės	FI/H/0827/001	LT/1/95/0848/010	VIATRIS HEALTHCARE LTD	LT
Betaserc 24 mg tabletės	not available	LT/1/95/0848/004	VIATRIS SIA	LT
Betaserc 24 mg tabletės	not available	LT/1/95/0848/005	VIATRIS SIA	LT
Betaserc 24 mg tabletės	not available	LT/1/95/0848/003	VIATRIS SIA	LT
Betaserc 8 mg tabletės	not available	LT/1/95/0848/001	VIATRIS SIA	LT
Betahistine EG 24 mg comprimés	not available	2014090206	EUROGENERICS N.V./S.A.	LU
Betaserc 16 mg comprimés	not available	2009020193	VIATRIS HEALTHCARE	LU
Betaserc 16 mg Tabletten	not available	2009020193	VIATRIS HEALTHCARE	LU
Betaserc 8 mg Tabletten	not available	2009020192	VIATRIS HEALTHCARE	LU
Betaserc 8 mg, comprimés	not available	2009020192	VIATRIS HEALTHCARE	LU
LECTIL 16 mg, comprimé sécable	not available	0278424	BOUCHARA RECORDATI	LU
LECTIL 24 mg, comprimé	not available	1324/2008120049	BOUCHARA RECORDATI	LU
LECTIL 24 mg, comprimé	not available	1324/2008120049	BOUCHARA RECORDATI	LU
LECTIL 24 mg, comprimé	not available	1324/2008120049	BOUCHARA RECORDATI	LU
Betaserc 16 mg tabletes	not available	03-0036	VIATRIS SIA	LV
Betaserc 24 mg mutē disperģējamās tabletes	FI/H/0827/001	14-0269	VIATRIS HEALTHCARE LTD	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
Betaserc 24 mg tabletes	not available	03-0317	VIATRIS SIA	LV
Betaserc 8 mg tabletes	not available	00-0129	VIATRIS SIA	LV
Betaserc® 16 mg tablets	not available	MA 1187/00802	VIATRIS HEALTHCARE LTD	MT
Betaserc® 24 mg tablets	not available	MA 1187/00803	VIATRIS HEALTHCARE LTD	MT
Betabare 24 mg tabletten	NL/H/1639/001	RVG 103403	EGIS PHARMACEUTICALS PLC	NL
Betahistine diHCl 24 mg Teva, tabletten	not available	RVG 101754	TEVA NEDERLAND B.V.	NL
Betahistine diHCl Aurobindo 24 mg, tabletten	PT/H/0867/003	RVG 115063	AUROBINDO PHARMA B.V.	NL
Betahistine Sandoz 24 mg, tabletten	NL/H/3700/003	RVG 118843	SANDOZ B.V.	NL
Betahistine Sandoz 24 mg, tabletten	NL/H/3705/003	RVG 118848	SANDOZ B.V.	NL
Betahistine Sandoz 24 mg, tabletten	NL/H/3706/003	RVG 118851	SANDOZ B.V.	NL
Betaserc 24, tabletten 24 mg	AT/H/0446/001	RVG 111897	MYLAN HEALTHCARE B.V.	NL
Betaserc 16, tabletten 16 mg	not available	RVG 13612	MYLAN HEALTHCARE B.V.	NL
Betaserc 8, tabletten 8 mg	not available	RVG 05852	MYLAN HEALTHCARE B.V.	NL
Betaserc ODT, 24 mg, tabletki ulegające rozpadowi w jamie ustnej	FI/H/0827/001	22273	VIATRIS HEALTHCARE LTD	PL
BETASERC, 24 mg, tabletki	not available	11836	VIATRIS HEALTHCARE SP. Z O.O.	PL
BETASERC, 8 mg, tabletki	not available	R/3705	VIATRIS HEALTHCARE SP. Z O.O.	PL
Beta-histina Labesfal 12 mg comprimido	PT/H/1980/002	PT/H/1980/002	GENERIS FARMACÊUTICA, S.A.	PT
Beta-histina Labesfal 12 mg comprimidos	PT/H/1980/002	PT/H/1980/002	GENERIS FARMACÊUTICA, S.A.	PT
Beta-histina Labesfal 12 mg comprimidos	PT/H/1980/002	PT/H/1980/002	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
Beta-histina Labesfal 12 mg comprimidos	PT/H/1980/002	PT/H/1980/002	GENERIS FARMACÊUTICA, S.A.	PT
Beta-histina Labesfal 12 mg comprimidos	PT/H/1980/002	PT/H/1980/002	GENERIS FARMACÊUTICA, S.A.	PT
Betaserc 16 mg comprimidos	not available	8354951	BGP PRODUCTS UNIPESOAL, LDA.	PT
Betaserc 16 mg comprimidos	not available	8354969	BGP PRODUCTS UNIPESOAL, LDA.	PT
Betaserc 24 mg comprimidos	not available	5304381	BGP PRODUCTS UNIPESOAL, LDA.	PT
Betaserc 24 mg comprimidos	not available	5304282	BGP PRODUCTS UNIPESOAL, LDA.	PT
Betaserc Odis 24 mg comprimidos orodispersíveis	FI/H/0827/001	5644752	BGP PRODUCTS UNIPESOAL, LDA.	PT
Betaserc Odis 24 mg comprimidos orodispersíveis	FI/H/0827/001	5644760	BGP PRODUCTS UNIPESOAL, LDA.	PT
Betaserc 24 mg comprimate orodispersabile	FI/H/0827/001	12796/2019/01	VIATRIS HEALTHCARE LTD	RO
Betaserc 24 mg comprimate orodispersabile	FI/H/0827/001	12796/2019/02	VIATRIS HEALTHCARE LTD	RO
Betaserc 24 mg comprimate orodispersabile	FI/H/0827/001	12796/2019/03	VIATRIS HEALTHCARE LTD	RO
Betaserc 24 mg comprimate orodispersabile	FI/H/0827/001	12796/2019/04	VIATRIS HEALTHCARE LTD	RO
Betaserc 24 mg comprimate orodispersabile	FI/H/0827/001	12796/2019/05	VIATRIS HEALTHCARE LTD	RO
Betaserc 24 mg, comprimate	not available	2717/2010/02	VIATRIS HEALTHCARE LTD	RO
Betaserc 24 mg, comprimate	not available	2717/2010/03	VIATRIS HEALTHCARE LTD	RO

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Betaserc 24 mg, comprimate	not available	2717/2010/04	VIATRIS HEALTHCARE LTD	RO
Betaserc 24 mg, comprimate	not available	2717/2010/01	VIATRIS HEALTHCARE LTD	RO
Betaserc 8 mg, comprimate	not available	2192/2009/02	VIATRIS HEALTHCARE LTD	RO
Betaserc 8 mg, comprimate	not available	2192/2009/01	VIATRIS HEALTHCARE LTD	RO
Betaserc 24 mg orodispersibilne tablete	FI/H/0827/001	H/04/00271/004	VIATRIS HEALTHCARE LTD	SI
Betaserc 24 mg orodispersibilne tablete	FI/H/0827/001	H/04/00271/008	VIATRIS HEALTHCARE LTD	SI
Betaserc 24 mg orodispersibilne tablete	FI/H/0827/001	H/04/00271/007	VIATRIS HEALTHCARE LTD	SI
Betaserc 24 mg orodispersibilne tablete	FI/H/0827/001	H/04/00271/006	VIATRIS HEALTHCARE LTD	SI
Betaserc 24 mg orodispersibilne tablete	FI/H/0827/001	H/04/00271/005	VIATRIS HEALTHCARE LTD	SI
Betaserc 24 mg tablete	not available	H/04/00271/002	VIATRIS HEALTHCARE LTD	SI
Betaserc 24 mg tablete	not available	H/04/00271/003	VIATRIS HEALTHCARE LTD	SI
Betaserc 24 mg tablete	not available	H/04/00271/001	VIATRIS HEALTHCARE LTD	SI
MeniSerc 16 tablety	not available	83/0157/01-S	TS PHARMA S.R.O.	SK
MeniSerc 24 tablety	not available	83/0275/04-S	TS PHARMA S.R.O.	SK
Betahistine Dihydrochloride 16 mg Tablets	not available	PL 49445/0125	AMAROX LIMITED	XI
Betahistine Dihydrochloride 16mg Tablets	not available	PL 43461/0050	FLAMINGO PHARMA UK LTD	XI
Betahistine Dihydrochloride 16mg Tablets	not available	PL 17907/0687	BRISTOL LABORATORIES LIMITED	XI
Betahistine Dihydrochloride 8 mg Tablets	not available	PL 49445/0124	AMAROX LIMITED	XI

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
Betahistine Dihydrochloride 8mg Tablets	not available	PL 43461/0049	FLAMINGO PHARMA UK LTD	XI
Betahistine Dihydrochloride 8mg Tablets	not available	PL 17907/0686	BRISTOL LABORATORIES LIMITED	XI
Serc®-16	not available	PL 46302/0048	MYLAN PRODUCTS LIMITED	XI
Serc®-8	not available	PL 46302/0049	MYLAN PRODUCTS LIMITED	XI