10 September 2015
EMA/587351/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: betahistine

Procedure No.: PSUSA/0000389/201412

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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	Legal basis
Acuver	AT/H/0191/001/DC	1379/2009/01-02	Cyathus Exquirere Pharmaforschungsgmbh	RO	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Acuver	AT/H/0191/001/DC	72778.00.00	Cyathus Exquirere Pharmaforschungsgmbh	DE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Acuver	AT/H/0191/001/DC	83/0136/09-S	Cyathus Exquirere Pharmaforschungsgmbh	SK	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Acuver	AT/H/0191/001/E01	5363-I-46/14 (60 ML)	Cyathus Exquirere Pharmaforschungsgmbh	SI	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Acuver	AT/H/0191/001/E01	5363-I-47/14 (120 ML)	Cyathus Exquirere Pharmaforschungsgmbh	SI	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Aequamen		3382.01.00	Takeda Gmbh (Konstanz)	DE	Full application (Article 8(3) of Directive No 2001/83/EC)
Aequamen Forte		3382.00.00	Takeda Gmbh (Konstanz)	DE	Full application (Article 8(3) of Directive No 2001/83/EC)
Antivom		17906	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	CY	Full application (Article 8(3) of Directive No 2001/83/EC)
Antivom		29837/01.10.2013	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	GR	Full application (Article 8(3) of Directive No 2001/83/EC)
Antivom		74191/09.11.2012	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	GR	Full application (Article 8(3) of Directive No 2001/83/EC)
Antivom		75137/01.10.2013	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	GR	Full application (Article 8(3) of Directive No 2001/83/EC)
Bestin	AT/H/0191/001/DC	1-27938	Cyathus Exquirere Pharmaforschungsgmbh	AT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Bestin	AT/H/0191/001/DC	83/046/09-C	Cyathus Exquirere Pharmaforschungs GmbH	CZ	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betabire	NL/H/1781/001	RVG 103708	Farmasyn S.A.	NL	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahecon		PA 2007/1/1	Bgp Products Limited	IE	Full application (Article 8(3) of Directive No 2001/83/EC)
Betahistin Arcana	CZ/H/0399/001	1-27995	Arcana Arzneimittel Gmbh	AT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)

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Betahistin Mylan	CZ/H/0399/001	83/0546/08-S	Generics [uk] Limited	SK	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistin Rockspring Healthcare	AT/H/0446/001	2013120602	Rockspring Healthcare Limited	LU	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine 2hcl Mylan	CZ/H/0399/001	RVG 35028	Mylan B.V.	NL	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Biphar Abbott Products		34009 348 892 4	Abbott Products Sas	FR	Informed consent application (Article 10c of Directive No 2001/83/EC)
Betahistine Biphar Abbott Products		34009 355 648 8 7	Abbott Products Sas	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Betahistine Bouchara-Recordati 16 mg scored tablet		NL 25254	Bouchara Recordati	FR	Informed consent application (Article 10c of Directive No 2001/83/EC)
Betahistine Dihcl 24 Mg Teva	RVG 101754	RVG 101754	Teva Nederland B.V.	NL	Article 10(3)
Betahistine Disphar		RVG 104029	Disphar International B.V.	NL	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Mylan	CZ/H/0399/001	BE353245	Mylan Bvba/Sprl	BE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Rockspring Healthcare	AT/H/0446/001	2013120602	Rockspring Healthcare Limited	LU	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 24743	352 223-6	Sandoz	FR	
Betahistine Sandoz	NL 24743	365 975-1	Sandoz	FR	
Betahistine Sandoz	NL 24743	366 174-2	Sandoz	FR	
Betahistine Sandoz	NL 24743	561 736-6	Sandoz	FR	
Betahistine Sandoz	NL 34750	383 389-3	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	383 390-1	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	383 391-8	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine	NL 34750	383 392-4	Sandoz	FR	Hybrid application (Article 10(3) of Directive

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Sandoz					No 2001/83/EC)
Betahistine Sandoz	NL 34750	571 968-7	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	571 969-3	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	571 970-1	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	571 971-8	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	571 972-4	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	571 973-0	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	571 974-7	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Sandoz	NL 34750	571 975-3	Sandoz	FR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betahistine Teva	PL-H-0240-001-DC	14518	Teva Pharmaceuticals Polska Sp. Z O.O.	PL	Article 10(3)
Betahistinum 123ratio	PL-H-0240-001-DC	14518	123ratio Sp. Z O.O.	PL	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betaistina Mylan Generics Italia	CZ/H/0399/001	038374017	Mylan S.P.A.	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betaistina Mylan Generics Italia	CZ/H/0399/001	038374029	Mylan S.P.A.	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betaistina Mylan Generics Italia	CZ/H/0399/001	038374031	Mylan S.P.A.	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betaistina Mylan Generics Italia	CZ/H/0399/001	038374043	Mylan S.P.A.	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betaistina	CZ/H/0399/001	038374056	Mylan S.P.A.	IT	Hybrid application (Article 10(3) of Directive

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Mylan Generics Italia					No 2001/83/EC)
Betaistina Mylan Generics Italia	CZ/H/0399/001	038374068	Mylan S.P.A.	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betalune	NL/H/1640/001	RVG 103192	Disphar International B.V.	NL	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Betaserc		00-0129	Abbott Healthcare Products B.V. (Weesp)	LV	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		0191/09020192	Abbott Sa/Nv (Belgium)	LU	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		0191/09020193	Abbott Sa/Nv (Belgium)	LU	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		03-0036	Abbott Healthcare Products B.V. (Weesp)	LV	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		03-0317	Abbott Healthcare Products B.V. (Weesp)	LV	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		06099	Abbott Healthcare Products B.V. (Weesp)	DK	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		1-19125; 14785; 1-24043; 135031	Bgp Products Ges. M. B. H.	AT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		10683	Abbott Healthcare Products B.V. (Weesp)	FI	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		11836	Abbott Healthcare Products B.V. (Weesp)	PL	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		118795	BGP Products B.V.	EE	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		118895	BGP Products B.V.	EE	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		12603	Abbott Healthcare Products B.V. (Weesp)	DK	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		18447	Abbott Healthcare Products B.V. (Weesp)	FI	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		18754	Varnavas Hadjipanayis Ltd. (Latsia)	CY	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		2192/2009/01-02	Abbott Healthcare	RO	Full application (Article 8(3) of Directive No

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			Products B.V. (Weesp)		2001/83/EC)
Betaserc		2717/2010/01	Abbott Healthcare Products B.V. (Weesp)	RO	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		355 646-5	Abbott Products Sas	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		41610/07/06-06-2008	Abbott Laboratories (Hellas) S.A.	GR	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		41613 / 07 / 6-6-2008	Abbott Laboratories (Hellas) S.A. (Vouliagmenis)	GR	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		435004	BGP Products B.V.	EE	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		5304282, 5304381	Abbott Laboratorios Lda.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		5363-I-445/12	Abbott Healthcare Products B.V. (Weesp)	SI	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		7546	Varnavas Hadjipanayis Ltd. (Latsia)	CY	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		83/123/89-C	BGP Products B.V.	CZ	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		83/309/00-C	BGP Products B.V.	CZ	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		83/368/03-C	BGP Products B.V.	CZ	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		8354969, 8354951	Abbott Laboratorios Lda.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		9987	Abbott Healthcare Products B.V. (Weesp)	FI	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		BE071766	Abbott Sa/Nv (Belgium)	BE	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		BE150726	Abbott Sa/Nv (Belgium)	BE	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		LT/1/95/0848/001	Abbott Healthcare Products B.V. (Weesp)	LT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		LT/1/95/0848/002	Abbott Healthcare Products B.V. (Weesp)	LT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		LT/1/95/0848/003	Abbott Healthcare Products B.V. (Weesp)	LT	Full application (Article 8(3) of Directive No 2001/83/EC)

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Betaserc		MA013/00501	Abbott Healthcare Products B.V. (Weesp)	MT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		MA013/00502	Abbott Healthcare Products B.V. (Weesp)	MT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		MA013/00503	Abbott Healthcare Products B.V. (Weesp)	MT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		OGYI-T-10 004/01	Abbott Healthcare Products B.V. (Weesp)	HU	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		OGYI-T-10 004/05	Abbott Healthcare Products B.V. (Weesp)	HU	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		OGYI-T-10004/04	Abbott Healthcare Products B.V. (Weesp)	HU	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		R/3705	Abbott Healthcare Products B.V. (Weesp)	PL	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		RVG 05852	Abbott B.V.	NL	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		RVG 13612	Abbott B.V.	NL	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		UP/I-530-09/09-02/537	Abbott Laboratories D.O.O. (Koranska)	HR	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc		UP/I-530-09/09-02/538	Abbott Laboratories D.O.O. (Koranska)	HR	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc	AT/H/0446/001	BE439327	Abbott Sa/Nv (Belgium)	BE	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc	AT/H/0446/001	RVG 111897	Abbott B.V.	NL	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc	FI/H/0827/001	14-0269	Abbott Laboratories Baltics Sia	LV	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc	FI/H/0827/001	LT/1/95/0848/010	Abbott Laboratories Baltics Sia	LT	Full application (Article 8(3) of Directive No 2001/83/EC)
Betaserc	FI/H/0827/001/DC	OGYI-T-10004/06	Abbott Laboratories Magyarország Kft. (Lechner)	HU	Full application (Article 8(3) of Directive No 2001/83/EC)
Betavert	NL/H/1781/001	74650/3-11-2010	Farmasyn S.A.	GR	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Extovyl		34009 322 508 2 0	Laboratoires Juvise Pharmaceuticals	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Extovyl		34009 322 509 9 8	Laboratoires Juvise	FR	Full application (Article 8(3) of Directive No

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			Pharmaceuticals		2001/83/EC)
Extovyl		34009 322 510 7 0	Laboratoires Juvise Pharmaceuticals	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Fortamid		035876010	Farmaceutici Formenti S.P.A.	IT	Informed consent application (Article 10c of Directive No 2001/83/EC)
Fortamid		036876022	Farmaceutici Formenti S.P.A.	IT	Informed consent application (Article 10c of Directive No 2001/83/EC)
Histigen	CZ/H/0399/001	14599	Generics [uk] Limited	PL	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Lectil 16 mg scored tablet		NL 24374	Bouchara Recordati	LU	Informed consent application (Article 10c of Directive No 2001/83/EC)
Lectil 24 mg tablet		NL 27495	Bouchara Recordati	LU	Informed consent application (Article 10c of Directive No 2001/83/EC)
Lectil 16 mg scored tablet		NL 24374	Bouchara Recordati	FR	Informed consent application (Article 10c of Directive No 2001/83/EC)
Lectil 24 mg tablet		NL 27495	Bouchara Recordati	FR	Informed consent application (Article 10c of Directive No 2001/83/EC)
Marac	AT/H/0191/001/E01	5277561 (60 ML)	Cyathus Exquirere Pharmaforschungsgmbh	PT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Marac	AT/H/0191/001/E01	5277579 (120 ML)	Cyathus Exquirere Pharmaforschungsgmbh	PT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Marak	AT/H/0191/001/E01	039755018 (60 ML)	Cyathus Exquirere Pharmaforschungsgmbh	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Marak	AT/H/0191/001/E01	039755020 (120 ML)	Cyathus Exquirere Pharmaforschungsgmbh	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Microser		022622846	Grünenthal Italia S.R.L.	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Microser		022628010	Grünenthal Italia S.R.L.	IT	Full application (Article 8(3) of Directive No 2001/83/EC)
Microser		022628022	Grünenthal Italia S.R.L.	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Microser		022628034	Grünenthal Italia S.R.L.	IT	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Microser		2727/2002/01	Prodotti Formenti S.R.L.	RO	Full application (Article 8(3) of Directive No 2001/83/EC)
Neatin	AT/H/191/01/DC	15533	Icn Polfa Rzeszów S.A.	PL	
Ribrain	n/a	42767/07/23-04-2008	Galenica Sa	GR	Full application (Article 8(3) of Directive No 2001/83/EC)

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Ribrain	n/a	74468/14-11-2007; 41083/12/11-02-2013	Galenica Sa	GR	Full application (Article 8(3) of Directive No 2001/83/EC)
Serc		315 354-3	Abbott Products Sas	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Serc 8mg		55296	Qualigen, S.L.	ES	Full application (Article 8(3) of Directive No 2001/83/EC)
Serc		57.527	Abbott Laboratories, S.A.	ES	
Serc 8mg/ ml oral solution		57527	Qualigen, S.L.	ES	Full application (Article 8(3) of Directive No 2001/83/EC)
Serc		64.130	Abbott Laboratories, S.A.	ES	
Serc 16 mg		64130	Qualigen, S.L.	ES	Full application (Article 8(3) of Directive No 2001/83/EC)
Serc 24 mg		78431	Qualigen, S.L.	ES	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Serc		PA 108/11/1	Abbott Healthcare Products Ltd. (Maidenhead)	IE	Full application (Article 8(3) of Directive No 2001/83/EC)
Serc		PA 108/11/3	Abbott Healthcare Products Ltd. (Maidenhead)	IE	Full application (Article 8(3) of Directive No 2001/83/EC)
Serc		PL 00512/0076	Abbott Healthcare Products Ltd. (Maidenhead)	GB	Full application (Article 8(3) of Directive No 2001/83/EC)
Serc		PL 00512/0088	Abbott Healthcare Products Ltd. (Maidenhead)	GB	Full application (Article 8(3) of Directive No 2001/83/EC)
Vasomotal		7598.00.01	Abbott Arzneimittel Gmbh	DE	Full application (Article 8(3) of Directive No 2001/83/EC)
Vasomotal		7598.01.00	Abbott Arzneimittel Gmbh	DE	Full application (Article 8(3) of Directive No 2001/83/EC)
Vasomotal		7598.02.00	Abbott Arzneimittel Gmbh	DE	Full application (Article 8(3) of Directive No 2001/83/EC)
Vertiserc		027232014	Abbott S.R.L.	IT	Full application (Article 8(3) of Directive No 2001/83/EC)
Vertiserc		027232026	Abbott S.R.L.	IT	Full application (Article 8(3) of Directive No

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					2001/83/EC)
Vertiserc		027232040	Abbott S.R.L.	IT	Full application (Article 8(3) of Directive No 2001/83/EC)
Vertiserc		027232053	Abbott S.R.L.	IT	Full application (Article 8(3) of Directive No 2001/83/EC)
акувер; Acuver	AT/H/0191/001/DC	20090148	Cyathus Exquirere Pharmaforschungsgmbh	BG	Hybrid application (Article 10(3) of Directive No 2001/83/EC)
бетасерк		20030511	Abbott Laboratories Gmbh (Hannover)	BG	Full application (Article 8(3) of Directive No 2001/83/EC)
бетасерк		II-11493/03.10.2005; 20000360	Abbott Healthcare Products B.V. (Weesp)	BG	Full application (Article 8(3) of Directive No 2001/83/EC)
Betahistine DOC 2HCl	NL/H/1419/001/MR	RVG 101752	DOC Generici S.r.l.	NL	Hybrid application (Article 10(3) of Directive No 2001/83/EC)