2 September 2016
EMA/705701/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): Botulinum toxin a

Procedure No.: PSUSA/00000426/201512

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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
Botox		096295 & 743911	Allergan Pharmaceuticals Ireland	Estonia
Botox		17064	Allergan Pharmaceuticals Ireland	Poland
Botox		19591	Allergan Pharmaceuticals Ireland	Poland
Botox		34009 3708314 0 & 34009 3708320 1	Allergan France	France
Botox		34009 5620888 3	Allergan France	France
Botox		63/0021/93-S & 63/0465/11-S	Allergan Pharmaceuticals Ireland	Slovakia
Botox		63/0604/09-S	Allergan Pharmaceuticals Ireland	Slovakia
Botox		63/568/93-C	Allergan Pharmaceuticals Ireland	Czech Republic
Botox		PL 00426/0074	Allergan Ltd	United Kingdom
Botox		PL 00426/0118	Allergan Ltd	United Kingdom
Botox		PL 00426/0119	Allergan Ltd	United Kingdom
Botox		R/6748	Allergan Pharmaceuticals Ireland	Poland
Botox	IE/H/0113/001	034883013	Allergan Pharmaceuticals Ireland	Italy
Botox	IE/H/0113/001	1-23699	Allergan Pharmaceuticals Ireland	Austria
Botox	IE/H/0113/001	1217/00/07/5771	Allergan Pharmaceuticals Ireland	Luxembourg
Botox	IE/H/0113/001	3186186	Allergan Pharmaceuticals Ireland	Portugal
Botox	IE/H/0113/001	55006.00.00	Allergan Pharmaceuticals Ireland	Germany
Botox	IE/H/0113/001	63.194	Allergan Pharmaceuticals Ireland	Spain
Botox	IE/H/0113/001 & IE/H/0113/002	22314/12/22-10-2013	Allergan Pharmaceuticals Ireland	Greece
Botox	IE/H/0113/001 & IE/H/0113/002 & IE/H/0113/003	00-171 & 08-6051 & 09-7187	Allergan Pharmaceuticals Ireland	Norway
Botox	IE/H/0113/001 & IE/H/0113/002 & IE/H/0113/003	096295 & 644409 & 743911	Allergan Pharmaceuticals Ireland	Estonia
Botox	IE/H/0113/001 & IE/H/0113/002 & IE/H/0113/003	15424 & 25162 & 28146	Allergan Pharmaceuticals Ireland	Finland

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Botox	IE/H/0113/001 & IE/H/0113/002 & IE/H/0113/003	31350 & 43623 & 46039	Allergan Pharmaceuticals Ireland	Denmark
Botox	IE/H/0113/001 & IE/H/0113/002 & IE/H/0113/003	8183/2015/01 & 8183/2015/02 & 8183/2015/03 & 8183/2015/04 & 8183/2015/05 & 8184/2015/01 & 8184/2015/02 & 8184/2015/03 & 8184/2015/04 & 8184/2015/05 & 8185/2015/01 & 8185/2015/02 & 8185/2015/03 & 8185/2015/04	Allergan Pharmaceuticals Ireland	Romania
Botox	IE/H/0113/001 & IE/H/0113/002 & IE/H/0113/003	BE215126 & BE329341 & BE411573	Allergan Pharmaceuticals Ireland	Belgium
Botox	IE/H/0113/001 & IE/H/0113/002 & IE/H/0113/003	LT/1/15/3824/001 & LT/1/15/3824/002 & LT/1/15/3824/003 & LT/1/15/3824/004 & LT/1/15/3824/005 & LT/1/15/3824/006 & LT/1/15/3824/007 & LT/1/15/3824/008 & LT/1/15/3824/009 & LT/1/15/3824/010 & LT/1/15/3824/011 & LT/1/15/3824/012 & LT/1/15/3824/013 & LT/1/15/3824/014	Allergan Pharmaceuticals Ireland	Lithuania
Botox	IE/H/0113/001 & IE/H/0113/003	15424 & 28146	Allergan Pharmaceuticals Ireland	Finland
Botox	IE/H/0113/001 & IE/H/0113/003	16116 & 43372	Allergan Pharmaceuticals Ireland	Sweden
Botox	IE/H/0113/001 & IE/H/0113/003	BE215126 & BE411573	Allergan Pharmaceuticals Ireland	Belgium
Botox	IE/H/0113/001 & IE/H/0113/003	BE215126 & BE411573	Allergan Pharmaceuticals Ireland	Belgium
Botox	IE/H/0113/001 & IE/H/0113/003	MA 102/00301 & MA 102/00303	Allergan Pharmaceuticals Ireland	Malta
Botox	IE/H/0113/001 & IE/H/0113/003	OGYI-T-8420/01 & OGYI-T-8420/06 & OGYI-T-8420/07 & OGYI-T-8420/08 & OGYI-T-8420/09	Allergan Pharmaceuticals Ireland	Hungary
Botox	IE/H/0113/001 & IE/H/0113/003	PA 0148/060/1 & PA 0148/060/3	Allergan Pharmaceuticals Ireland	Ireland
Botox	IE/H/0113/001 & IE/H/0113/003	RVG 117146 & RVG 117147	Allergan Pharmaceuticals Ireland	Netherlands
Botox	IE/H/0113/002	2010010008	Allergan Pharmaceuticals Ireland	Luxembourg

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Botox	IE/H/0113/002	25162	Allergan Pharmaceuticals Ireland	Finland
Botox	IE/H/0113/002	27639	Allergan Pharmaceuticals Ireland	Sweden
Botox	IE/H/0113/002	5185608 & 5185616 & 5185624	Allergan Pharmaceuticals Ireland	Portugal
Botox	IE/H/0113/002	74281.00.00	Allergan Pharmaceuticals Ireland	Germany
Botox	IE/H/0113/002	BE329341	Allergan Pharmaceuticals Ireland	Belgium
Botox	IE/H/0113/002	BE329341	Allergan Pharmaceuticals Ireland	Belgium
Botox	IE/H/0113/002	MA 102/00302	Allergan Pharmaceuticals Ireland	Malta
Botox	IE/H/0113/002	OGYI-T-8420/02 & OGYI-T-8420/03 & OGYI-T-8420/04 & OGYI-T-8420/05	Allergan Pharmaceuticals Ireland	Hungary
Botox	IE/H/0113/002	PA 0148/060/2	Allergan Pharmaceuticals Ireland	Ireland
Botox	IE/H/0113/002	RVG 117145	Allergan Pharmaceuticals Ireland	Netherlands
Botox	IE/H/0113/002 & IE/H/0113/003	2-00358 & 2-00381	Allergan Pharmaceuticals Ireland	Austria
Botox	IE/H/0113/002 & IE/H/0113/003	70602 & 72377	Allergan Pharmaceuticals Ireland	Spain
Botox	IE/H/0113/002 & IE/H/0113/003	IS/1/09/003/01 & IS/1/10/046/01	Allergan Pharmaceuticals Ireland	Iceland
Botox	IE/H/0113/003	034883064	Allergan Pharmaceuticals Ireland	Italy
Botox	IE/H/0113/003	034883076 & 034883088	Allergan Pharmaceuticals Ireland	Italy
Botox	IE/H/0113/003	034883090	Allergan Pharmaceuticals Ireland	Italy
Botox	IE/H/0113/003	22314/12/22-10-2013	Allergan Pharmaceuticals Ireland	Greece
Botox	IE/H/0113/003	5316237	Allergan Pharmaceuticals Ireland	Portugal
Botox	IE/H/0113/003	80457.00.00	Allergan Pharmaceuticals Ireland	Germany
Botox	IE/H/0113/003	BE411573	Allergan Pharmaceuticals Ireland	Luxembourg
Botox 100 Units	IE/H/0113/001	IS/1/00/001/01	Allergan Pharmaceuticals Ireland	Iceland
Botox 50 Units		102/00302	Allergan Ltd	Malta
Botox		644409	Allergan Pharmaceuticals Ireland	Estonia

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Vistabel	FR/H/0230/001	03-1787	Allergan Pharmaceuticals Ireland	Norway
Vistabel	FR/H/0230/001	05-0144	Allergan Pharmaceuticals Ireland	Latvia
Vistabel	FR/H/0230/001	1-26323	Allergan Pharmaceuticals Ireland	Austria
Vistabel	FR/H/0230/001	14504	Allergan Pharmaceuticals Ireland	Poland
Vistabel	FR/H/0230/001	19431	Allergan Pharmaceuticals Ireland	Sweden
Vistabel	FR/H/0230/001	20022	Allergan Pharmaceuticals Ireland	Finland
Vistabel	FR/H/0230/001	20022	Allergan Pharmaceuticals Ireland	Finland
Vistabel	FR/H/0230/001	20032	Allergan Pharmaceuticals Ireland	Cyprus
Vistabel	FR/H/0230/001	32851/19-05-2011	Allergan Pharmaceuticals Ireland	Greece
Vistabel	FR/H/0230/001	34009 364 696 1 7	Allergan Pharmaceuticals Ireland	France
Vistabel	FR/H/0230/001	34907	Allergan Pharmaceuticals Ireland	Denmark
Vistabel	FR/H/0230/001	459505	Allergan Pharmaceuticals Ireland	Estonia
Vistabel	FR/H/0230/001	5285085	Allergan Pharmaceuticals Ireland	Portugal
Vistabel	FR/H/0230/001	63/0400/07-S	Allergan Pharmaceuticals Ireland	Slovakia
Vistabel	FR/H/0230/001	63/688/07-C	Allergan Pharmaceuticals Ireland	Czech Republic
Vistabel	FR/H/0230/001	63575.00.00	Allergan Pharmaceuticals Ireland	Germany
Vistabel	FR/H/0230/001	65.837	Allergan Pharmaceuticals Ireland	Spain
Vistabel	FR/H/0230/001	903/2008/01-02 & 903/2008/02	Allergan Pharmaceuticals Ireland	Romania
Vistabel	FR/H/0230/001	BE281477	Allergan Pharmaceuticals Ireland	Belgium
Vistabel	FR/H/0230/001	BE281477	Allergan Pharmaceuticals Ireland	Luxembourg
Vistabel	FR/H/0230/001	H/05/01650/001 & H/05/01650/002	Allergan Pharmaceuticals Ireland	Slovenia
Vistabel	FR/H/0230/001	IS/1/03/025/01	Allergan Pharmaceuticals Ireland	Iceland
Vistabel	FR/H/0230/001	LT/1/05/0211/ 002 & LT/1/05/0211/001	Allergan Pharmaceuticals Ireland	Lithuania
Vistabel	FR/H/0230/001	MA 102/00601	Allergan Pharmaceuticals Ireland	Malta
Vistabel	FR/H/0230/001	OGYI-T-10141/01 & OGYI-T-10141/02	Allergan Pharmaceuticals Ireland	Hungary

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Vistabel	FR/H/0230/001	PA 148/65/1	Allergan Pharmaceuticals Ireland	Ireland
Vistabel	FR/H/0230/001	PL 41443/0010	Allergan Pharmaceuticals Ireland	United Kingdom
Vistabel	FR/H/0230/001	RVG 100095	Allergan Pharmaceuticals Ireland	Netherlands
Vistabex	FR/H/0230/001	036103024	Allergan S.P.A.	Italy
ботокс	IE/H/0113/001 & IE/H/0113/002 & IE/H/0113/003	20150370 & 20150371 & 20150372	Allergan Pharmaceuticals Ireland	Bulgaria
вистабел	FR/H/0230/001	20070117	Allergan Pharmaceuticals Ireland	Bulgaria
Botox		HR-H-744022704	Allergan Pharmaceuticals Ireland	Croatia

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Tenoretic film-coated tablets		PL 17901/0049	Astrazeneca Uk Limited	GB
Tenoret		PL 17901/0048	Astrazeneca Uk Limited	GB
Atenolol Clortalidona Qualigen		56661	Qualigen, S.L.	ES
Atenololo Clortalidone Hexal	032805	032805018	Hexal S.P.A	IT
Atenololo Clortalidone Hexal	032805	032805020	Hexal S.P.A	IT
Atenololo/Clortalidone Sandoz	NL/H/0161/001	033455015/M	Sandoz S.P.A.	IT
Atenololo/Clortalidone Sandoz	NL/H/0161/001	033455027/M	Sandoz S.P.A.	IT
Atenololo/Clortalidone Sandoz	NL/H/0161/001	033455054/M	Sandoz S.P.A.	IT
Atenololo/Clortalidone Sandoz	NL/H/0161/002	033455039/M	Sandoz S.P.A.	IT
Atenololo/Clortalidone Sandoz	NL/H/0161/002	033455041/M	Sandoz S.P.A.	IT
Atenololo/Clortalidone Sandoz	NL/H/0161/002	033455104/M	Sandoz S.P.A.	IT
Blokium-Diu		56.665	Almirall, S.A.	ES
Blokium-Diu		OGYI-T-02384	Almirall, S.A.	HU
Diube		024725032	Laboratorio Farmaceutico S.I.T. S.R.L.	IT
Diube		024725069	Laboratorio Farmaceutico S.I.T. S.R.L.	IT
Igroseles		024763056	Ucb Pharma Spa (Milan It)	IT
Igroseles		024763068	Ucb Pharma Spa (Milan It)	IT

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Atenolol Chlortalidone Sandoz		BE206376	SANDOZ N.V.	BE
Atenolol Chlortalidone Sandoz		BE206385	SANDOZ N.V.	BE
Atenolol comp. Sandoz® 50/12,5 mg		23824.00.00	SANDOZ	DE
Atehexal comp. mite		23826.00.00	HEXAL Ag	DE
Atehexal comp.		23826.01.00	HEXAL Ag	DE
Atenolol comp. Sandoz® 100/25 mg		39680.00.00	SANDOZ	DE
Atecor CT 50mg/12.5mg Fillm-coated		PA 711/20/1	ROWEX LTD	IE
Atecor CT 100mg/25mg Film-coated		PA 711/20/2	ROWEX LTD	IE
ATENOLOL/CHLOORTALIDON SANDOZ		RVG 15842	SANDOZ B.V.	NL
ATENOLOL/CHLOORTALIDON SANDOZ		RVG 15843	SANDOZ B.V.	NL
Atenolol/chloortalidon Sandoz 50/12,5		RVG 17035	SANDOZ B.V.	NL
Atenolol/chloortalidon Sandoz 100/25		RVG 17036	SANDOZ B.V.	NL