



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2016
EMA/706149/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): botulinum toxin a - haemagglutinin complex

Procedure No.: PSUSA/00000427/201512



Product Name	MRP DCP Authorisation Number	National Authorisation Number	MAH Name	Authorisation country
Azzalure	FR/H/0341/001	08-5655	Institut Produits Synthèse (Ipsen) Ab	Norway
Azzalure	FR/H/0341/001	1544-01	Ipsen Biopharm Ltd	Cyprus
Azzalure	FR/H/0341/001	2-00357	Ipsen Biopharm Ltd	Austria
Azzalure	FR/H/0341/001	24660	Institut Produits Synthèse (Ipsen) Ab	Finland
Azzalure	FR/H/0341/001	26541	Institut Produits Synthèse (Ipsen) Ab	Sweden
Azzalure	FR/H/0341/001	2905201	Ipsen Biopharm Ltd	Greece
Azzalure	FR/H/0341/001	39063019 & 39063021	Ipsen S.P.A.	Italy
Azzalure	FR/H/0341/001	393 419-2 & 393 420-0	Ipsen Pharma	France
Azzalure	FR/H/0341/001	42748	Institut Produits Synthèse (Ipsen) Ab	Denmark
Azzalure	FR/H/0341/001	5185640 & 5185657	Ipsen Developments Ltd	Portugal
Azzalure	FR/H/0341/001	63/0115/10-S	Ipsen Biopharm Ltd	Slovakia
Azzalure 10 SPEYWOOD JEDNOTEK/0,05 ML	FR/H/0341/001	63/120/10-C	Ipsen Biopharm Ltd	Czech Republic
Azzalure	FR/H/0341/001	71.300	Ipsen Pharma Sa	Spain
Azzalure	FR/H/0341/001	72249.00.00	Ipsen Biopharm Ltd	Germany
Azzalure	FR/H/0341/001	BE 337653 & BE337653	Ipsen Biopharm Ltd	Belgium
Azzalure	FR/H/0341/001	BE337653	Ipsen Biopharm Ltd	Luxembourg
Azzalure	FR/H/0341/001	NR 16393	Ipsen Ltd	Poland
Azzalure	FR/H/0341/001	OGYI-T-21618/01 & OGYI-T-21618/02	Ipsen Biopharm Ltd	Hungary
Azzalure	FR/H/0341/001	PA 1609/1/1	Ipsen Biopharm Ltd	Ireland
Azzalure	FR/H/0341/001	PL 06958/0031	Ipsen Ltd	United Kingdom
Azzalure	FR/H/0341/001	RVG 106065	Ipsen Biopharm Ltd	Netherlands
Azzalure	FR/H/0341/001	IS/1/09/023/01	Institut Produits Synthèse (Ipsen) Ab	Iceland
Botulinum Toxin Type A Ipsen		PL 34926/0009 & PL 34926/0015	Ipsen Ltd	United Kingdom
Dysline		60806	Ipsen E.P.E.	Greece

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Dysport		00-0352	Ipsen Ltd	Latvia
Dysport		028362034 & 028362046	Ipsen S.P.A.	Italy
Dysport		13-0226	Ipsen Ltd	Latvia
Dysport		13357	Institut Produits Synthèse (Ipsen) Ab	Finland
Dysport		14586	Institut Produits Synthèse (Ipsen) Ab	Denmark
Dysport		2-00212	Ipsen Pharma Gmbh	Austria
Dysport		2002020015	Ipsen N.V.	Luxembourg
Dysport		21303	Ipsen Ltd	Poland
Dysport		2165884 & 3799483	Ipsen Portugal Produtos Farmacêuticos, S.A.	Portugal
Dysport		28362022	Ipsen S.P.A.	Italy
Dysport		28541	Institut Produits Synthèse (Ipsen) Ab	Finland
Dysport		287399	Ipsen Ltd	Estonia
Dysport		34009 577 649 0 6 & 558 105-9	Ipsen Pharma	France
Dysport		43994	Institut Produits Synthèse (Ipsen) Ab	Sweden
Dysport		46570	Institut Produits Synthèse (Ipsen) Ab	Denmark
Dysport		50586.00.00 & 81122.00.00	Ipsen Pharma Gmbh	Germany
Dysport		61.155	Ipsen Pharma Sa	Spain
Dysport		63/0060/91-S	Ipsen Pharma	Slovakia
Dysport		63/0188/14-S	Ipsen Biopharm Ltd	Slovakia
Dysport 500 SPEYWOOD JEDNOTEK		63/060/91-S/C	Ipsen Biopharm Ltd	Czech Republic
Dysport 300 SPEYWOOD JEDNOTEK		63/335/12-C	Ipsen Biopharm Ltd	Czech Republic
Dysport 300 SPEYWOOD JEDNOTEK		65353 - 22/09/2011	Ipsen E.P.E.	Cyprus
Dysport		65353 – 22/09/2011	Ipsen E.P.E.	Greece

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Dysport		7334/2006/01	Ipsen Ltd	Romania
Dysport		75.790	Ipsen Pharma Sa	Spain
Dysport		807213	Ipsen Ltd	Estonia
Dysport		BE 180521	Ipsen N.V.	Belgium
Dysport		H/02/00520/001 & H/02/00520/002	Ipsen Pharma	Slovenia
Dysport		LT/1/99/0312/001 & LT/1/99/0312/002 & LT/1/99/0312/003 & LT/1/99/0312/004	Ipsen Ltd	Lithuania
Dysport		OGYI-T-8419/01 & OGYI-T-8419/02	Ipsen Pharma	Hungary
Dysport		OGYI-T-8419/03 & OGYI-T-8419/04	Ipsen Pharma	Hungary
Dysport		PA 1609/002/001	Ipsen Biopharm Ltd	Ireland
Dysport		PL 34926/0001 & PL 34926/0014	Ipsen Ltd	United Kingdom
Dysport		R/7292	Ipsen Ltd	Poland
Dysport		RVG 110868 & RVG 17505	Ipsen Farmaceutica B.V.	Netherlands
Dysport	SE/H/0283/001	02-1442	Institut Produits Synthèse (Ipsen) Ab	Norway
Dysport	SE/H/0283/001	14099	Institut Produits Synthèse (Ipsen) Ab	Sweden
диспорт		20030679 & 20140212	Ipsen Biopharm Ltd	Bulgaria