



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/590274/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: botulinum toxin a - haemagglutinin complex

Procedure no.: PSUSA/00000427/201812

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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
Azzalure 10 Speywood jednotiek/0,05 ml prášok na injekčný roztok	FR/H/0341/001	63/0115/10-S	IPSEN BIOPHARM LTD	SK
Azzalure 125 Speywood egység por oldatos injekcióhoz	FR/H/0341/001	OGYI-T-21618/01	IPSEN PHARMA	HU
Azzalure 125 Speywood egység por oldatos injekcióhoz	FR/H/0341/001	OGYI-T-21618/02	IPSEN PHARMA	HU
Azzalure 125 Speywood jednotek prášek pro injekční roztok	FR/H/0341/001	63/120/10-C	IPSEN PHARMA	CZ
Azzalure 125 Speywood-Einheiten, Pulver zur Herstellung einer Injektionslösung	FR/H/0341/001	2-00357	IPSEN PHARMA	AT
Azzalure 125 Speywood-Einheiten, Pulver zur Herstellung einer Injektionslösung	FR/H/0341/001	72249.00.00	IPSEN PHARMA	DE
Azzalure, 10 Speywood- eenheden/0,05ml, poeder voor oplossing voor injectie	FR/H/0341/001	RVG 106065	IPSEN PHARMA	NL
Azzalure, 10 unidades Speywood/0,05 ml, polvo para solución inyectable	FR/H/0341/001	71.300	IPSEN PHARMA SA	ES
Azzalure, 10 μονάδες Speywood / 0,05 mL, κόνις για ενέσιμο διάλυμα.	FR/H/0341/001	65175	IPSEN PHARMA	GR

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Azzalure, 125 jednostek Speywood, proszek do sporządzania roztworu do wstrzykiwań	FR/H/0341/001	16393	IPSEN PHARMA	PL
Azzalure, 125 Speywood einingar, stungulyfsstofn, lausn	FR/H/0341/001	IS/1/09/023/01	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	IS
Azzalure, 125 Speywood units, powder for solution for injection	FR/H/0341/001	PA 1613/001/001	IPSEN PHARMA	IE
Azzalure, 125 Speywood units, powder for solution for injection	FR/H/0341/001	PL 06958/0031	IPSEN LTD	UK
Azzalure, 125 Speywood-eenheden, poeder voor oplossing voor injectie	FR/H/0341/001	BE337653	IPSEN PHARMA	BE
Azzalure, 125 Speywood-Einheiten, Pulver zur Herstellung einer Injektionslösung	FR/H/0341/001	BE337653	IPSEN PHARMA	BE
Azzalure, 125 Speywood-enheter, pulver til injeksjonsvæske, oppløsning	FR/H/0341/001	08-5655	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	NO
Azzalure, 125 Speywood-enheter, pulver till injektionsvätska, lösning	FR/H/0341/001	24660	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Azzalure, 125 Speywood-yksikköä, injektiokuiva-aine liuosta varten	FR/H/0341/001	24660	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Azzalure, 125 unidades Speywood, pó para solução injetável	FR/H/0341/001	5185640	IPSEN PHARMA	PT
Azzalure, 125 unidades	FR/H/0341/001	5185657	IPSEN PHARMA	PT

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Speywood, pó para solução injetável				
Azzalure, 125 unità Speywood, polvere per soluzione iniettabile.	FR/H/0341/001	039063021	IPSEN S.P.A.	IT
Azzalure, 125 unità Speywood, polvere per soluzione iniettabile.	FR/H/0341/001	039063019	IPSEN S.P.A.	IT
Azzalure, 125 unités Speywood, poudre pour solution injectable	FR/H/0341/001	BE337653	IPSEN PHARMA	BE
AZZALURE, 125 unités Speywood, poudre pour solution injectable	FR/H/0341/001	34009 393 420 0 9	IPSEN PHARMA	FR
AZZALURE, 125 unités Speywood, poudre pour solution injectable	FR/H/0341/001	34009 393 419 2 7	IPSEN PHARMA	FR
Azzalure, 125 unités Speywood, poudre pour solution injectable	FR/H/0341/001	0142/09080004	IPSEN PHARMA	LU
Azzalure, 125 μονάδες Speywood, κόνις για ενέσιμο διάλυμα.	FR/H/0341/001	20968	IPSEN PHARMA	CY
Azzalure, pulver til injektionsvæske opløsning	FR/H/0341/001	42748	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	DK
Azzalure125 Speywood-enheter, pulver till injektionsvätska, lösning	FR/H/0341/001	26541	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	SE
Botulinum Toxin Type A 300 units Powder for solution for injection	not available	PL 34926/0015	IPSEN LTD	UK
Botulinum Toxin Type A 500 units Powder for	not available	PL 34926/0009	IPSEN LTD	UK

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solution for injection				
Dysline, 300 U/VIAL, κόνις για ενέσιμο διάλυμα	not available	60806	IPSEN E.P.E.	GR
Dysport ® 500 U/VIAL	not available	19337	IPSEN E.P.E.	CY
Dysport ® 500 U/VIAL	not available	88322-15/11/2016	IPSEN E.P.E.	GR
Dysport 300 E por oldatos injekcióhoz	not available	OGYI-T-8419/03	IPSEN PHARMA	HU
Dysport 300 E por oldatos injekcióhoz	not available	OGYI-T-8419/04	IPSEN PHARMA	HU
Dysport 300 E, poeder voor oplossing voor injectie	not available	RVG 110868	IPSEN FARMACEUTICA B.V.	NL
Dysport 300 enheter (E), pulver till injektionsvätska, lösning	not available	43994	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	SE
DYSPORT 300 Speywood jednotek prášek pro injekční roztok	not available	63/335/12-C	IPSEN PHARMA	CZ
Dysport 300 U injektiokuiva-aine, liuosta varten	not available	28541	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Dysport 300 U prášok na injekčný roztok	not available	63/0188/14-S	IPSEN PHARMA	SK
DYSPORT 300 UNITES SPEYWOOD, poudre pour solution injectable	not available	34009 577 649 0 6	IPSEN PHARMA	FR
Dysport 300 units Powder for solution for injection	not available	PL 34926/0014	IPSEN LTD	UK
Dysport 300 V Milteliai injekciniam tirpalui	not available	LT/1/99/0312/003	IPSEN PHARMA	LT
Dysport 300 V Milteliai injekciniam tirpalui	not available	LT/1/99/0312/004	IPSEN PHARMA	LT

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Dysport 300 V pulveris injekciju šķīduma pagatavošanai Toxinum A Clostridii botulini haemagglutininum multiplex	not available	13-0226	IPSEN PHARMA	LV
Dysport 500 E por oldatos injekcióhoz	not available	OGYI-T-8419/02	IPSEN PHARMA	HU
Dysport 500 E por oldatos injekcióhoz	not available	OGYI-T-8419/01	IPSEN PHARMA	HU
DYSPORT 500 E pulver til injeksjonsvæske, oppløsning	SE/H/0283/001	02-1442	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	NO
Dysport 500 E, poeder voor oplossing voor injectie	not available	BE180521	IPSEN N.V.	BE
Dysport 500 E, pulver till injektionsvätska, lösning	SE/H/0283/001	14099	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	SE
Dysport 500 E, Pulver zur Herstellung einer Injektionslösung	not available	BE180521	IPSEN N.V.	BE
DYSPORT 500 enot prašek za raztopino za injiciranje	not available	H/02/00520/002	IPSEN PHARMA	SI
DYSPORT 500 enot prašek za raztopino za injiciranje	not available	H/02/00520/001	IPSEN PHARMA	SI
DYSPORT 500 Speywood jednotek prášek pro injekční roztok	not available	63/060/91-S/C	IPSEN PHARMA	CZ
Dysport 500 U injektiokuiva-aine, liuosta varten	not available	13357	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
DYSPORT 500 U pó para	not available	3799483	IPSEN PORTUGAL	PT

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solução injetável			PRODUTOS FARMACÊUTICOS, S.A.	
DYSPOORT 500 U pó para solução injetável	not available	2165884	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
DYSPOORT 500 U POLVO PARA SOLUCIÓN INYECTABLE	not available	61.155	IPSEN PHARMA SA	ES
Dysport 500 U prášok na injekčný roztok	not available	63/0060/91-S	IPSEN PHARMA	SK
Dysport 500 U, poudre pour solution injectable	not available	BE180521	IPSEN N.V.	BE
Dysport 500 U, poudre pour solution injectable	not available	2002020015	IPSEN N.V.	LU
DYSPOORT 500 unità Polvere per soluzione iniettabile per uso intramuscolare e sottocutaneo Tossina botulinica tipo A da C. botulinum complesso - emoagglutinina	not available	028362022	IPSEN S.P.A.	IT
DYSPOORT 500 unitati pulbere pentru solutie injectabila	not available	10661/2018/01	IPSEN PHARMA	RO
DYSPOORT 500 UNITES SPEYWOOD, poudre pour solution injectable	not available	34009 558 105 9 9	IPSEN PHARMA	FR
Dysport 500 units Powder for solution for injection	not available	PL 34926/0001	IPSEN LTD	UK
Dysport 500 V milteliai injekciniam tirpalui	not available	LT/1/99/0312/002	IPSEN PHARMA	LT

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
Dysport 500 V milteliai injekciniam tirpalui	not available	LT/1/99/0312/001	IPSEN PHARMA	LT
Dysport 500 V pulveris injekciju šķīduma pagatavošanai Toxinum A Clostridii botulini haemagglutininum multiplex	not available	00-0352	IPSEN PHARMA	LV
Dysport pulver til injektionsvæske opløsning 300 enheder	not available	46570	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	DK
Dysport pulver til injektionsvæske opløsning 500 enheder	not available	14586	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	DK
Dysport 500 units Powder for solution for injection	not available	PA 1613/002/001	IPSEN PHARMA	IE
Dysport, 300 j. kompleksu neurotoksyny Clostridium botulinum typu A/fiolkę proszek do sporządzania roztworu do wstrzykiwań	not available	21303	IPSEN PHARMA	PL
DYSPORT, 300 Ü süstelähuse pulber	not available	807213	IPSEN PHARMA	EE
Dysport, 500 j. kompleksu neurotoksyny Clostridium botulinum typu A/fiolkę proszek do sporządzania roztworu do wstrzykiwań	not available	R/7292	IPSEN PHARMA	PL
DYSPORT, 500Ü süstelähuse pulber	not available	287399	IPSEN PHARMA	EE

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Dysport, poeder voor injectievloeistof 500 E	not available	RVG 17505	IPSEN FARMACEUTICA B.V.	NL
Dysport, poeder voor injectievloeistof 500 E	not available	RVG 17505	IPSEN FARMACEUTICA B.V.	NL
Dysport® 300 Einheiten Pulver zur Herstellung einer Injektionslösung	not available	81122.00.00	IPSEN PHARMA GMBH	DE
Dysport® 500 Einheiten Pulver zur Herstellung einer Injektionslösung	not available	50586.00.00	IPSEN PHARMA GMBH	DE
Dysport® 500 Einheiten, Pulver zur Herstellung einer Injektionslösung	not available	2-00212	IPSEN PHARMA GMBH	AT
Dysport® Pulver till injektionsvätska, lösning 300 U	not available	28541	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Dysport® Pulver till injektionsvätska, lösning 500 U	not available	13357	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Диспорт 300 U прах за инжекционен разтвор	not available	20140212	IPSEN PHARMA	BG
Диспорт 500 U прах за инжекционен разтвор,	not available	20030679	IPSEN PHARMA	BG