



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2024
EMA/PRAC/750/2024
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): lanreotide

Procedure no.: PSUSA/00001826/202305



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
SOMATULINE L.P. 30 mg, poudre et solvant pour suspension injectable (IM) à libération prolongée	not available	34009 337 354 6 3	IPSEN PHARMA	FR
SOMATULINE L.P. 30 mg, poudre et solvant pour suspension injectable (IM) à libération prolongée	not available	34009 337 355 2 4	IPSEN PHARMA	FR
SOMATULINE L.P. 30 mg, poudre et solvant pour suspension injectable (IM) à libération prolongée	not available	34009 337 352 3 4	IPSEN PHARMA	FR
Somatuline Autogel 90 mg injektioneste, liuos esitäftetyssä ruiskussa.	not available	16366	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Somatuline Autogel 120 mg injektioneste, liuos esitäftetyssä ruiskussa.	not available	16367	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Somatuline Autogel 60 mg, injektioneste, liuos esitäftetyssä ruiskussa.	not available	16339	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Somatuline Autogel 120 mg injektionsvätska, lösning i förfylld spruta.	not available	16367	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Somatuline Autogel 60 mg injektionsvätska, lösning i förfylld spruta.	not available	16339	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
Somatuline Autogel 90 mg injektionsvätska, lösning i förfylld spruta.	not available	16366	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	FI
SOMATULINE AUTOGEL 60 mg šķīdums injekcijām pilnšļircē	not available	03-0241	IPSEN PHARMA	LV
SOMATULINE AUTOGEL 120 mg šķīdums injekcijām pilnšļircē	not available	03-0243	IPSEN PHARMA	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
SOMATULINE AUTOGEL 90 mg šķīdums injekcijām pilnšļircē	not available	03-0242	IPSEN PHARMA	LV
Somatuline AUTOGEL, 120 mg, roztwór do wstrzykiwań w ampułko-strzykawce	not available	10946	IPSEN PHARMA	PL
Somatuline AUTOGEL, 90 mg, roztwór do wstrzykiwań w ampułko-strzykawce	not available	10945	IPSEN PHARMA	PL
Somatuline AUTOGEL, 60 mg, roztwór do wstrzykiwań w ampułko-strzykawce	not available	10944	IPSEN PHARMA	PL
Somatuline Autogel® 120 mg Injektionslösung in einer Fertigspritze	not available	1-25024	IPSEN PHARMA GMBH	AT
Somatuline Autogel® 60 mg Injektionslösung in einer Fertigspritze	not available	1-25023	IPSEN PHARMA GMBH	AT
Somatuline Autogel® 90 mg Injektionslösung in einer Fertigspritze	not available	1-25025	IPSEN PHARMA GMBH	AT
Somatuline Autogel 60 mg, solution for injection in a pre-filled syringe	not available	PA869/4/2	IPSEN PHARMACEUTICALS LTD.	IE
Somatuline Autogel 120 mg, solution for injection in a pre-filled syringe	not available	PA869/4/4	IPSEN PHARMACEUTICALS LTD.	IE
Somatuline Autogel 90 mg, solution for injection in a pre-filled syringe	not available	PA869/4/3	IPSEN PHARMACEUTICALS LTD.	IE
IPSTYL “120 mg soluzione iniettabile in siringa priempita”	not available	029399134	IPSEN S.P.A.	IT
IPSTYL “90 mg soluzione iniettabile in siringa priempita”	not available	029399122	IPSEN S.P.A.	IT
IPSTYL “60 mg soluzione iniettabile in siringa priempita”	not available	029399110	IPSEN S.P.A.	IT
SOMATULINE AUTOGEL 120 mg soluție injectabilă în seringă preumplută	not available	4589/2012/01	IPSEN PHARMA	RO

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
Somatuline Autogel Injectable 120 mg Injektionslösung in einer Fertigspritze	not available	BE 234087	IPSEN N.V.	BE
Somatuline Autogel Injectable 90 mg Injektionslösung in einer Fertigspritze	not available	BE 234071	IPSEN N.V.	BE
Somatuline Autogel Injectable 60 mg Injektionslösung in einer Fertigspritze	not available	BE 234062	IPSEN N.V.	BE
Somatuline Autogel Injectable 90 mg solution injectable en seringue préremplie	not available	BE234071	IPSEN N.V.	BE
Somatuline Autogel Injectable 90 mg oplossing voor injectie in een voorgevulde spuit	not available	BE234071	IPSEN N.V.	BE
Somatuline Autogel Injectable 120 mg oplossing voor injectie in een voorgevulde spuit	not available	BE234087	IPSEN N.V.	BE
Somatuline Autogel Injectable 120 mg solution injectable en seringue préremplie	not available	BE234087	IPSEN N.V.	BE
Somatuline Autogel Injectable 60 mg oplossing voor injectie in een voorgevulde spuit	not available	BE234062	IPSEN N.V.	BE
Somatuline Autogel Injectable 60 mg solution injectable en seringue préremplie	not available	BE234062	IPSEN N.V.	BE
Somatuline Autogel 90 mg, süstelahus süstlis	not available	442504	IPSEN PHARMA	EE
Somatuline Autogel 120 mg, süstelahus süstlis	not available	442704	IPSEN PHARMA	EE
Somatuline Autogel 60 mg, süstelahus süstlis	not available	442604	IPSEN PHARMA	EE
Somatulina Autogel 90 mg solução injetável em seringa pré-cheia	not available	3589082	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
Somatulina Autogel 120 mg solução injetável em seringa pré-cheia	not available	3589181	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, 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
Somatulina Autogel 60 mg solução injetável em seringa pré-cheia	not available	3588985	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
Somatuline Autogel® 90 mg Injektionslösung in einer Fertigspritze	DE/H/1144/002	61332.01.00	IPSEN PHARMA GMBH	DE
Somatuline Autogel® 120 mg Injektionslösung in einer Fertigspritze	DE/H/1144/003	61332.02.00	IPSEN PHARMA GMBH	DE
Somatuline Autogel® 60 mg Injektionslösung in einer Fertigspritze	DE/H/1144/001	61332.00.00	IPSEN PHARMA GMBH	DE
Somatuline Autogel 120 mg injekční roztok v předplněné injekční stříkačce	not available	56/004/03-C	IPSEN PHARMA	CZ
Somatuline Autogel 60 mg injekční roztok v předplněné injekční stříkačce	not available	56/002/03-C	IPSEN PHARMA	CZ
Ipstyl Autogel 90 mg injektionsvæske, opløsning i fyldt injektionssprøjte	not available	32163	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	DK
Ipstyl Autogel 120 mg injektionsvæske, opløsning i fyldt injektionssprøjte	not available	32164	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	DK
Ipstyl Autogel 60 mg injektionsvæske, opløsning i fyldt injektionssprøjte	not available	32162	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	DK
Somatuline AutoSolution 90 mg, oplossing voor injectie in een voorgevulde spuit.	not available	RVG 26302	IPSEN FARMACEUTICA B.V.	NL
Somatuline AutoSolution 60 mg, oplossing voor injectie in een voorgevulde spuit.	not available	RVG 26301	IPSEN FARMACEUTICA B.V.	NL
Somatuline AutoSolution 120 mg, oplossing voor injectie in een voorgevulde spuit.	not available	RVG 26303	IPSEN FARMACEUTICA B.V.	NL
Somatuline Autogel 60 mg injektionsvätska, lösning i förfylld spruta.	not available	16941	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	SE
Somatuline Autogel 90 mg injektionsvätska, lösning i förfylld spruta.	not available	18955	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	SE

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
Somatuline Autogel 120 mg injektionsvätska, lösning i förfylld spruta.	not available	18956	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	SE
Ipstyl Autogel 120 mg injeksjonsvæske, oppløsning i ferdigfylt sprøyte	not available	01-59	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	NO
Ipstyl Autogel 90 mg injeksjonsvæske, oppløsning i ferdigfylt sprøyte	not available	01-58	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	NO
Ipstyl Autogel 60 mg injeksjonsvæske, oppløsning i ferdigfylt sprøyte	not available	00-9692	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	NO
SOMATULINE AUTOGEL 90 mg raztopina za injiciranje v napolnjeni injekcijski brizgi	not available	H/02/01444/002	IPSEN PHARMA	SI
SOMATULINE AUTOGEL 120 mg raztopina za injiciranje v napolnjeni injekcijski brizgi	not available	H/02/01444/003	IPSEN PHARMA	SI
SOMATULINE AUTOGEL 60 mg raztopina za injiciranje v napolnjeni injekcijski brizgi	not available	H/02/01444/001	IPSEN PHARMA	SI
SOMATULINA AUTOGEL 60 mg solución inyectable en jeringa precargada.	not available	64.837	IPSEN PHARMA SA	ES
SOMATULINA AUTOGEL 120 mg solución inyectable en jeringa precargada.	not available	64.839	IPSEN PHARMA SA	ES
SOMATULINA AUTOGEL 90 mg solución inyectable en jeringa precargada.	not available	64.838	IPSEN PHARMA SA	ES
Somatuline Autogel 120 mg oldatos injekció előretöltött fecskendőben	not available	OGYI-T-9807/03	IPSEN PHARMA	HU
Somatuline Autogel 90 mg oldatos injekció előretöltött fecskendőben	not available	OGYI-T-9807/02	IPSEN PHARMA	HU
Somatuline Autogel 60 mg oldatos injekció előretöltött fecskendőben	not available	OGYI-T-9807/01	IPSEN PHARMA	HU
SOMATULINE L.P. 120 mg, solution injectable à libération prolongée en seringue préremplie	not available	34009 357 289 5 1	IPSEN PHARMA	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
SOMATULINE L.P. 90 mg, solution injectable à libération prolongée en seringue préremplie	not available	34009 357 288 9 0	IPSEN PHARMA	FR
SOMATULINE L.P. 60 mg, solution injectable à libération prolongée en seringue préremplie	not available	34009 357 287 2 2	IPSEN PHARMA	FR
Somatuline Autogel 60 mg, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα.	not available	80980/13-07/10/2016	IPSEN M.E.P.E.	GR
Somatuline Autogel 120 mg, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα.	not available	80980/13-07/10/2016	IPSEN M.E.P.E.	GR
Somatuline Autogel 90 mg, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα.	not available	80980/13-07/10/2016	IPSEN M.E.P.E.	GR
Somatuline Autogel Injectable 90 mg solution injectable en seringue préremplie	not available	0340808	IPSEN N.V.	LU
Somatuline Autogel Injectable 60 mg solution injectable en seringue préremplie	not available	0340792	IPSEN N.V.	LU
Somatuline Autogel Injectable 120 mg solution injectable en seringue préremplie	not available	0340811	IPSEN N.V.	LU
Somatuline Autogel 60 mg injekcinis tirpalas užpildytame švirkšte	not available	LT/1/05/0197/001	IPSEN PHARMA	LT
Somatuline Autogel 90 mg injekcinis tirpalas užpildytame švirkšte	not available	LT/1/05/0197/002	IPSEN PHARMA	LT
Somatuline Autogel 120 mg injekcinis tirpalas užpildytame švirkšte	not available	LT/1/05/0197/003	IPSEN PHARMA	LT
Somatuline Autogel 120 mg injekčný roztok v naplnenej injekčnej striekačke	not available	56/0124/03-S	IPSEN PHARMA	SK
Somatuline Autogel 90 mg injekčný roztok v naplnenej injekčnej striekačke	not available	56/0123/03-S	IPSEN PHARMA	SK
Somatuline Autogel 60 mg injekčný roztok v naplnenej injekčnej striekačke	not available	56/0122/03-S	IPSEN PHARMA	SK