



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2021
EMA/4790/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): lanreotide

Procedure No.: PSUSA/00001826/202005

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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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 |
|--|-------------------------------------|--------------------------------------|---|---|
| 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 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 |
| SOMATULINEP PR, 30 mg, proszek i rozpuszczalnik do sporządzenia zawiesiny do wstrzykiwań o przedłużonym uwalnianiu | not available | 4207 | IPSEN PHARMA | PL |
| Somatuline® Autogel® 60 mg, solution for | not available | PL 34926/0005 | IPSEN LTD | UK |

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| injection in a pre-filled syringe | | | | |
| Somatuline® Autogel® 90 mg, solution for injection in a pre-filled syringe | not available | PL 34926/0006 | IPSEN LTD | UK |
| Somatuline® Autogel® 120 mg, solution for injection in a pre-filled syringe | not available | PL 34926/0007 | IPSEN LTD | UK |
| Somatuline® Autogel® 60 mg, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα | not available | 80980/13-07/10/2016 | IPSEN E.P.E. | GR |
| Somatuline® Autogel® 120 mg, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα | not available | 80980/13-07/10/2016 | IPSEN E.P.E. | GR |
| Somatuline® Autogel® 90 mg, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα | not available | 80980/13-07/10/2016 | IPSEN E.P.E. | GR |
| Somatuline Autogel Injectable 90 mg solution injectable en seringue préremplie | not available | 2003020041 | IPSEN N.V. | LU |
| Somatuline Autogel Injectable 60 mg solution injectable en seringue préremplie | not available | 2003020040 | IPSEN N.V. | LU |
| Somatuline Autogel Injectable 120 mg solution injectable en seringue préremplie | not available | 2003020042 | IPSEN N.V. | LU |
| 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 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 | not available | H/02/01444/001 | IPSEN PHARMA | SI |

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| injiciranje v napolnjeni injekcijski brizgi | | | | |
| 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 |
| SOMATULINE AUTOGEL 90 mg šķīdums injekcijām pilnšļircē | not available | 03-0242 | IPSEN PHARMA | LV |
| Somatuline Autogel 60 mg injekcinis tirpalas uždildytame švirkšte | not available | LT/1/05/0197/001 | IPSEN PHARMA | LT |
| Somatuline Autogel 90 mg injekcinis tirpalas uždildytame švirkšte | not available | LT/1/05/0197/002 | IPSEN PHARMA | LT |
| Somatuline Autogel 120 mg injekcinis tirpalas uždildytame švirkšte | not available | LT/1/05/0197/003 | IPSEN PHARMA | LT |
| Ipstyl Autogel 120 mg injekcijasvāse, oppløsning i ferdigfylt sprøyte | not available | 01-59 | INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB | NO |
| Ipstyl Autogel 90 mg injekcijasvāse, oppløsning i ferdigfylt sprøyte | not available | 01-58 | INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB | NO |
| Ipstyl Autogel 60 mg injekcijasvāse, oppløsning i ferdigfylt sprøyte | not available | 00-9692 | INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB | NO |
| SOMATULINE L.P. 120 mg, solution injectable à libération prolongée en seringue préremplie | not available | 34009 357 289 5 1 | IPSEN PHARMA | FR |
| 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 |
| IPSTYL 120 mg soluzione iniettabile | not available | 029399134 | IPSEN S.P.A. | IT |
| IPSTYL 90 mg soluzione iniettabile | not available | 029399122 | IPSEN S.P.A. | IT |
| IPSTYL 60 mg soluzione iniettabile | not available | 029399110 | IPSEN S.P.A. | IT |

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| SOMATULINE AUTOGEL 120 mg soluție injectabilă în seringă preumplută | not available | 4589/2012/01 | IPSEN PHARMA | RO |
| 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 |
| Somatuline Autogel 120 mg injektionsvätska, lösning i förfylld spruta. | not available | 18956 | INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB | SE |
| Somatuline Prolonged Release 30 mg, poudre et solvant pour suspension injectable à libération prolongée | not available | 1999055568 | IPSEN N.V. | LU |
| Somatuline LA 30 mg, powder and solvent for prolonged-release suspension for injection | not available | PA 869/4/1 | IPSEN PHARMACEUTICALS LTD. | IE |
| SOMATULINE® 30mg, κόνις και διαλύτης για παρασκευή ενέσιμου ελαιώδηματος παρατεταμένης αποδέσμευσης. | not available | 61850-15/09/2011 | IPSEN M.E.P.E. | GR |
| Somatuline Autogel 90 mg injektioneste, liuos esitäytetyssä ruiskussa. | not available | 16366 | INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB | FI |
| Somatuline Autogel 120 mg injektioneste, liuos esitäytetyssä ruiskussa. | not available | 16367 | INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB | FI |
| Somatuline Autogel 60 mg, injektioneste, liuos esitäytetyssä 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 |

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| Somatulina LP 30 mg, pó e veículo para suspensão injetável de libertação prolongada | not available | 2522589 | IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Somatulina LP 30 mg, pó e veículo para suspensão injetável de libertação prolongada | not available | 2522688 | IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Somatulina LP 30 mg, pó e veículo para suspensão injetável de libertação prolongada | not available | 2522480 | IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Somatuline Prolonged Release 30 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionssuspension mit verzögerter | not available | BE179006 | IPSEN N.V. | BE |
| Somatuline Prolonged Release 30 mg, poudre et solvant pour suspension injectable à libération prolongée | not available | BE179006 | IPSEN N.V. | BE |
| Somatuline Prolonged Release 30 mg, poeder en oplosmiddel voor suspensie voor injectie met verlengde afgifte | not available | BE179006 | IPSEN N.V. | BE |
| 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 |
| SOMATULINA 30 mg, polvo y disolvente para | not available | 60.914 | IPSEN PHARMA SA | ES |

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| suspensión inyectable de liberación prolongada. | | | | |
| 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 120 mg injekční roztok v předplněné injekční stříkačce | not available | 56/004/03-C | IPSEN PHARMA | CZ |
| Somatuline Autogel 90 mg injekční roztok v předplněné injekční stříkačce | not available | 56/003/03-C | IPSEN PHARMA | CZ |
| Somatuline Autogel 60 mg injekční roztok v předplněné injekční stříkačce | not available | 56/002/03-C | IPSEN PHARMA | CZ |
| 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 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, 120 mg, roztwór do wstrzykiwań w ampułko-strzykawce | not available | 10946 | IPSEN PHARMA | PL |

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| 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 LA 30 mg, powder for suspension for injection. | not available | PL 34926/0004 | IPSEN LTD | UK |
| IPSTYL 30mg/2ml polvere e solvente per sospensione iniettabile a rilascio prolungato | not available | 029399019 | IPSEN S.P.A. | IT |
| 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 |
| Somatuline PR 30 mg pulbere și solvent pentru suspensie injectabilii cu eliberare prelungită | not available | 10662/2018/01 | IPSEN PHARMA | RO |
| Somatuline Autogel 90 mg, süstelähus süstlis | not available | 442504 | IPSEN PHARMA | EE |
| Somatuline Autogel 120 mg, süstelähus süstlis | not available | 442704 | IPSEN PHARMA | EE |
| Somatuline Autogel 60 mg, süstelähus süstlis | not available | 442604 | IPSEN PHARMA | EE |
| Somatuline PR 30 mg, poeder en oplosmiddel voor suspensie voor injectie, met verlengde afgifte. | not available | RVG 21386 | IPSEN FARMACEUTICA B.V. | NL |
| 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 |

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| 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 |
| 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 |