

PATIENT SELF-INJECTION SUPPORT PROGRAMME



Somatuline® Autogel® is licensed for patient or carer administration*, giving patients the independence and flexibility to have greater control over their treatment after the appropriate training.

*The decision regarding administration by the patient or a trained person should be taken by a healthcare professional.

OUR COMMITMENT

Ipsen is fully committed to supporting patient choice, which is typified by our free programme to support patients who have been prescribed Somatuline® Autogel®. This patient support programme has been set up to meet the requirements of your patients at a difficult time in their lives.

For patients who are receiving treatment for acromegaly or the symptoms of a neuroendocrine tumour (NET) Somatuline® Autogel® is licensed for self or carer injection¹ *. Should you feel that this is an appropriate option for your patient, the Ipsen patient support programme can provide the necessary training to ensure your patients' complete confidence.

This service offers a team of nurses through our programme provider TCP, specialising in injection training, education and ongoing support for you and your patients.

TCP Homecare was first established in 2000 as a logistics company to deliver temperature sensitive pharmaceutical products to hospitals, GPs and patient homes in our patented fleet of temperature controlled vans. We have seen rapid expansion over this time to a position today where we employ over 165 people throughout the country and at our offices in Dublin. Operating a 365 day a year service, TCP Homecare are centrally involved in pharmacy dispensing, patient training, cold-chain drug delivery, administering treatment, patient support, compliance support and medical waste management on behalf of and under the care of the hospital team.

All nurse visits are arranged in advance by phone. The TCP Nurse will arrive at an arranged time, carry identification and be dressed in a navy blue TCP Homecare uniform.

This dedicated team of nurses are highly trained to help you to provide support to the level required by each individual patient. For example, a TCP nurse can give injection training to a patient, their carer or trusted friend, or to a practice nurse. The TCP nurse can visit your patient at home as many times as needed to ensure complete confidence, with ongoing telephone support through the TCP Patient Care Bureau.

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1. Somatuline Autogel® SmPC. Available at www.medicines.ie

PRACTICE NURSE TRAINING

TCP can also provide injection training and support to practice nurses if a patient prefers to have injections at their GP surgery. This can be organised by prior appointment with the GP/Practice Nurse.

While Somatuline® Autogel® injections are very simple to give, practice nurses may not be familiar with the product or the therapeutic indications, and often value guidance on the best way to administer the injection, as well as information on the condition it is being used to treat for their patient.

TCP nurses can provide training, education and support in all of these areas, helping to ensure that your patient continues to get the best possible care between visits with you and the other members of their hospital team. TCP nurses will always keep you fully up-to-date with any services that they have provided for your patient.

We recognise that it is vital to keep you up to date with the progress of your patients. After every visit, an evaluation of care report will be emailed to you in real time to let you know how your patient is doing. TCP aims to take away some of the pressures, but not control of your patient's care.

Seamless service is ensured by a team of highly trained Patient Service Coordinators, just a phone call away to address any issues or concerns that patients may have, although they are not able to answer specific medical questions. The team is available Monday to Friday, 8am to 5pm.

Sharps bins, provided as part of the self-injection service, are collected by TCP from the patient's home when full for safe disposal.

SELF-INJECTION TRAINING IN PRACTICE

You discuss with your patient the self-injection programme, then with their consent:

- Fill in a simple registration form
- Send to TCP as a scanned copy by email or via fax



- TCP will make contact with the patient within 24hrs of receipt of the referral form to arrange a training date. The training will take place within 5 days of the initial contact
- The TCP nurse will train the patient or carer on how to prepare for the injection, injection technique and disposal of the device in the sharps bin provided
- Following training an evaluation of care report will be sent to the prescribing doctor and/or nurses email address indicated on the referral form



- TCP will keep you fully informed if your patients have any interaction with the Patient Care Bureau

SOMATULINE® AUTOGEL®

Presented in the ready to use syringe:

- Available in pre-filled syringes avoiding the need for reconstitution and the potential problems of needle block¹
- 3 dose strengths (60mg, 90mg and 120mg) for administration via a deep subcutaneous injection

Indicated for the treatment of²:

- Long term treatment of acromegaly when the circulating levels of growth hormone and/or IGF-1 remain abnormal after surgery and/or radiotherapy or in patients who otherwise require medical treatment
- Relief of symptoms associated with acromegaly
- The treatment of G1 and a subset of G2 (Ki67 index < 10%) gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of midgut, pancreatic or unknown origin (where hindgut have been excluded), in adults with unresectable locally advanced or metastatic disease
- Treatment of symptoms associated with carcinoid tumours

Licensed for patient or carer administration*, giving patients the flexibility to have greater control over their treatment after the appropriate training

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1. Adelman D, Smith S, Liebert K et al. Time saving self- or partner-administration of lanreotide in acromegalic patients: results from the SALSA study. Poster presented at the 91st Annual Meeting of the Endocrine Society, Washington DC, USA, June 10-13 2009, P1-764
2. Somatuline® Autogel® SmPC. Available at www.medicines.ie

ABBREVIATED PRESCRIBING INFORMATION

Somatuline® Autogel® (lanreotide acetate) solution for injection in a pre-filled syringe. See full Summary of Product Characteristics before prescribing. Available at: www.medicines.ie Presentation: Pre-filled syringe containing a solution of lanreotide acetate 60, 90 or 120mg per syringe.

Indications: (1) The long-term treatment of acromegaly when the circulating levels of growth hormone (GH) and/or Insulin-like Growth Factor-1 (IGF-1) remain abnormal after surgery and/or radiotherapy, or in patients who otherwise require medical treatment. (2) Relief of symptoms associated with acromegaly. (3) The treatment of Grade 1 and a subset of Grade 2 (Ki67 index up to 10%) gastroenteropancreatic neuroendocrine tumours (GEP- NETs) of midgut, pancreatic or unknown origin (where hindgut have been excluded), in adults with unresectable locally advanced or metastatic disease. (4) Treatment of symptoms associated with carcinoid tumours. **Dosage:** *Acromegaly:* Starting dose 60 to 120mg administered via deep subcutaneous injection every 28 days. Dose individualised according to patient's response (judged by reduction in symptoms and/or reduction in GH and/or IGF-1 levels). If complete control is obtained, the dose may be decreased. Patients well controlled on a somatostatin analogue can be treated with Somatuline Autogel 120 mg every 42 or 56 days. *Neuroendocrine Tumours (NET) treatment:* The recommended dose is one injection of Somatuline Autogel 120mg administered every 28 days. Continue treatment for as long as needed for tumour control. *NET (carcinoid) symptoms:* Starting dose 60 to 120mg administered via deep subcutaneous injection every 28 days. Dose adjusted according to degree of symptomatic relief obtained. Patients well controlled on a somatostatin analogue can be treated with Somatuline Autogel 120mg every 42-56 days. There should be close monitoring of symptoms when treatment is switched to the extended dosing interval. *Elderly, renal and/or hepatic impairment:* No dose adjustment necessary due to the wide therapeutic window. *Paediatrics:* not recommended in children/adolescents due to lack of safety and efficacy data.

Method of Administration: Somatuline Autogel should be injected via deep subcutaneous route into the superior external quadrant of the buttock or in the upper outer thigh. For patients who receive a stable dose of Somatuline Autogel and after appropriate training, the injection may be given by the patient themselves or another trained person. In the case of self-injection, the injection should be given in the upper outer thigh. A healthcare professional should decide who should administer the injections. Regardless of the injection site, the skin should not be folded, and the needle should be inserted rapidly and to its full length, perpendicularly to the skin. The injection site should alternate between the right and left side. **Contraindications:** Hypersensitivity to lanreotide, somatostatin or related peptides or any of the excipients. **Warnings/Precautions:** May reduce gallbladder motility and lead to gallstone formation. Patients may require periodic monitoring. It is advised, during prolonged treatment, to perform before treatment and every 6 months, an echography of the gallbladder. There have been post-marketing reports of gallstones resulting in complications, including cholecystitis, cholangitis, and pancreatitis, requiring cholecystectomy in patients taking lanreotide. If complications of cholelithiasis are suspected, discontinue lanreotide and treat appropriately. Patients treated with Somatuline Autogel may experience hypo- or hyperglycaemia. Blood glucose levels should be monitored at the start of the treatment or when the dose is altered; and any anti-diabetic medication should be adjusted accordingly. Slight decreases in thyroid function have been observed in patients with acromegaly. Thyroid function tests are recommended where clinically indicated. Somatuline Autogel may lead to a decrease of heart rate in patients without underlying cardiac problems. Sinus bradycardia may occur in patients with pre-existing cardiac disorders. Care should be taken when initiating treatment in patients with bradycardia. Symptoms of pancreatic exocrine insufficiency (PEI) including steatorrhea, loose stools, abdominal bloating, and weight loss have been observed in patients receiving lanreotide treatment for GEP-NETs. Screening and appropriate treatment for PEI should be considered for symptomatic patients. In patients with acromegaly, use of lanreotide is not exempt from the monitoring of the volume of the pituitary tumour. **Interactions:** The pharmacological gastrointestinal effects of lanreotide may result in a reduction of the intestinal absorption of co-administered drugs including ciclosporin. Concomitant administration of ciclosporin with lanreotide may decrease the relative bioavailability of ciclosporin and therefore may necessitate the adjustment of ciclosporin dose to maintain therapeutic levels. Concomitant administration of bromocriptine may increase the bioavailability of bromocriptine. Concomitant administration of bradycardia inducing drugs (e.g., beta blockers) may have an additive effect on the slight reduction of heart rate associated with lanreotide. Dose adjustments of such concomitant medications may be necessary. The limited published data available indicate that somatostatin analogues may decrease clearance of drugs metabolised via CYP450 enzymes. Drugs with a low therapeutic index mainly metabolised via CYP3A4 (e.g. quinidine, terfenadine) should be used with caution. Dose adjustments of insulin and antidiabetics may be necessary when Somatuline is administered simultaneously. Risk of hypoglycaemia or hyperglycaemia: decrease in the needs of anti-diabetic treatment following decrease or increase in endogen glucagon secretions. The glycaemic self-monitoring must be reinforced and the posology of anti-diabetic treatment during treatment by lanreotide should be adapted as required. **Pregnancy/Lactation:** *Pregnancy:* Limited data indicate no adverse effects; only use in pregnancy if lanreotide is clearly needed. *Lactation:* Unknown whether lanreotide is excreted in breast milk; caution when administered during lactation. **Undesirable effects: Very common:** Diarrhoea, loose stools, abdominal pain, cholelithiasis. **Common:** Hypoglycaemia, decreased appetite, hyperglycaemia, diabetes mellitus, dizziness, headache, lethargy, sinus bradycardia, nausea, vomiting, constipation, flatulence, abdominal distension, abdominal discomfort, dyspepsia, steatorrhea, biliary dilatation, musculoskeletal pain, myalgia, alopecia, hypotrichosis, asthenia, fatigue, injection site reactions, ASAT increased, ALAT abnormal, blood bilirubin increased, blood glucose increased, glycosylated hemoglobin increased, weight decreased, pancreatic enzymes decreased. **Uncommon:** Insomnia, hot flushes, faeces discoloured, ASAT increased, blood alkaline phosphatase increased, blood bilirubin abnormal, blood sodium decreased. Post-marketing safety experience (frequency not known): Pancreatic exocrine insufficiency, pancreatitis, cholecystitis, cholangitis, injection site abscess, allergic reactions (including angioedema, anaphylaxis, hypersensitivity). *Prescribers should consult the Summary of Product Characteristics in relation to other side effects.* **Pharmaceutical Particulars:** Store in a refrigerator (2° C to 8°C) in the original package. Box of one 0.5ml prefilled syringe with automatic safety system and one needle. **Legal category:** POM. **Marketing Authorisation Number(s):** 60mg PA869/4/2, 90mg PA869/4/3, 120mg PA869/4/4. **Marketing Authorisation Holder:** Ipsen Pharmaceuticals Ltd, Blanchardstown Industrial Park, Blanchardstown, Dublin 15. Further information can be obtained from IPSEN Pharmaceuticals Ltd, Blanchardstown Industrial Park, Blanchardstown, Dublin 15, Ireland, Tel: (01)8098256. Somatuline® and Autogel® are registered trademarks. **Date of Preparation of PI:** July 2024. SOM-IE-000623.

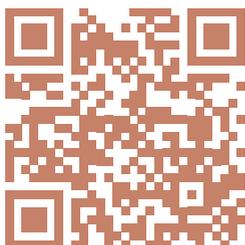
Adverse events should be reported.

Reporting forms and information can be found at www.hpra.ie or email medsafety@hpra.ie. The HPRA can also be contacted on 016764971. Adverse events should also be reported to Ipsen via email at pharmacovigilance.uk-ie@ipsen.com or phone on +441753 627777, IE phone 018098256.

Somatuline® Autogel® Patient Support Website

The following website contains information & resources for HCP's and patients about treatment with Somatuline® Autogel®, details about the Patient Support Programme, as well as videos on injection technique.

HCP ACCESS



www.focus-on-living.ie
Password: 454837

PATIENT ACCESS



www.focus-on-living.ie
Password: 97155

Further information

Contact Ipsen Medical Information Department
Tel: +353 1 8098256
Email: medical.information.uk@ipсен.com



Somatuline® autogel®
lanreotide

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