18th Annual Conference

UKINETS

IPSEN-sponsored Online Satellite Symposium

Thursday 3rd December 2020 - 14:45 – 15:45

NETs and Somatostatin Analogues: Moving Treatment from Hospital to Home

Chair: Professor Nick Reed

Agenda

Each presentation will be followed by a live Q&A

Speaker	Presentation
Dr Thomas Barber Associate Professor, Honorary Consultant Endocrinologist, University of Warwick, The ARDEN NET Centre, ENETS Centre of Excellence University Hospitals Coventry and Warwickshire	**Impact of COVID-19 on Neuroendocrine Tumour Services in England**
Dr David Mcintosh Consultant GI and Neuroendocrine Oncology, Beatson Oncology Centre (BOC), Glasgow	**Somatostatin Analogues in Neuroendocrine Tumours and Patient Independence**
Elizabeth Quaglia Lead Nurse – Neuroendocrine Tumours, Royal Free London NHS Foundation Trust	**Homecare Service Audit**

This webinar is for healthcare professionals only.

Attendance is open to all registered delegates.

This promotional symposium is organised and funded by Ipsen

SOMATULINE® AUTOGEL® Prescribing Information UK

Somatuline® Autogel® (lanreotide acetate) solution for injection in a pre-filled syringe
See full Summary of Product Characteristics (SmPC) before prescribing. Available at www.medicines.org.uk
Presentation: Pre-filled syringe containing a solution of lanreotide (as acetate) 60, 90 or 120mg per syringe. **Indications: (1)** Treatment of acromegaly when 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)** 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 sites have been excluded) in adults with unresectable locally advanced or metastatic disease. **(3)** Treatment of symptoms associated with neuroendocrine (particularly 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) up to a maximum of 120mg every 28 days. Patients well controlled on a somatostatin analogue can alternatively be treated with Somatuline Autogel 120 mg every 42-56 days (6 to 8 weeks). *GEP-NETs Treatment:* One deep subcutaneous injection of 120mg every 28 days for as long as needed for tumour control. *NET Symptoms:* Starting dose 60 to 120mg administered via deep subcutaneous injection every 28 days. The dose should be adjusted according to degree of symptomatic relief obtained. *Elderly, renal and/or hepatic impairment:* No dose modification necessary due to the wide therapeutic window. *Paediatric population:* The safety and efficacy in children and adolescents has not been established. **Method of administration:** Somatuline Autogel should be injected via the deep subcutaneous route into the superior external quadrant of the buttock or in the upper outer thigh. For patients who receive a stable dose, 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. **Precautions and warnings:** Somatuline Autogel may reduce gallbladder motility and lead to gallstone formation. Patients may require periodic monitoring. 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 Somatuline Autogel and treat appropriately. Patients treated with Somatuline Autogel may experience hypoglycaemia or hyperglycaemia. Blood glucose levels should be monitored at the start of treatment or when the dose is altered, and any anti-diabetic requirements 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 with underlying cardiac problems, and sinus bradycardia in those with cardiac disorders. Care should be taken when initiating treatment in patients with bradycardia. **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 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. **Pregnancy and lactation:** Somatuline Autogel should be administered to pregnant women only if clearly needed and caution exercised when administered during lactation. **Undesirable effects:** *Very common:* diarrhoea, loose stools, abdominal pain, cholelithiasis. *Common:* ALAT increased, ASAT abnormal, ALAT abnormal, blood bilirubin increased, blood glucose increased, glycosylated haemoglobin increased, weight decreased, pancreatic enzymes decreased, nausea, vomiting, constipation, flatulence, abdominal distension, abdominal discomfort, dyspepsia, steatorrhoea, sinus bradycardia, dizziness, headache, lethargy, alopecia, hypothrichosis, hypoglycaemia, decreased appetite, hyperglycaemia, diabetes mellitus, asthenia, fatigue, injection site reactions (pain, mass, induration, nodule, pruritus), biliary dilatation, musculoskeletal pain, myalgia. Post-marketing: Pancreatitis, allergic reactions (including angioedema, anaphylaxis, hypersensitivity), injection site abscess, cholecystitis and cholangitis. *Prescribers should consult the Summary of Product Characteristics in relation to other side effects.* **Pharmaceutical precautions:** Store in a refrigerator between 2º and 8ºC in the original package. **Legal category:** POM. **Basic NHS cost:** 60mg £551; 90mg £736; 120mg £937. **Packs quantity:** Each box contains one 0.5ml pre-filled syringe with automatic safety system and one needle. **Marketing authorisation numbers:** 60mg PL 34926/0005, 90mg PL 34926/0006 and 120mg PL 34926/0007. **Marketing authorisation holder:** IPSEN Ltd, 190 Bath Road, Slough, Berkshire, SL1 3XE. Further information can be obtained from IPSEN Ltd, 190 Bath Road, Slough, Berkshire, SL1 3XE. Tel: 01753 627777. Somatuline® and Autogel® are registered trademarks. **Date of preparation of PI**: October 2020. **SOM-UK-004795**

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store.
Adverse events should also be reported to the Ipsen Medical Information department on 01753 627777 or medical.information.uk@ipsen.com

SOMATULINE® AUTOGEL® Prescribing Information Ireland

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] Long-term treatment of acromegaly when the remaining 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. Previous treatment with other lanreotide acetate preparations affect suggested starting dose. 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 or Somatuline Autogel 120mg given every 42-56 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. *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. 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 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. **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. **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:* Nausea, vomiting, constipation, flatulence, abdominal distension, abdominal discomfort, dyspepsia, steatorrhoea, sinus bradycardia, hypoglycaemia, decreased appetite, hyperglycaemia, diabetes mellitus, alopecia, hypotrichosis, musculoskeletal pain, myalgia, dizziness, headache, lethargy, fatigue, asthenia, injection site reactions (pain, mass, induration, nodule, pruritus), biliary dilatation, ALAT increased, ASAT abnormal, ALAT abnormal, blood bilirubin increased, decreased weight, blood glucose increased, glycosylated haemoglobin increased, pancreatic enzymes decreased. *Post-marketing:* Pancreatitis, allergic reactions (including angioedema, anaphylaxis, hypersensitivity), injection site abscess, cholecystitis and cholangitis. *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:** October 2020. SOM-IE-000324.

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 +35316764971.
Adverse events should also be reported to the Ipsen Medical Information Department on +35318098256 or medical.information.uk@ipsen.com