16th October 2020, Glen Waverley

Ipsen Pty Ltd ("IPSEN") statement on the discontinuation of **Somatuline® LA 30mg (lanreotide acetate)** on 15th December, 2020.

To Whom It May Concern:

IPSEN has notified the Therapeutic Goods Administration (TGA) that as of **15th December, 2020**, Somatuline® LA 30mg (lanreotide acetate) **will no longer be supplied** in Australia (due to the low volume of requests and the presence of a suitable replacement, Somatuline® Autogel®). A notice of the discontinuation of the product will be published on both the IPSEN Australia website and the TGA website.

Somatuline® LA 30mg is currently approved for the ***treatment of acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy or in patients who are dopamine agonist treatment refractory***.[1]

To ensure ongoing supply of lanreotide to Australian patients, IPSEN have an alternate presentation of lanreotide: Somatuline® Autogel® (lanreotide as acetate) in 60mg/90mg/120mg solution for injection in a ready-to-use prefilled syringe[2].

The indications[2] for Somatuline® Autogel® are:

- the treatment of acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy or in patients who are dopamine agonist treatment refractory
- the treatment of symptoms of carcinoid syndrome associated with carcinoid tumours
- the treatment of gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adult patients with unresectable locally advanced or metastatic disease.

While the formulations are different, the active ingredient of Somatuline® LA 30mg and Somatuline® Autogel® 60mg/90mg/120mg solution for injection prefilled syringe, is identical (**lanreotide acetate**)[1,2]. Somatuline® LA is formulated as a prolonged-release depot suspension for intramuscular injection[1]. Somatuline® Autogel® is formulated as a prolonged-release solution for deep subcutaneous injection[2].

In patients previously treated with Somatuline® LA once every 14 days for acromegaly, the initial dose of Somatuline® Autogel® should be 60mg every 28 days. Please refer to the Somatuline® Autogel® Product Information for more information on transitioning patients[2].

Somatuline® Autogel® is available on the Pharmaceutical Benefits Scheme. Additional detail is provided below, however we recommend that you consult the PBS (www.pbs.gov.au) for further information regarding the availability of Somatuline® Autogel®.

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SEPT 2020, SOM-AU-000801

Should you require further information regarding the discontinuation of Somatuline® LA 30mg, please contact the IPSEN Medical Information Department on 1800 317 033.

Respectfully,

Gina Kladis
Neuroscience & Rare Disease Business Unit Head

Alan Paul
Medical Director

PBS Information: Authority required (STREAMLINED). This product is a highly specialised drug listed on the PBS as a Section 100 item. Refer to PBS Schedule for full authority information.

Before prescribing please refer to full Product Information which is available from Ipsen Medical Information. Ph: 1800 317 033 or from Somatuline® Autogel® Product Information:
http://www.guildlink.com.au/gc/ws/ipsen/pi.cfm?product=ispsatgi
Somatuline® LA 30mg Product Information: http://www.guildlink.com.au/gc/ws/ipsen/pi.cfm?product=ispsomai

Somatuline® Autogel®: Lanreotide as acetate in a pre-filled syringe (60, 90 and 120 mg). **Indications**: Treatment of acromegaly when circulating growth hormone and IGF-1 levels remain abnormal after surgery and/or radiotherapy or in patients who have failed dopamine agonist therapy; the treatment of symptoms of carcinoid syndrome associated with carcinoid tumours; the treatment of gastroenteropancreatic neuroendocrine tumours (GEPNETs) in adult patients with unresectable locally advanced or metastatic disease. **Contraindications**: Lactation; hypersensitivity to lanreotide or related peptides or other excipients. **Precautions**: May experience hypoglycaemia or hyperglycaemia (monitor blood glucose levels); slight decrease in thyroid function; may reduce gall bladder motility (recommend gall bladder echography); monitor kidney and liver function; may reduce heart rate in patients without an underlying cardiac problem (monitor heart rate; caution with treatment initiation in patients with bradycardia). Not recommended for use in children. See full PI for further information. **Interactions with Other Medicines**: Reduced absorption of cyclosporin A, decreased bioavailability of cyclosporine, increased availability of bromocriptine, additive bradycardia effects with beta-blockers, decreased clearance of quinidine, terfenadine. **Effect on driving / using machinery**: If affected by dizziness do not drive or use machinery. **Adverse Effects**: Very common: diarrhoea or loose stools, abdominal pain, cholelithiasis; Common: hypoglycaemia, hyperglycaemia, diabetes mellitus aggravated, fatigue, lethargy, asthenia, dizziness, headache, sinus bradycardia, alopecia, hypotrichosis, nausea, vomiting, dyspepsia, flatulence, abdominal distension, abdominal discomfort, constipation, biliary dilatation, steatorrhoea, injection site reactions (pain, mass, induration, nodule, pruritis), laboratory investigation changes, weight decreased, decreased appetite, musculo-skeletal pain, myalgia. See full PI for further information. **Dose**: Acromegaly: For first time treatment the starting dose is 60 mg every 28 days; for patients previously treated with Somatuline LA every 14, 10 or 7 days, the starting dose is 60 mg, 90 mg or 120 mg respectively every 28 days. Dosage should be adjusted according to GH and/or IGF-1 response. Patients well controlled on lanreotide can be treated with 120mg every 42-56 days. Carcinoid Syndrome: 60 to 120 mg every 28 days, adjusted according to symptomatic relief. GEP-NETs: 120mg every 28 days; treatment should be continued for as long as needed for tumour control. **Administration**: Deep subcutaneous injection in the superior external quadrant of the buttock (healthcare professional or carer); or the upper, outer thigh (self-administration). Decision for injection by patient or carer to be made by a healthcare professional. Patients must be controlled on Somatuline Autogel and patients/carers must be motivated, competent and trained to inject. **Storage**: 2-8°C.

References:

1. Somatuline® LA Product Information
2. Somatuline® Autogel® Product Information

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