Lupin Group Company

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DD MMM 2024

Dear Healthcare Professional,

Shortage of and alternative supply of the following medicines under Section 19A of the Therapeutic Goods Act 1989.

- **Octreotide GH octreotide as acetate 50 mcg/1 mL injection ampoule (AUST R 148404)**
- **Octreotide GH octreotide as acetate 100 mcg/1mL injection ampoule (AUST R 148402)**
- **Octreotide GH octreotide as acetate 500 mcg/ 1mL injection ampoule (AUST R 148403)**

The Australian registered medicines mentioned above, sponsored by Generic Health are in short supply due to a worldwide shortage of the active ingredient. Supply of Octreotide GH Injection is expected to resume in 2025.

Generic Health has been able to arrange supply of alternative products on a temporary basis:

- **Octreotide Acetate Omega 50mcg/mL solution for injection single use vials (Canada)**
- **Octreotide Acetate Omega 100mcg/mL solution for injection single use vials (Canada)**
- **Octreotide Acetate Omega 500mcg/mL solution for injection single use vials (Canada)**

These products are NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until [expiry date of the notice of approval] for the following indication(s):

- For symptomatic control and reduction of growth hormone and IGF-1 plasma levels in patients with acromegaly, including those who are inadequately controlled by surgery, radiotherapy, or dopamine agonist treatment. Octreotide treatment is also indicated in acromegalic patients unfit or unwilling to undergo surgery, or in the interim period until radiotherapy becomes fully effective.
- For the relief of symptoms associated with the following functional tumours of the gastro-entero-pancreatic endocrine system:
  - Carcinoid tumours with features of the carcinoid syndrome;
  - Vasoactive intestinal peptide secreting tumours (VIPomas).

  Octreotide is not curative in these patients.
- For reduction of the incidence of complications following pancreatic surgery.

Octreotide Acetate Omega 50mcg/mL solution for injection single use vials (Canada), Octreotide Acetate Omega 100mcg/mL solution for injection single use vials (Canada) and Octreotide Acetate Omega 500mcg/mL solution for injection single use vials (Canada) are registered and marketed in Canada**.**

Southern Cross Pharma
Lupin Group Company

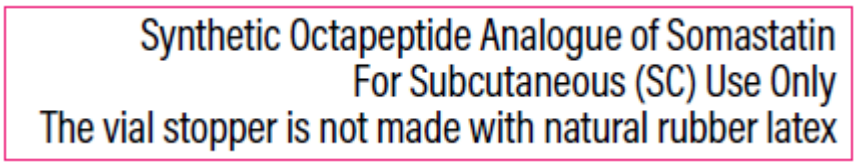
LUPIN

Please note the following information regarding the differences between:

- **Octreotide GH octreotide as acetate 50 mcg/1 mL injection ampoule (AUST R 148404), Octreotide GH octreotide as acetate 100 mcg/1mL injection ampoule (AUST R 148402) and Octreotide GH octreotide as acetate 500 mcg/ 1mL injection ampoule (AUST R 148403); and**
- **Octreotide Acetate Omega 50mcg/mL solution for injection single use vials (Canada), Octreotide Acetate Omega 100mcg/mL solution for injection single use vials (Canada) and Octreotide Acetate Omega 500mcg/mL solution for injection single use vials (Canada).**

	ARTG product	S19A product
Product Name	**Octreotide GH octreotide as acetate 50 mcg /1 mL injection (Generic Health)** **Octreotide GH octreotide as acetate 100 mcg /1 mL injection (Generic Health)** **Octreotide GH octreotide as acetate 500 mcg /1 mL injection (Generic Health)**	**Octreotide Acetate Omega 50mcg/mL solution for injection single use vials (Canada)** **Octreotide Acetate Omega 100mcg/mL solution for injection single use vials (Canada)** **Octreotide Acetate Omega 500mcg/mL solution for injection single use vials (Canada)**
Presentation	5 x 1mL ampoules in each box Outer packaging and ampoules labelled 'For subcutaneous administration'.	5 x 1mL vials in one carton Carton labelled 'Subcutaneous (SC) / Intravenous (IV) Infusion Use' Vials marked 'SC / IV INFUSION'
Route of administration	For Subcutaneous administration	Subcutaneous and intravenous administration
Excipients	Dilute hydrochloric acid, glycine, mannitol and water for injections	Glacial acetic acid, sodium acetate trihydrate, sodium chloride and water for injection

Please note that the section 19A-approved product includes the following overlabel:



Please refer to the Australian Product Information pdf (tga.gov.au) or from the products sections of our company website www.generichealth.com.au/product-listing for information on recommended dosage and administration.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Octreotide Acetate Omega 50mcg/mL solution for injection single use vials (Canada), Octreotide Acetate Omega 100mcg/mL solution for injection single use vials (Canada) and Octreotide Acetate Omega 500mcg/mL solution for injection single use vials (Canada)** should be reported by healthcare professionals and patients to the Medical Information team on 03 9809 7900 or via email on mailto:customer.service@generichealth.com.au. Alternatively, this information can be reported to the TGA.

For further information, please contact Generic Health via the following means:

Customer Service Team	03 9809 7900 or customer.service@generichealth.com.au	Customer Support including product availability
Medical Information Team	03 9809 7900 or qaproductsafety@generichealth.com.au	Medical enquiries

Please forward this information to relevant staff members in your organisation.

For further information, please contact the Generic Health Medical Information Team on Ph: (03) 9809 7900 or mailto:ghinfo@generichealth.com.au.

Yours sincerely,

Medical Information Team

Generic Health Pty Limited