



Lupin Group Company

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1 May 2024

Dear Healthcare Professional

**RE: Shortage 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 solution for injection ampoule (AUST R 148404)**
- **Octreotide GH octreotide (as acetate) 100 mcg/1 mL solution for injection ampoule (AUST R 148402)**
- **Octreotide GH octreotide (as acetate) 500 mcg/1 mL solution for 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 is expected to resume in 2025.

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

- **Octreotide Acetate Omega octreotide acetate 50 mcg/mL solution for injection single use vials (Canada)**
- **Octreotide Acetate Omega octreotide acetate 100 mcg/mL solution for injection single use vials (Canada)**
- **Octreotide Acetate Omega octreotide acetate 500 mcg/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 **30 April 2025** 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 octreotide acetate 50 mcg/mL solution for injection single use vials (Canada), Octreotide Acetate Omega octreotide acetate 100 mcg/mL solution for injection single use vials (Canada) and Octreotide Acetate Omega octreotide acetate 500 mcg/mL solution for injection single use vials (Canada)** are registered and marketed in Canada.

Please note the information on the following page regarding the differences (highlighted in yellow) between **Octreotide GH octreotide (as acetate) solution for injection ampoule** and the alternative product **Octreotide Acetate Omega octreotide acetate solution for injection single use vials (Canada)**.

	ARTG Product	S19A Product
<b>Product Name</b>	Octreotide GH octreotide (as acetate) 50 mcg/1 mL solution for injection ampoules (Generic Health)  Octreotide GH octreotide (as acetate) 100 mcg/1 mL solution for injection ampoules (Generic Health)  Octreotide GH octreotide (as acetate) 500 mcg/1 mL solution for injection ampoules (Generic Health)	Octreotide Acetate Omega octreotide acetate 50 mcg/mL solution for injection single use vials (Canada)  Octreotide Acetate Omega octreotide acetate 100 mcg/mL solution for injection single use vials (Canada)  Octreotide Acetate Omega octreotide acetate 500 mcg/mL solution for injection single use vials (Canada)
<b>Presentation</b>	5 x 1mL <b>ampoules</b> in each carton. Product labelling for carton and ampoules states <b>'For subcutaneous administration'</b> .	5 x 1mL <b>vials</b> in each carton. Product labelling for carton states <b>'Subcutaneous (SC) / Intravenous (IV) Infusion Use'</b> . Product labelling for vials states <b>'SC / IV INFUSION'</b> .
<b>Route of Administration</b>	<b>For Subcutaneous administration.</b>	<b>Subcutaneous and intravenous administration.</b>
<b>Excipients</b>	<b>Dilute hydrochloric acid, glycine, mannitol</b> and water for injection.	<b>Glacial acetic acid, sodium acetate trihydrate, sodium chloride</b> and water for injection.
<b>Storage Conditions for Unopened Product</b>	Store at 2-8°C. (Refrigerate. Do not freeze.) Protect from light.	Store at 2-8°C. Do not freeze. Protect from light.

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

Synthetic Octapeptide Analogue of Somastatin  
For Subcutaneous (SC) Use Only  
The vial stopper is not made with natural rubber latex

Please refer to the Australian Product Information available on the TGA website at [www.ebs.tga.gov.au](http://www.ebs.tga.gov.au) or from the Our Products section of our company website [www.generichealth.com.au/product-listing](http://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 octreotide acetate 50 mcg/mL solution for injection single use vials (Canada)**, **Octreotide Acetate Omega octreotide acetate 100 mcg/mL solution for injection single use vials (Canada)** or **Octreotide Acetate Omega octreotide acetate 500 mcg/mL solution for injection single use vials (Canada)** should be reported by healthcare professionals and patients to Generic Health's Medical Information team on 03 9809 7900 or via email at [qaproductsafety@generichealth.com.au](mailto:qaproductsafety@generichealth.com.au). Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

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

	<b>Contact Details</b>	<b>For Queries Regarding</b>
<b>Customer Service Team</b>	03 9809 7900 or <a href="mailto:customer.service@generichealth.com.au">customer.service@generichealth.com.au</a>	Customer support including product availability
<b>Medical Information Team</b>	03 9809 7900 or <a href="mailto:gaproductsafety@generichealth.com.au">gaproductsafety@generichealth.com.au</a>	Medical information enquiries or reporting adverse events

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

Yours sincerely,

**Medical Information Team**  
**Generic Health Pty Limited**