

5.25 SOMATROPIN

Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative), SciTropin A™, SciGen (Australia) Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought the re-listing of a previously listed somatropin product, which was removed from the PBS on 1 September 2017, and now re-marketed by a new sponsor under a new brand name.

2 Requested listing

- 2.1 The submission sought the same listing (restriction and price per mg) as the previously-listed somatropin product, Omnitrope® which is identical to SciTropin A™.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Background

- 3.1 Omnitrope® branded somatropin 5 mg/1.5ml injection is a recombinant human growth hormone previously marketed by Sandoz that was de-listed from the PBS on 1 September 2017.

- 3.2 Sandoz subsequently licensed the marketing rights for Omnitrope® somatropin 5 mg/1.5ml to SciGen (Australia) Pty Ltd and it is currently available under the trade name SciTropin A™.

- 3.3 The pharmacological and clinical characteristics, dosage and administration, composition (active ingredients and excipients), manufacturing processes, and indications for SciTropin A™ somatropin 5 mg/1.5ml and Omnitrope® somatropin 5 mg/1.5ml are identical.

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Estimated PBS usage & financial implications

- 4.3 The minor submission estimated there to be no financial implications to the PBS/changes in PBS usage as the drug involves the re-listing of a previously-listed somatropin product, and as such those patients previously treated by Omnitrope® 5mg/1.5ml will be replaced by Scitropin A™ 5mg/1.5ml. Furthermore, the market for somatropin is well established with several brands currently PBS listed, and somatropin is in the F2 formulary.

5 PBAC Outcome

- 5.1 The PBAC recommended the re-listing of 5 mg (15 i.u.) in 1.5 mL form of somatropin under the SciTropin A brand in the Section 100 Growth Hormone Programme under the same conditions under the same conditions for which the Omnitrope® brand was listed.
- 5.2 The PBAC noted that this brand of somatropin sought the same listing as the previously listed product, Omnitrope®, which was removed from the PBS on 1 September 2017, and is now re-marketed by SciGen (Australia) Pty Ltd under a new brand name, SciTropin A.
- 5.3 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Add new items:

Restrictions not reproduced in full due to size and complexity. Restrictions to be the same as Omnitrope Surepal 5 PBS listings, item codes 10507B, 10512G, 10518N.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
SOMATROPIN 5 mg/1.5 mL injection, 1.5 mL cartridge	1	1	SciTropin A	SciGen (Australia) Pty Ltd

Category / Program	Section 100 – Growth Hormone Program
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Episodicity:	
Severity:	
Condition:	Short stature and slow growth
PBS Indication:	Short stature and slow growth

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.