

14.02 Insect allergen extract-honey bee venom, Injection set containing 550 micrograms with diluent, Hymenoptera Honey Bee Venom®, Stallergenes Australia Pty Ltd

Insect allergen extract-yellow jacket venom, Injection set containing 550 micrograms with diluent, Hymenoptera Yellow Jacket Venom®, Stallergenes Australia Pty Ltd

Insect allergen extract-paper wasp venom, Injection set containing 550 micrograms with diluent, Hymenoptera Paper Wasp Venom®, Stallergenes Australia Pty Ltd

1 Purpose of Application

- 1.1 To request listing of insect allergen extract - honey bee venom, yellow jacket venom and paper wasp venom.
- 1.2 The sponsor requested listing of these substitute products as a replacement form of the currently listed bee venom, paper wasp venom and yellow jacket venom products which due to a shortage of supply.

2 Consideration of the evidence

- 2.1 The sponsor had been unable to guarantee supply of the currently listed Albey Honey Bee Venom (PBS item 2886X), Albey Paper Wasp Venom (2918N), and Albey Yellow Jacket Venom (2883R).
- 2.2 The sponsor has arranged to supply alternative Jubilant HollisterStier equivalent stock for the out of stock products for six months under Section 19A of the Therapeutic Goods Act 1989. These replacement products are presented in a slightly different form to the currently listed product, necessitating a new listing on the PBS.
- 2.3 The President of the Australasian Society of Clinical Immunology and Allergy (ASCIA) wrote to the PBAC Chair expressing support for the expedited listing of these replacement products and emphasising their life saving nature.

3 PBAC Outcome

- 3.1 The PBAC recommended listing the new forms of insect allergen extract-bee venom, insect allergen extract-paper wasp venom, and insect allergen extract-yellow jacket venom on the PBS on the basis of equivalent cost to the currently listed respective venom products.
- 3.2 The PBAC recommended that these new listings should be consistent with that for the currently listed venom products.

- 3.3 The PBAC noted the correspondence from the President of the Australasian Society of Clinical Immunology and allergy (ASCIA) expressing support for the expedited listing of these replacement products and emphasising their life saving nature.
- 3.4 The PBAC considered that there is a clinical need for the supply of these venoms to be maintained on the PBS. The PBAC further considered that the listing should remain during the validity of the Section 19A approval by the TGA. For a longer term listing of the product, a submission to the PBAC would be required.
- 3.5 The PBAC advised, at this time and due to the circumstances of this temporary listing, under Section 101 (3BA) of the National Health Act, these venoms should be not treated as interchangeable on an individual patient basis with any other drug, and Hymenoptera brand of venom and Albey brand of venom should not be considered equivalent for the purposes of substitution.

Outcome:

Recommended

4 Recommended listing

4.1 Add new items:

| Name, Restriction, Manner of administration and form | Max. Qty | No. of Rpts | Proprietary Name and Manufacturer | |
|--|-------------|----------------|-----------------------------------|--------------------------------------|
| BEE VENOM 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack | 1 | 0 | Hymenoptera Bee Venom | Stallergenes Australia Pty Ltd |

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|---------------------------|---|--|--|--|
| Category / Program | GENERAL – General Schedule (Code GE) | | | |
| 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 | | | |

| Name, Restriction, Manner of administration and form | Max. Qty | No. of Rpts | Proprietary Name and Manufacturer | |
|---|-------------|----------------|-----------------------------------|--------------------------------------|
| PAPER WASP VENOM 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack | 1 | 0 | Hymenoptera Paper Wasp Venom | Stallergenes Australia Pty Ltd |

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|------------------------------|---|--|--|--|
| Category / Program | GENERAL – General Schedule (Code GE) | | | |
| 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 | | | |
| Administrative Advice | Paper wasp venom is not European wasp venom | | | |

Public Summary Document – March 2016 PBAC Meeting

| Name, Restriction, Manner of administration and form | Max. Qty | No. of Rpts | Proprietary Name and Manufacturer | |
|---|-------------|----------------|------------------------------------|--------------------------------------|
| VESPULA SPP VENOM 550 microgram injection [1 vial] (& inert substance diluent [9 mL vial], 1 pack | 1 | 0 | Hymenoptera Yellow Jacket Venom | Stallergenes Australia Pty Ltd |

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|-----------------------|---|
| Category / Program | GENERAL – General Schedule (Code GE) |
| 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 |

5 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.

6 Sponsor's Comment

The sponsor had no comment.