

5.21 MUPIROCIN

Nasal ointment 20 mg (as calcium) per g, 5 g Medsurge mupirocin nasal ointment, Medsurge Healthcare Pty Ltd.

1 Purpose of Application

- 1.1 The submission requested an Authority Required (STREAMLINED) listing of a new form of mupirocin 2% nasal ointment in a larger pack size of 5g, on the General Schedule for the treatment of nasal colonisation of staphylococcus aureus infection in Aboriginal and Torres Strait Islander persons. This was the first submission to the PBAC for Medsurge mupirocin nasal ointment (Medsurge from herein) in a 5g pack size.

2 Requested listing

- 2.1 The same listing as the currently listed pack of mupirocin 2% nasal ointment, 3g (Bactroban®) was sought.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
MUPIROCIN 2% ointment, 5g	1	0	\$25.00	Medsurge mupirocin nasal ointment	Medsurge Healthcare Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Staphylococcus aureus infection
PBS Indication:	Staphylococcus aureus infection
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have nasal colonisation with the bacteria
Population criteria:	Patient must be an Aboriginal or a Torres Strait Islander person

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Administrative advice:	Note: No increase in the maximum quantity or number of units may be authorised.
	Note: No increase in the maximum number of repeats may be authorised.

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

3 Background

Registration status

- 3.1 Mupirocin 2% ointment (Medsurge) in 3g and 5g pack sizes was registered with the TGA on 5 April 2019 for the elimination of nasal carriage of staphylococci, including methicillin resistant staphylococcus aureus (MRSA). The TGA established that Medsurge brand can be considered bioequivalent to Bactroban® brand mupirocin nasal ointment. Only the 5g pack size requested to be listed on the PBS.
- 3.2 Mupirocin 2% nasal ointment, 3g (Bactroban®) was listed on the PBS on 1 July 2009 for the treatment of nasal colonisation of staphylococcus aureus infection in Aboriginal and Torres Strait Islander persons.

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 sponsor proposed an AEMP of \$12.57. This proposed AEMP of Medsurge mupirocin ointment, 5g is the same as the AEMP of Bactroban® nasal ointment, 3g.
- 4.4 As the two pack sizes were proposed to be priced the same, there is likely to be no financial implications to the PBS as mupirocin 2% ointment, 5g (Medsurge) is expected to only substitute for mupirocin 2% nasal ointment, 3g (Bactroban®).
- 4.5 The Secretariat examined the number of prescriptions dispensed for mupirocin 2% nasal ointment (Bactroban®, item 9440W). A six month cohort of patients first initiating on the medicine was selected from December 2017 to May 2018. This allowed at least a 12 month follow-up period to the most current data at the time of the analysis (April 2019), based on the date of supply. The number of prescriptions dispensed per patient was counted over a 12 month period from the date of the patient's first initiation. For this initiating cohort (n=1,510), 94 patients (6.2%) were

dispensed more than one script of mupirocin 2% nasal ointment (Bactroban®) within 12 months of their first script. This is likely to indicate that across the population the need for a second prescription is low, and is expected to constitute a small population even upon the prospective listing of the 5g pack size. The listing is therefore unlikely to result in any quantifiable savings to the PBS. The Secretariat provided utilisation data for Bactroban®. This showed that between 2015 and 2018, script numbers varied from 6,190 to 12,490 per year with no clear trend in utilisation.

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

5 PBAC Outcome

- 5.1 The PBAC recommended the Section 85 Authority Required (STREAMLINED) listing of a new presentation of mupirocin, in the form 2% nasal ointment 5g (Medsurge) as an alternative to the currently listed mupirocin 2% nasal ointment, 3g (Bactroban®) for the treatment of nasal colonisation of staphylococcus aureus infection in Aboriginal and Torres Strait Islander persons.
- 5.2 The PBAC noted that the TGA had accepted that bioequivalence had been established between the Medsurge mupirocin nasal ointment, 5g and the Bactroban®, 3g products.
- 5.3 The PBAC noted that the sponsor had proposed the same price as the currently listed 3g pack size of Bactroban®.
- 5.4 The PBAC noted the utilisation data for PBS-subsidised Bactroban® between 2015 and 2018 and considered that it was difficult to estimate of utilisation and financial impact from listing the alternative brand. The PBAC noted that use of the currently listed Bactroban® brand was moderate and considered that the estimated utilisation and financial impact to the PBS were unlikely to be substantially altered by the addition of the new brand to the PBS, as current use showed that most patients do not receive a second prescription of mupirocin under the current listing. The PBAC therefore considered that listing of mupirocin 2% ointment (Medsurge) in a larger pack size of 5g was not expected to result in financial implications to the PBS/RPBS.
- 5.5 The PBAC considered that listing of a larger pack size of mupirocin was unlikely to increase the risk of developing antimicrobial resistance in community settings.
- 5.6 The PBAC advised that mupirocin 2% ointment, 5g (Medsurge) was suitable for prescribing by nurse practitioners, consistent with the listing for Bactroban® nasal ointment, 3g.
- 5.7 The PBAC recommended that the Early Supply Rule should not apply, which was consistent with the currently listed Bactroban® nasal ointment, 3g.
- 5.8 The PBAC noted that its recommendation was for a new form of an already listed drug and advised that because the recommended listing was not expected to alter the efficacy or toxicity of the treatment, or address a high and urgent unmet clinical need,

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the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.

- 5.9 The PBAC noted that this submission is not eligible for an Independent Review, as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

- 6.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
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Category / Program	GENERAL – General Schedule (Code GE)
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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.