

5.21 MILK POWDER - LACTOSE INTOLERANCE FORMULA

Oral liquid: powder for, 900 g can, S-26[®] Original LI, Aspen Pharmacare Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested a change in trade name and formulation from S-26[®] LF (milk powder lactose free formula) to S-26[®] Original LI (milk powder lactose intolerance formula).

2 Requested Listing:

- 2.1 The submission requested the following changes to the existing listing. Suggested deletions proposed by the Secretariat are crossed out with ~~strike through~~:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
MILK POWDER - LACTOSE INTOLERANCE FORMULA Oral liquid: powder for, 900g can	5	0	\$102.38	S-26 [®] Original LI	Aspen Pharmacare Australia 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:	Acute lactose intolerance Proven chronic lactose intolerance
PBS Indication:	Acute lactose intolerance Proven chronic lactose intolerance
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Population criteria:	Patient must be up to the age of 12 months.
Prescriber Instructions	The date of birth of the patient must be included in the authority application.

For more detail on PBAC's view, see section 6 "PBAC outcome"

3 Background

- 3.1 The sponsor of S-26[®] Original LI confirmed that it meets the requirements for foods that have medical purposes as set out under *The Australia New Zealand Food Standards Code* — Standard 2.9.5: Food for Special Medical Purposes.
- 3.2 The original product was formulated to comply with “*Federal Register of Legislative Instruments F2014C01200, Australia New Zealand Food Standards Code - Standard 2.9.1 - Infant Formula Products*”.
- 3.3 In April 2012, Aspen acquired the “S-26” range of products from Nestle, which led to a change of the manufacture site from Ireland to Mexico.
- 3.4 As a result of the change to the manufacturing site, the product’s proposed lactose level will be 0.0034 g /100 mL (5.0 mg / 100 kcal). The sponsor claims that this level is clinically insignificant.
- 3.5 The new formulation contains L-cysteine, while S-26[®] LF did not previously.
- 3.6 S-26[®] Original LI has not been considered by PBAC previously. S-26[®] LF was originally listed on the PBS in August 1995. The PBAC has previously considered changes to the S-26[®] LF listing in July 2007 and to continue the listing of S-26[®] LF at the March 2008 PBAC meeting.

For more detail on PBAC’s view, see section 6 “PBAC outcome”

4 Comparator

- 4.1 As a minor submission, there was no economic comparison.

5 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Clinical trials

- 5.3 As a minor submission, no clinical trials were presented in the submission.
- 5.4 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted:

- The proposed change to the existing listing was clinically and nutritionally appropriate, with suitable restriction criteria.
 - The change in trade name and formulation required the currently listed S-26[®] LF be delisted and replaced by S-26[®] Original LI.
 - The submission stated an increase in lactose levels, compared to the original formulation, due to a change in the manufacturer site. The NPWP had no safety concerns over the 0.0034 g /100 mL amount of lactose in the new formulation, as they deemed it a non-clinically relevant amount.
 - As the sponsor did not provide a requested PBS listing, the PBAC Secretariat assumed that the proposed listing of S-26[®] Original LI was equivalent to the currently-listed S-26[®] LF.
 - The current PBS indications for S-26[®] LF include “proven chronic lactose intolerance” for infants up to the age of 12 months. The NPWP suggested that the use of chronic lactose intolerance is an error in the indication, and that the new formulation should be listed for the same indication as S-26[®] LF.
 - The NPWP noted the change in formulation to “lactose intolerance formula” and suggested that similar PBS-listed formulations - such as “lactose-free formula”, “lactose modified pre-digested”, or “lactose free formula pre-digested” – should be grouped within this new formulation.
- 5.5 The NPWP supported the delisting of S-26[®] LF and the listing of S-26[®] Original LI as a written Authority Required for acute lactose intolerance on a cost-minimisation basis, against S-26[®] Original LI at an equivalent dispensed price for maximum quantity (DPMQ).

For more detail on PBAC’s view, see section 6 “PBAC outcome”

Clinical claim

- 5.6 In the pre-PBAC response (p1), the sponsor requested that S-26[®] Original LI be listed for both acute and proven chronic lactose intolerance to maintain consistency. The sponsor stated that the currently-listed S-26[®] LF includes both indications, as do other milk formulas for lactose intolerance on the PBS, such as Aptamil Gold+ De-Lact[®]. The pre-PBAC response also noted that listing the product as a treatment for chronic lactose intolerance will allow up to 5 repeats of 5 cans, compared to no repeats under the “acute lactose intolerance” indication.

Estimated PBS usage & financial implications

- 5.7 The sponsor has not proposed any pricing changes. The current approved ex-manufacturer price (AEMP = \$17.10) and dispensed price maximum quantity (DPMQ = \$102.38) would therefore apply to the new listing.

- 5.8 The sponsor did not provide an estimate of financial cost however, the Secretariat notes that a nil financial cost to the PBS was expected. The use of S-26[®] Original LI was expected to substitute the currently PBS-listed S-26[®] LF for the same indication and patient group.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of S-26[®] Original LI as a Authority Required (telephone) benefit for the treatment of acute lactose intolerance, on a cost-minimisation basis against S-26[®] LF at an equivalent DPMQ.
- 6.2 The PBAC noted the advice of the NPWP that supported the listing of S-26[®] Original LI on the PBS.
- 6.3 The PBAC noted that the submission estimated a nil cost to the PBS as it was expected to replace the existing product, S-26[®] LF.
- 6.4 The PBAC agreed with the NPWP's advice that there are no safety concerns over the non-clinically relevant amount of lactose in the new formulation.
- 6.5 The PBAC noted the NPWP's suggestion that S-26[®] Original LI should only be PBS-listed for the treatment of "acute lactose intolerance", as the NPWP considered that "proven chronic lactose intolerance" is an error in the current PBS listing of S-26[®] LF. The pre-PBAC response to the suggested indication was that S-26[®] Original LI remain listed for both acute and proven chronic lactose intolerance to maintain consistency. The response also noted listing the product as a treatment for chronic lactose intolerance will allow up to 5 repeats of 5 cans, compared to no repeats under the "acute lactose intolerance" indication. The PBAC noted the sponsor's pre-PBAC response and considered that "acute lactose intolerance" follows the short-term indications for similar products on the PBS, and agreed with the NPWP's suggestion. The PBAC agreed to further investigate the indications of other milk formula products for lactose intolerance treatments, and whether a similar approach should apply to these products.
- 6.6 The PBAC noted the NPWP's suggestion of grouping PBS-listed products with similar lactose intolerance formulations into the broader formulation of "lactose intolerance formula".
- 6.7 In accordance with subsection 101(3BA) of the Act the PBAC advised that, on the basis of the material available to its July 2016 meeting, S-26[®] Original LI should be treated as interchangeable on an individual patient basis with any other nutritional product.

- 6.8 The PBAC recommended that S-26[®] Original LI is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.9 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC's view that general nutrients be exempt.
- 6.10 The PBAC noted that this submission was not eligible for an Independent Review, as it had received a positive recommendation.

Outcome:

Recommended

ADDENDUM

Subsequent to the July 2016 meeting, the sponsor requested that the PBAC address the perceived inequity in listing S-26[®] Original LI for only acute lactose intolerance.

The PBAC recommended the listing of S-26[®] Original LI as a Authority Required (Telephone) benefit for the treatment of acute lactose intolerance and upon further consideration further recommend that this recommendation should be applied to all currently listed lactose intolerance nutritional products with the removal of chronic lactose intolerance as an approved indication.

7 Recommended listing

7.1 Delete item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer		
MILK POWDER – LACTOSE-FREE FORMULA Oral liquid: powder for, 900g can	5	0	S-26 LF®	Aspen Pharmacare Pty Ltd®	Australia

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:	Acute lactose intolerance
PBS Indication:	Acute lactose intolerance
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Population criteria:	Patient must be up to the age of 12 months.
Prescriber Instructions	The date of birth of the patient must be included in the authority application.

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7.2 Delete item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
MILK POWDER – LACTOSE-FREE FORMULA Oral liquid: powder for, 900g can	5	5	S-26 LF®	Aspen Pharmacare Australia 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:	Proven chronic lactose intolerance
PBS Indication:	Proven chronic lactose intolerance
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Population criteria:	Patient must be up to the age of 12 months.
Prescriber Instructions	The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either: (a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or (b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or (c) hydrogen breath test

7.3 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer		
MILK POWDER - LACTOSE INTOLERANCE FORMULA Oral liquid: powder for, 900g can	5	0	S-26 Original LI®	Aspen Pharmacare Pty Ltd	Australia

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:	Acute lactose intolerance
PBS Indication:	Acute lactose intolerance
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Population criteria:	Patient must be up to the age of 12 months.
Prescriber Instructions	The date of birth of the patient must be provided at the time of application.

8 **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.

9 **Sponsor's Comment**

The sponsor had no comment.