

## 5.24 WHEY PROTEIN FORMULA with MEDIUM CHAIN TRIGLYCERIDES, CARBOHYDRATE, VITAMINS and MINERALS

Oral liquid, 24 × 200 mL bottles,  
Infatrini Peptisorb<sup>®</sup>, Nutricia Australia Pty Ltd

### 1 Purpose of Application

- 1.1 The minor submission requested a restricted benefit listing for the dietary management of conditions requiring a source of medium chain triglycerides.

### 2 Requested listing

- 2.1 The submission requested the following new listing:
- 2.2 No changes to the proposed listing were suggested by the Secretariat.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
WHEY PROTEIN FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES, CARBOHYDRATE, VITAMINS AND MINERALS Oral liquid, 24 × 200 mL bottles	8	5	\$ [REDACTED]	Infatrini Peptisorb <sup>®</sup>	Nutricia Australia Pty Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Dietary management of conditions requiring a source of medium chain triglycerides
<b>PBS Indication:</b>	Dietary management of conditions requiring a source of medium chain triglycerides
<b>Restriction Level / Method:</b>	<input checked="" 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 type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must have fat malabsorption due to liver disease; OR Patient must have fat malabsorption due to short gut syndrome; OR Patient must have fat malabsorption due to cystic fibrosis; OR Patient must have fat malabsorption due to gastrointestinal disorders.

<b>Population criteria:</b>	Patient must be aged from newborn up to 18 months; OR Patient must be up to 9kg.
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For more detail on PBAC's view, see section 6 "PBAC outcome"

### 3 Background

- 3.1 The sponsor of Infatrini Peptisorb<sup>®</sup> confirmed that it meets the requirements for foods that have medical purposes as set out under *The Australia New Zealand Food Standards Code* – Standard 2.9.1 – Division 4 – Subdivision 1 – Infant formula products formulated for metabolic, immunological, renal hepatic and malabsorptive conditions.
- 3.2 A similar product, MCT Pro-Cal<sup>®</sup>, is currently available on the PBS as an Authority Required restriction.
- 3.3 Infatrini Peptisorb<sup>®</sup> had not been considered by PBAC previously.
- 3.4 The submission stated that the product can be used by newborn infants up to 18 months, or for infants weighing up to 9 kg.
- 3.5 The product is an enteral formula which can be administered via naso-enteric tube, gastrostomy or jejunostomy.
- 3.6 The amount prescribed should be determined by a suitably qualified clinician and/or dietician. This will vary according to each individual patient's calculated energy requirements.
- 3.7 Infatrini Peptisorb<sup>®</sup> has a higher protein content (10.4% total energy) and higher energy (1kcal/mL) than the proposed comparator, Monogen<sup>®</sup>.
- 3.8 The product also contains a low lactose level of 0.1g/100 mL to accommodate some infants with impaired GI tolerance who suffer from transient lactose intolerance.
- 3.9 The submission noted that the level of zinc and vitamin A exceeds the Upper Level (UL) of Intake, while other nutrients exceed the Adequate Intakes/Recommended Daily Intakes (AI/RDI), as set by the National Health and Medical Research Council.
- 3.10 The submission stated that Zinc deficiency is commonly reported in patients with fat malabsorption, and the above-UL content is to compensate for this deficiency. Furthermore, the sponsor claims that it is reasonable to have an above-UL amount of vitamin A as it is fat-soluble, and is therefore assumed to be low in patients with fat malabsorption.
- 3.11 The submission also noted that Potassium and Manganese levels were below the AI/RDI for patients aged 1 – 1.5 years. However, the sponsor states that the levels still meet the minimum levels set by *The Australia New Zealand Food Standards*

Code – Standard 2.9.1 for products represented as an infant formula for special dietary use.

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

#### **4 Comparator**

- 4.1 The minor submission nominated the currently PBS-listed Monogen<sup>®</sup> as the main comparator. It is a medium chain triglycerides powdered formula which can be used orally, or administered as an enteral tube feed, by patients with the same clinical criteria. Monogen<sup>®</sup> is the most commonly prescribed fat malabsorption treatment for infants aged 0 – 12 months.
- 4.2 The submission also nominated Peptamen Junior<sup>®</sup> as a comparator, as it is the most commonly prescribed fat malabsorption treatment for infants aged 12 – 18 months.
- 4.3 The sponsor proposed that the product can replace, or be used in combination with, other nutritional products listed on the PBS for fat malabsorption.

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

#### **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 listing was clinically and nutritionally appropriate, with suitable restriction criteria.

The proposed restriction level was a "Restricted Benefit", based on the submission's two nominated comparators; the currently PBS-listed brands Monogen<sup>®</sup> and Peptamen Junior<sup>®</sup>. The submission stated that Monogen<sup>®</sup> and Peptamen Junior<sup>®</sup> were nominated because they are the highest selling products for infants with fat malabsorption aged 0 – 12 months and 12 – 18 months respectively.

Other similar PBS-listed treatments, such as Alfaré<sup>®</sup> and Aptamil Gold+ Pepti-Junior<sup>®</sup>, are listed with an “Authority Required” restriction. The NPWP stated that these brands of formulas contain hydrolysed proteins and approximately 40 – 50% medium chain triglycerides (MCT); which provides an equivalent nutritional profile to Infatrini Peptisorb<sup>®</sup>. However, one of the proposed comparators, Monogen<sup>®</sup>, contains non-hydrolysed proteins and 80% MCT. The NPWP noted this discrepancy and deemed Monogen<sup>®</sup> to be an unsuitable comparator for Infatrini Peptisorb<sup>®</sup> due to its higher MCT content and intact protein source.

The NPWP noted that the proposed comparators were not suitable, and suggested products such as Alfaré<sup>®</sup> and Aptamil Gold+ Pepti-Junior<sup>®</sup> as more suitable comparators.

- 5.5 The NPWP suggested deferring listing Infatrini Peptisorb<sup>®</sup> on the basis that the proposed comparators were unsuitable. The NPWP advised that the sponsor resubmits the new listing proposal with a more suitable comparator.

### **Estimated PBS usage & financial implications**

- 5.6 The DPMQ for Infatrini Peptisorb<sup>®</sup> (\$██████) was calculated based on the cost per kilojoule of energy (\$██████) of the comparators Monogen<sup>®</sup> and Peptamen Junior<sup>®</sup>.
- 5.7 The Secretariat noted that the DPMQ from the sponsor was calculated on a cost per kJ of energy basis, rather than cost per gram of Protein Equivalent.
- 5.8 The submission estimated that approximately █████% of infants aged 0 – 12 months currently using Monogen<sup>®</sup>, and approximately █████% of infants aged 12 – 18 months currently using Peptamen Junior<sup>®</sup>, will replace their treatment with Infatrini Peptisorb<sup>®</sup>. No justification for these estimates was provided in the submission.
- 5.9 Based on these calculations, the submission estimated dispensing █████ prescriptions of Infatrini Peptisorb<sup>®</sup> within the first year, increasing to █████ in year 5. As noted above in paragraph 5.3, the accuracy of these estimates has not been verified.
- 5.10 The submission estimated an overall saving on the PBS, as a proportion of patients in different age groups are expected to substitute from an existing PBS-listed treatment to Infatrini Peptisorb<sup>®</sup>. The estimates of overall savings to the PBS have not been verified.

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

## **6 PBAC Outcome**

- 6.1 The PBAC deferred its decision on listing Infatrini Peptisorb<sup>®</sup> as a Restricted Benefit for the dietary management of conditions requiring a source of medium chain triglycerides. The PBAC considered that the main comparator was unsuitable due to the discrepancies in nutritional composition to Monogen<sup>®</sup>.

- 6.2 The PBAC noted the advice of the NPWP that supported deferring the decision on listing Infatrini Peptisorb<sup>®</sup> on the PBS.
- 6.3 The PBAC agreed with the NPWP's advice that the proposed comparator was inappropriate for Infatrini Peptisorb<sup>®</sup>. The PBAC noted that the main comparator, Monogen<sup>®</sup>, contains non-hydrolysed proteins and 80% of total fat content is comprised of medium chain triglycerides (MCT), whereas Infatrini Peptisorb<sup>®</sup> is a 100% hydrolysed whey protein with 50% MCT (minor submission, pg 11). The PBAC therefore concluded that the differences in protein structure and amount of MCT deemed Monogen<sup>®</sup> an inappropriate main comparator for Infatrini Peptisorb<sup>®</sup>.
- 6.4 The PBAC agreed with the NPWP's suggestion that the sponsor use a more appropriate comparator for Infatrini Peptisorb<sup>®</sup>. The PBAC noted that other PBS-listed products are more similar to Infatrini Peptisorb<sup>®</sup> than the proposed comparators. The PBAC agreed that Alfaré<sup>®</sup> and Aptamil Gold+ Pepti-Junior<sup>®</sup> were more suitable comparators for Infatrini Peptisorb<sup>®</sup>, as they contain hydrolysed proteins and approximately 40 – 50% MCT.
- 6.5 The PBAC noted that there was no Pre-PBAC response from the sponsor for this item.
- 6.6 The PBAC considered that a minor resubmission was required, should the sponsor wish to accept the suggestion of reconsidering their proposed comparator.
- 6.7 The PBAC noted that the NPWP's suggested comparators, Alfaré<sup>®</sup> and Aptamil Gold+ Pepti-Junior<sup>®</sup>, are currently listed on the PBS as an Authority Required benefit.
- 6.8 The PBAC advised that, if the sponsor wishes to make a minor resubmission for Infatrini Peptisorb<sup>®</sup> with an appropriate comparator, the proposed restriction should be an Authority Required benefit to maintain consistency across similar PBS-listed products.
- 6.9 The PBAC noted that this submission was eligible for an Independent Review as no positive recommendation was made.

**Outcome:**

Deferred

**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.