

5.25 VITAMINS, MINERALS AND TRACE ELEMENTS

FORMULA

**Sachets containing oral powder 7 g, 30 (Phlexy-Vits),
Phlexy-Vits[®], 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 highly restrictive therapeutic diet.

2 Requested Listing

- 2.1 The submission requested the following new listing:
- 2.2 The suggestions by the Secretariat are shown in italics in the proposed restriction.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
VITAMINS, MINERALS AND TRACE ELEMENTS FORMULA Powder for oral liquid, 30 x 7 g sachets	1	5	\$274.16	Phlexy-Vits®	Nutricia 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:	Dietary management of conditions requiring a highly restrictive therapeutic diet
PBS Indication:	Dietary management of conditions requiring a highly restrictive therapeutic diet
Restriction Level / Method:	<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

Clinical criteria:	Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.
Population criteria:	Patient must be aged 1 year or older
Administrative Advice:	<i>Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician</i>

3 Background

- 3.1 The sponsor of Phlexy-Vits® 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 Phlexy-Vits® has not been considered by the PBAC previously.
- 3.3 The minor submission anticipated that the majority of users of Phlexy-Vits® will be in patients following a ketogenic diet for the dietary management of refractory epilepsy, and a minority of patients would have inborn errors of metabolism.
- 3.4 Phlexy-Vits® is not intended to contribute to the macronutrient intake of patients following a restrictive therapeutic diet.
- 3.5 It is noted that sodium, potassium and chloride are present at lower levels, and chlorine and fluoride have not been added to Phlexy-Vits®. The sponsor claimed that these nutrients can be obtained from a variety of other sources even on a restrictive diet.
- 3.6 Phlexy-Vits® contains folate and magnesium at levels that exceed the upper limit of the Nutrient Reference Values. The sponsor claimed that a protein or carbohydrate restricted diet will severely limit the dietary intake of these nutrients and therefore excess folate and magnesium is not of nutritional concern.
- 3.7 Phlexy-Vits® contains some nutrients that are below the Adequate Intake/Recommended Daily Intake, which were not specifically addressed in the minor submission. The sponsor claimed that Phlexy-Vits® is intended to supplement the diet rather than replacing the diet.

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

4 Comparator

- 4.1 The minor submission nominated FruitiVits® as the main comparator as it is also a vitamin, mineral and trace element powdered supplement (6 g sachet) for patients (3 years and older) on a restrictive therapeutic diet.
- 4.2 Phlexy-Vits® contains significantly less energy than the main comparator FruitiVits® (15 kcal per 100 g in Phlexy-Vits® compared to 41 kcal per 100 g in FruitiVits®).

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.

Basis for submission

- 5.3 The minor submission claimed that Phlexy-Vits® meets an unmet clinical need for patients aged 1-3 years and over 10 years of age following a ketogenic diet. The minor submission claimed that the main comparator, FruitiVits® is not suitable for this population, and that there are currently no listed products for this patient population. The Secretariat noted that a similar product to Phlexy-Vits®, Paediatric Seravit® is currently listed for the same indication for infants or a child, while FruitiVits® is restricted to patients 3 years and older.

Clinical trials

- 5.4 As a minor submission, no clinical trials were presented in the submission.
- 5.5 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted that:
- The sponsor provided a suitable comparison against the requirements of the Australia New Zealand Food Standards Code - Standard 2.9.5: Food for Special Medical Purposes.

- The product was not suitable for patients between the ages of 1-3 years, noting that the formula contained low levels of physiologically critical vitamin C, vitamin D, vitamin E, iron, iodine and phosphorus and no choline.
- The NPWP considered that one 7g sachet of Phlexy Vits® was equi-effective to one 6g sachet of the nominated comparator FruitiVits®.

5.6 The NPWP supported the listing of Phlexy Vits® for the dietary management of conditions requiring a highly restrictive therapeutic diet for patients aged 3 and above at an equivalent price per sachet to the comparator FruitiVits®.

Estimated PBS usage & financial implications

5.7 The proposed DPMQ for Phlexy-Vits® is the same as the comparator FruitiVits® at \$274.16. It is noted that the PBAC previously recommended the listing of FruitiVits® at its July 2014 meeting at the same price per gram of key nutrients as Paediatric Seravit®.

5.8 The minor submission estimated a total net cost to the PBS of substantially less than \$10 million over the first 5 years of listing.

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

6 PBAC Outcome

6.1 The PBAC recommended the Restricted Benefit listing of Phlexy-Vits® for the dietary management of conditions requiring a highly restrictive therapeutic diet, on a cost-minimisation basis against FruitiVits® at an equivalent cost per sachet.

6.2 The PBAC agreed with the NPWP's advice that the product is unsuitable for patients between the ages of 1-3 years. The PBAC noted that the sponsor indicated in their pre-PBAC response that they no longer intended to pursue a request to list Phlexy Vits® for that particular age group (1-3 years).

6.3 The PBAC considered that FruitiVits® was the appropriate main comparator.

6.4 The PBAC noted that the requested maximum quantity and number of repeats is consistent with the current listing of the main comparator FruitiVits®.

6.5 The PBAC noted that the two other products listed for the same indication contain an administrative advice stating that the product must only be used under strict

supervision of a dietician and a paediatrician. The PBAC advised that a similar noted should be included in the restriction for Phlexy-Vits®.

- 6.6 The PBAC agreed with the NPWP’s advice that one 7 g sachet of Phlexy Vits® was equi-effective to one 6 g sachet of the nominated comparator FruitiVits®.
- 6.7 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC’s view that general nutrients be exempt.
- 6.8 The PBAC recommended that Phlexy-Vits® be made available for PBS prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.9 In accordance with Section 101 (3BA) of the National Health Act, the PBAC advised that on the basis of the material available to its July 2017 meeting, Phlexy-Vits® should be treated as interchangeable on an individual patient basis with any other similar nutritional product.
- 6.10 The PBAC noted that this submission was not eligible for an Independent Review, as it had received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
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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:	Dietary management of conditions requiring a highly restrictive therapeutic diet
PBS Indication:	Dietary management of conditions requiring a highly restrictive therapeutic diet

Restriction Method:	Level /	<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
Clinical criteria:		Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.
Population criteria:		Patient must be aged 3 years or older
Administrative Advice:		Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician

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.