

6.17 VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

oral liquid: powder for, 6 g sachets, 30

FruitiVits® ,

Vitaflo Australia Pty Ltd.

1 Purpose of Application

1.1 The minor submission requested amending the restricted benefit listing for vitamins, minerals and trace elements with carbohydrate (FruitiVits®) to include patients from 1 year of age.

2 Requested Listing

2.1 The submission requested the following changes to the existing listing (deletions in strikethrough and additions in italics):

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE oral liquid: powder for, 6 g sachets, 30	1	5	\$ [REDACTED]	FruitiVits® Vitaflo 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 3 years <i>1 year</i> or older

- 2.2 No changes to the proposed listing were suggested by the Secretariat.

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

3 Background

- 3.1 FruitiVits® is currently listed as a restricted benefit for the dietary management of conditions requiring a highly restrictive therapeutic diet.

- 3.2 The minor submission stated that the sweeteners acesulfame K and sucralose and the pigment carotene (E160a) included in FruitiVits® are permitted under *The Australia New Zealand Food Standards Code — Standard 1.3.1 – Food Additives*.

4 Comparator

- 4.1 The minor submission nominated Paediatric Seravit® (vitamins, minerals and trace elements with carbohydrate, powder for oral liquid, 200 g) as the main comparator.

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 The basis of the requested change was a nutrient composition comparison against Paediatric Seravit® and the Australian & New Zealand Nutrient Reference Values (NRVs) for 1-3 years.

- 5.5 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted that:

- The product contained less than half the iron of the nominated comparator, Paediatric Seravit®, at 5 mg iron per 3 g (1/2 sachet) of FruitiVits® compared with 10.4 mg iron per 15 g Paediatric Seravit®.
- The low iron levels (56% of the NRV for patients aged 1-3 years) in the product were concerning, as iron deficiency is common in the target patient population due to patients' restrictive diets.

- 5.6 The NPWP did not support the requested amendment to the restricted benefit listing for FruitiVits® to include patients from 1 year of age. The NPWP noted that there was no clinical need for the sponsor's request, as the comparator Paediatric Seravit® contains the recommended amount of iron for children aged 1-3 years. The NPWP suggested that the sponsor resubmit the request to amend the listing for FruitiVits® after increasing the amount of iron in the product to a nutritionally appropriate level.

Estimated PBS usage & financial implications

- 5.7 The submission stated that the requested amendment to include patients in the 1-3 year range is expected to have a minimal financial impact on the PBS. The submission projected that less than 10,000 additional patients per year would use FruitiVits®. The submission did not state whether these patients would otherwise be expected to receive PBS subsidised Paediatric Seravit®.

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

6 PBAC Outcome

- 6.1 The PBAC did not recommend amending the restricted benefit listing for vitamins, minerals and trace elements with carbohydrate in the form of Sachets containing oral powder 6 g, 30 (FruitiVits®) to include patients from 1 year of age on the basis that the product contained less than half the iron of the nominated comparator Paediatric Seravit® and at 56% of the NRV of patients aged 1-3 years.
- 6.2 The PBAC noted the advice of the Nutritional Products Working Party (NPWP) that did not support the requested amendment to the restricted benefit listing for FruitiVits®.
- 6.3 The PBAC considered there was no clinical need for FruitiVits® in patients aged 1 to less than 3 years on the basis of the low level of iron in the product. The PBAC noted that comparator contains the 116% of the NRV for iron for children aged 1-3 years.
- 6.4 The PBAC suggested that the sponsor resubmit the request to amend the listing for FruitiVits® after increasing the amount of iron in the product to a nutritionally appropriate level.
- 6.5 The PBAC noted that this submission is eligible for an Independent Review.

Outcome:

Rejected

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.