6.17 VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

oral liquid: powder for, 6 g sachets, 30

FruitiVits®,
Vitaflo Australia Pty Ltd.

# Purpose of Application

* 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.

# Requested Listing

* 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** | **№.of****Rpts** | **Dispensed Price for Max. Qty** | **Proprietary Name and Manufacturer** |
| VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATEoral liquid: powder for, 6 g sachets, 30 | 1 | 5 | $'''''''''''''''''' | FruitiVits® | Vitaflo Australia Pty Ltd |
|  |
| **Category /** **Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | [ ] Dental [x] Medical Practitioners [x] Nurse practitioners [ ] Optometrists[ ] 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:** | [x] Restricted benefit[ ] Authority Required - In Writing[ ] Authority Required - Telephone[ ] Authority Required – Emergency[ ] Authority Required - Electronic[ ] Streamlined |
| **Clinical criteria** | Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet,ANDPatient 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~~ *1 year* or older |

* 1. No changes to the proposed listing were suggested by the Secretariat.

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

# Background

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

# Comparator

* 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*

# Consideration of the evidence

## Sponsor hearing

* 1. There was no hearing for this item as it was a minor submission.

## Consumer comments

* 1. The PBAC noted that no consumer comments were received for this item.

## Clinical trials

* 1. As a minor submission, no clinical trials were presented in the submission.
	2. 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.
	3. 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.
	1. 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

* 1. 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*

# PBAC Outcome

* 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.
	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®.
	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.
	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.
	5. The PBAC noted that this submission is eligible for an Independent Review.

**Outcome:**

Rejected

1. **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.

1. **Sponsor’s Comment**

The sponsor had no comment.