

14.2 VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE, vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 X 6 g sachets FruitiVits[®], Vitaflo Australia Pty Ltd

1 Purpose of application

1.1 To request an Authority Required listing for children whose vitamin and mineral intake is insufficient due to a specific diagnosis requiring a highly restrictive therapeutic diet, and whose vitamin, mineral and trace element needs cannot be adequately met with other proprietary vitamin and mineral.

2 Requested listing

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
VITAMINS, MINERALS and TRACE ELEMENTS with CARBOHYDRATE oral liquid powder for, 30 x 6 g sachets	4	5	FruitiVits [®] VF

Condition/Indication:	Dietary management of conditions requiring a highly restrictive therapeutic diet
Restriction:	Authority required
Clinical criteria:	<p>Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a high restrictive therapeutic diet;</p> <p>AND</p> <p>Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.</p>
Administrative Advice:	<p><u>Note</u> FruitiVits is suitable for use in ketogenic therapeutic diets in management of refractory epilepsy, Glucose Transporter 1 protein deficiency and pyruvate dehydrogenase deficiency, due to the low carbohydrate content.</p>

3 PBAC Outcome

3.1 Listing for FruitiVits[®] was requested at the same price per gram of key nutrients as the main comparator, Paediatric Seravit[®]. The PBAC considered that this was appropriate.

3.2 The requested listing included a note that would allow use in patients requiring a ketogenic diet given its lower carbohydrate content. The PBAC considered that omitting the requested note would allow prescribers to decide whether the product would meet their patient's dietary needs, without making reference to suitability of the product for use in patients requiring a ketogenic diet. The PBAC also noted that the current listing for Paediatric Seravit, the main comparator, does not preclude the use in patients requiring a ketogenic diet. However, the carbohydrate content of

Paediatric Seravit means that it is not suitable for this indication. The PBAC recommended omitting the note requested by the sponsor.

- 3.3 The submission stated that FruitiVits is suitable for patients from 3 years of age. The PBAC recommended the inclusion of a population criterion stating that patients must be aged 3 years or older. The PBAC noted that this was consistent with the listing for Paediatric Seravit which specifies use in 'infants and children'.
- 3.4 The current listing for Paediatric Seravit contains a NOTE stating that the product should only be used under strict supervision of a dietitian and a paediatrician. The PBAC considered that the same would be appropriate for FruitiVits.
- 3.5 The PBAC noted that the Nutritional Products Working Party (NPWP) recommended listing of FruitiVits as an Authority Required benefit for the dietary management of conditions requiring a highly restrictive therapeutic diet. The NPWP recommended that the restriction should be consistent with the current restriction for Paediatric Seravit, and that the maximum quantity be 1 carton of 30 sachets, with 5 repeats. The PBAC agreed with the advice of the NPWP.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
VITAMINS, MINERALS and TRACE ELEMENTS with CARBOHYDRATE			
Vitamins, minerals and trace elements with carbohydrate, oral liquid powder for, 30 x 6 g sachets	4	1	5
			FruitiVits® VF

Condition/Indication:	Dietary management of conditions requiring a highly restrictive therapeutic diet
Restriction:	Authority required
Clinical criteria:	<p>Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a high restrictive therapeutic diet;</p> <p>AND</p> <p>Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.</p>
Population criteria:	<i>Patient must be aged 3 years or older</i>
Administrative Advice:	<p><u>Note</u></p> <p>FruitiVits is suitable for use in ketogenic therapeutic diets in management of refractory epilepsy, Glucose Transporter 1 protein deficiency and pyruvate dehydrogenase deficiency, due to the low carbohydrate content.</p>
Administrative Advice:	<p><u>Note</u></p> <p><i>FruitiVits must only be used under strict supervision of a dietitian and a paediatrician</i></p>

4 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.

5 Sponsor's Comment

The sponsor had no comment.