

14.03(i) VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Oral powder 200 g, Paediatric Seravit[®], Nutricia Australia Pty Ltd

1 Purpose of Application

- 1.1 The Committee Secretariat Submission requested a formulation change to Paediatric Seravit[®] based on new European compositional standards.

2 Background

- 2.1 Paediatric Seravit was listed on the PBS on 1 April 2010.
- 2.2 The sponsor previously indicated that Paediatric Seravit met the requirements for “Food for Special Medical Purposes” (FSMP) as set out under The Australia New Zealand Food Standards Code 2.9.5 Food for Special Medical Purposes.
- 2.3 The submission stated that the requested change to the formulation of Paediatric Seravit was to comply with the compositional standards specified in the European Union (EU) Commission Delegated Regulation (EU) 2016/127 on infants (IF) and follow-on formulae (FOF) and the European Union (EU) Commission Delegated Regulation (EU) 2016/128 on FSMP.

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

3 Requested listing

- 3.1 The submission proposed no changes to the existing listing (PBS item code 9328Y).

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

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a Committee Secretariat submission.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

- 4.3 No clinical trials were presented in the submission.

Other relevant matters

4.4 The main changes to the nutritional profile proposed in the submission included an increase in the levels of iodine, folic acid and choline, and a decrease in the levels of molybdenum, chromium and vitamin K. The full changes to the formulation of Paediatric Seravit are presented in Table 1.

Table 1: Nutritional composition changes to Paediatric Seravit

Parameter	Unit per 100g	Current Paediatric Seravit	New Paediatric Seravit
Energy value	kJ	1275	1246
Energy Value	kcal	300	293
Sugars	g	6.75	5.9
Maltose	g	4.4	4.6
Polysaccharides	g	64.1	61.9
Sodium	mg	<20	<40
Potassium	mg	<30	<30
Chloride	mg	<20	<30
Calcium	mg	2570	2750
Magnesium	mg	357	500
Phosphorus	mg	1714	1850
Iron	mg	69	50
Copper	mg	4.6	4.2
Zinc	mg	46	36
Manganese	mg	4.6	1.6
Molybdenum	µg	351	108
Selenium	µg	137	137
Chromium	µg	137	90
Iodine	µg	332	820
Vitamin A	µg RE	4200	3200
Vitamin E (αTE)	mg	21.4	54.2
Vitamin K	µg	166	108
Vitamin D	µg	55.5	100
Thiamin (B1)	mg	3.2	3.2
Riboflavin (B2)	mg	4.4	4.4
Niacin (B3)	mg	35	41
Panthenic acid (B5)	mg	17	24
Vitamin B6	mg	3.4	3.6
Folic acid	µg	303	600
Vitamin B12	µg	8.6	9.0
Biotin	µg	214	120
Vitamin C	mg	400	400
Choline	mg	350	1250
Inositol	mg	700	700

Source: Table 1, p 2 of the submission

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

5 NPWP consideration

5.1 The NPWP noted the requested change to formulation for Paediatric Seravit due to new European compositional standards.

- 5.2 The NPWP noted that the manganese levels were lower than the Australian adequate intake (AI) levels. However, the NPWP considered that this was not a concern as drinking water, vegetables and cereals were the main dietary sources for manganese and no RDI for manganese had been set.
- 5.3 The NPWP noted that the stated aim of the submission was to request changes to the formulation of Paediatric Seravit to comply with the EU Commission Delegated Regulation 2016/127 on IF and FOF. The NPWP considered that Paediatric Seravit did not appear to comply with the new European compositional standards for several nutrients, but considered that it contained reasonable levels of micronutrients compared to RDI.
- 5.4 The NPWP noted the revised formulation included a range of changes to the nutritional profile, including the vitamin, mineral and micronutrient profile. The NPWP considered that the nutritional values spreadsheets and comparison with appropriate FSANZ and EU Food standards included in the submission were informative and agreed it would be useful for submissions to continue to present information in this format.
- 5.5 The NPWP considered the new formulation complied with FSANZ and had no concerns that the changes to formulation would pose a risk to the health and safety of patients.

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

6 PBAC Outcome

- 6.1 The PBAC recommended continuing the Restricted Benefit listing of vitamins, minerals and trace elements with carbohydrate, Paediatric Seravit, for the dietary management of conditions requiring a highly restrictive therapeutic diet in infants and young children following its reformulation due to changes in European compositional standards.
- 6.2 The PBAC noted that the NPWP considered that although the manganese levels were lower than the Australian adequate intake (AI) levels, this was not a concern as drinking water, vegetables and cereals were the main dietary sources for manganese.
- 6.3 The PBAC noted that while Paediatric Seravit did not appear to comply with the new European compositional standards for several nutrients, the NPWP had no concerns that the changes in formulation would pose a risk to the health and safety of patients.
- 6.4 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 No change to the existing listing

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.