

**14.03e MILK PROTEIN AND FAT FORMULA WITH VITAMINS
AND MINERALS - CARBOHYDRATE FREE
Oral Powder 225 g,
Carbohydrate Free Mixture[®],
Nutricia Australia Pty Ltd**

1 Purpose of Application

- 1.1 The Committee Secretariat submission requested a change to the formulation of the milk protein and fat formula with vitamins and minerals – carbohydrate free formula, (Carbohydrate Free Mixture[®]), for infants and children with multiple monosaccharide intolerance or requiring a ketogenic diet, based on new European compositional standards.

2 Background

- 2.1 Carbohydrate Free Mixture was first listed on the PBS in 2003.
- 2.2 The submission requested a change to the formulation of Carbohydrate Free Mixture to meet new European Commission Delegated Regulations on Food for Special Medical Purposes (FSMP) intended to satisfy the nutritional requirements of infants [Commission Delegated Regulation (EU) 2016/128]. Regulation 2016/128 sets out new maximum and minimum levels of vitamin and mineral substances for products that will provide a sole source of nutrition, and new maximum levels of vitamins and minerals for products that are not a sole source of nutrition. This regulation also requires additional nutrient declarations on the packaging with the intent guarantee appropriate use of the product. Further information on the compositional changes are presented in Section 5.

3 Requested listing

- 3.1 The submission proposed no change to the current listing of Carbohydrate Free Mixture (PBS item 8630F).

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 As a Committee Secretariat submission, no clinical trials were presented in the submission.

Other relevant matters

4.4 The main changes to the nutritional profile proposed in the submission include a decrease in the levels of potassium, vitamin A, vitamin K and an increase in the levels on choline. Key changes to the nutritional profile are presented in Table 1.

Table 1: Summary of changes to Carbohydrate Free Mixture

Type of change/parameter (units of measurement)	Old formulation	New formulation
Energy value (kJ/100g)	2767	2805
Energy value (kcal/100g)	668	678
Carbohydrate (g/100g)	0.1	<0.14
Sugars (g/100g)	0.1	0.09
Salt (g/100g)	0.79	0.85
Protein (g/100g)	28.3	28.6
Fat (g/100g)	60.6	62
Saturated fat (g/100g)	21.3	23.6
Monounsaturated fat (g/100g)	28.9	28.2
Polysaturated fat (g/100g)	7.5	10.1
Potassium (mg/100g)	935	339
Vitamin A (µg RE)	1150	914
Vitamin K (µg/100g)	82	45.0
Arachidonic acid (g/100gFA)	-	0.45
Docosahexaenoic acid (DHA) (g/100gFA)	-	0.45

Table 1. Nutritional composition change to Carbohydrate Free Mix; Minor Submission page 3.

4.5 The submission also stated that there would be a decrease in shelf life from 24 months to 18 months with the reformulation.

5 NPWP Consideration

5.1 The NPWP noted the requested change to formulation for Carbohydrate Free Mixture®, for infants and children with multiple monosaccharide intolerance or requiring a ketogenic diet, due to new European compositional standards.

5.2 The NPWP observed that some mineral and vitamin levels were very high for infants and young children but that the product would usually be used with an additional source of carbohydrate or fat. The NPWP noted the product meets Infant Formula Standard 2.9.1 from FSANZ except for low levels of manganese. However, Carbohydrate Free Mixture does meet requirements for manganese in the EU infant formula standards. Some micronutrients are high compared to EU standards but this is not of concern given the way the product is used.

5.3 The NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients and accepted the request to change the formulation.

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 milk protein and fat formula-carbohydrate free, Carbohydrate Free Mixture, for infants and children with multiple monosaccharide intolerance or requiring a ketogenic diet, following its reformulation due to changes in European compositional standards.
- 6.2 The PBAC noted the NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients.
- 6.3 The PBAC advised that its previous advice for milk protein and fat-carbohydrate free formula regarding Nurse Practitioner Prescribing, the Early Supply Rule and interchangeability advice under Section 101(3BA) of the *National Health Act 1953* remained appropriate.
- 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 changes 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.