

**14.03c HIGH FAT FORMULA WITH VITAMINS, MINERALS
AND TRACE ELEMENTS AND LOW IN PROTEIN AND
CARBOHYDRATE,
Oral powder 300 g,
KetoCal 3:1,
Nutricia Australia Pty Ltd**

**HIGH FAT FORMULA WITH VITAMINS, MINERALS
AND TRACE ELEMENTS AND LOW IN PROTEIN AND
CARBOHYDRATE,
Oral powder 300 g,
KetoCal 4:1,
Nutricia Australia Pty Ltd**

1 Purpose of Application

- 1.1 The committee secretariat submission requested changes in the nutrient composition of the currently PBS-listed KetoCal 3:1 and KetoCal 4:1. These changes are intended to comply with the new European Commission Delegated Regulations on Food for Special Medical Purposes (FSMP) to satisfy the nutritional requirements of infants [Commission Delegated Regulation (EU) 2016/128].

2 Background

- 2.1 In the March 2009 PBAC meeting, the PBAC recommended listing KetoCal (later renamed to KetoCal 4:1 in April 2013) for ketogenic diet. KetoCal 4:1 was PBS listed from 1 August 2009.
- 2.2 In the March 2013 PBAC meeting, the PBAC recommended listing KetoCal 3:1 as a restricted benefit with the same restrictions as KetoCal 4:1. KetoCal 3:1 was PBS listed from 1 August 2013.

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

3 Requested listing

The submission requested no changes to existing listings of KetoCal 3:1 (2652N) and KetoCal 4:1 (9446E).

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.

Consumer comments

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

Other relevant matters

4.3 Key changes to the nutritional profiles are presented in Table 1 and 2.

Table 1: Comparison of the current and new composition profile KetoCal 3:1

Nutrient	Unit per 100g	Old formulation	New formulation
Energy value	kJ	2887	2935
Energy value	Kcal	699	711
Protein	g	15.3	15.4
Sugars	g	6.0	5.4
Fat	g	67.7	68.6
sodium	mg	315	355
Potassium	mg	993	920
Chloride	mg	481	545
Calcium	mg	838	810
Phosphorus	mg	559	546
Magnesium	mg	105	78.1
Iron	mg	12.0	12.1
Zinc	mg	8.2	8.53
Copper	µg	830	510
Manganese	µg	630	140
Molybdenum	µg	34.4	34.9
Selenium	µg	21.0	27.0
Chromium	µg	28.8	29.0
Iodine	µg	124	104
Vitamin A	µg	525	389
Vitamin D3	µg	12.7	17.0
Vitamin E	mg	7.9	9.02

Public Summary Document – March 2021 PBAC Meeting

Nutrient	Unit per 100g	Old formulation	New formulation
Vitamin K	µg	55.9	55.4
Thiamin (B1)	mg	0.70	0.71
Riboflavin (B2)	mg	0.70	0.71
Niacin (B3)	mg	4.9	4.97
Niacin equivalent	mg	11.2	11.3
Pantothenic acid (B5)	mg	2.8	6.03
Vitamin B6	mg	0.70	0.71
Folate			177
Folic acid	µg	140	106
Biotin	µg	13.9	14.2
Vitamin C	mg	84	95.6
L-Carnitine	mg	48.0	48.8
Choline	mg	180	225
Inositol	mg	153	155
Taurine	mg	48.0	48.7
Arachidonic acid (AA)	g/100gFA	0.18	0.27
Docosahexaenoic acid (DHA)	g/100gFA	0.18	0.27
Osmolarity	mOsmol/l	90	95
Osmolality	mOsmol/kg water	100	105
Potential Renal Solute Load	mOsmol/l	148	149
Allergen		Milk & Soy and products thereof	Milk and products thereof (soy lecithin has been removed)
Age range		Suitable for use as a sole source of nutrition for infants and children from birth to 6 years or as a supplementary feed for children aged over 6 years	The product is suitable as a sole source of nutrition until 3 years and as a supplementary feed for infants and children aged over 3 years.
Storage after reconstitution		Suitable for use as a sole source of nutrition for infants and children from birth to 6 years or as a supplementary feed for children aged over 6 years	The product is suitable as a sole source of nutrition until 3 years and as a supplementary feed for infants and children aged over 3 years.
Recommended dilution		9.5g+90ml to make a 100ml dilution	9.3g+90ml to make a 100ml dilution (change due to kcal change)

Public Summary Document – March 2021 PBAC Meeting

Source: Table 1 of the submission.

Table 2: Comparison of the current and new composition profile KetoCal 4:1 (Unflavoured and Vanilla)

Nutrient	Unit per 100g	Old formulation	New formulation
Energy value	kJ	2897	2906
Energy value	Kcal	703	704
Protein	g	14.4	14.3
Carbohydrate	g	2,9	2.8
Sugars	g	1.0	0.68
Dietary Fibre	g	5.3	5.4
Potassium	mg	848	855
Chloride	mg	799	800
Calcium	mg	770	780
Zinc	mg	4.0	4.4
Manganese	mg	0.91	.44
Fluoride	µg	3.7	Nil added
Chromium	µg	16.3	15.7
Vitamin A	µg	370	320
Vitamin E	Mg a-TE	10.7	11.7
Vitamin K	µg	31	51.4
Riboflavin (B2)	mg	0.70	0.87
Vitamin B6	mg	0.70	0.87
Vitamin C	mg	40	60
Choline	mg	320	324
Inositol	mg	19.1	22.1
Potential Renal Solute Load	mOsmol/L	233	231

Source: Table 2 of the submission

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

5 NPWP Consideration

5.1 The Nutritional Products Working Party (NPWP) supported retaining the listing of the new formulations of KetoCal 3:1 and KetoCal 4:1 for eligible patients with ketogenic diet. The NPWP had no concerns with the changes to the formulation as it would not pose a risk to the health and safety of patients. The NPWP advised that the changes to the formulation will continue to meet the Australian adequate intake (AI) levels and recommended dietary intake (RDI) values of patients eligible for PBS subsidised use.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Restricted Benefit listings of high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (KetoCal 3:1 and KetoCal 4:1) for ketogenic diet, remain unchanged following its reformulation to meet the new European Commission Delegated Regulations on Food for Special Medical Purposes (FSMP) [Commission Delegated Regulation (EU) 2016/128].
- 6.2 The PBAC agreed with the NPWP advice detailed in Section 5 NPWP consideration.
- 6.3 The PBAC noted that there were no pre-PBAC response from the sponsors for this item.
- 6.4 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 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.

8 Sponsor's Comment

The sponsor had no comment.