14.03(e) MILK POWDER – SYNTHETIC LOW CALCIUM
Oral Powder 400 g,
Locasol®,
Nutricia Australia Pty Ltd

1 Purpose of Application

1.1 The Committee Secretariat submission requested a change to the formulation of milk powder synthetic low calcium, Locasol®, for the dietary management of hypercalcaemia of patients under the age of four years (inclusive), based on new European compositional standards.

2 Background

2.1 The submission requested a change to the formulation of Locasol to meet new European Commissioned 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 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 required additional nutrient declarations on the packaging with the intent to guarantee appropriate use of the product.

3 Requested listing

3.1 The submission did not request changes to the existing listing of Locasol (PBS code 23092R).

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 key differences between the current and new formulation of Locasol in meeting the EU compositional standards were:

- decreases in maltose, polysaccharide, potassium, Chloride, magnesium, phosphorus, manganese, molybdenum, chromium, vitamin K, B12, folic acid and taurine;
- increases in the level of iron, iodine, vitamin E, choline, carnitine, linoleic acid and alpha linoleic; and
- organic acid and folate were added.

4.5 Key changes to the nutritional profile are presented in Table 1.

Table 1: Comparison of the current and new composition profile for Locasol formulation

	Unit per 100g	**Current Locasol**	**New Locasol**
Energy value	kJ	2124	2144
Energy value	kcal	508	512
Carbohydrate	g	53.7	55.2
Sugars	g	52.5	54.8
Glucose	g	0.03	
Maltose	g	0.08	0.01
Maltotriose	g	0.10	
Lactose	g	52.4	54.8
Polysaccharides	g	1.1	0.28
Organic acids	g		0.12
Fat	g	26.1	25.8
Saturated fat	g	9.2	9.8
Monounsaturated fat	g	12.6	12.9
Polyunsaturated fat	g	3.1	3.2
Dietary fibre	g	Nil added	
Sodium	mg	219	227
Potassium	mg	640	466
Chloride	mg	460	310
Calcium	mg	<55	<29.1
Magnesium	mg	50	42.7
Phosphorus	mg	350	172
Iron	mg	4	7.78
Copper	mg	0.31	0.39
Zinc	mg	3	3.89
Manganese	mg	0.40	0.051
Molybdenum	µg	35.0	19.5
Chromium	µg	30.0	15.4
Iodine	µg	78	99.6
Selenium	µg	11.5	12.4
Vitamin A	µg RE	600	584
Vitamin E	mg	7.4	9.06
Vitamin K	µg	40.0	25.3
Thiamin (B1)	mg	0.30	0.46
Riboflavin (B2)	mg	0.80	0.77
Niacin (B3)	mg	4.5	4.66

	Unit per 100g	**Current Locasol**	**New Locasol**
Pantothenic Acid (B5)	mg	2.1	2.71
Folate	µg		90.5
Folic acid	µg	80	54.3
Vitamin B12	µg	1.5	0.97
Biotin	µg	12.0	14.0
Vitamin C	mg	60.0	69.6
Choline	mg	50.0	90.6
Inositol	mg	25.0	25.6
Taurine	mg	29.5	6.96
Carnitine	mg	6.9	30.2
Linoleic acid (LA)	g/100gFA	10.6	53.4
Alpha linoleic acid (ALA)	g/100gFA	1.95	9.26
Osmolarity	mOsmol/l		270
Osmolality	mOsmol/kg water	310	310
Allergens		Allergen listed for: • Milk and products thereof (including lactose	Allergen listed for: • Milk and products thereof (including lactose) • Soybeans and products thereof

Source: Table 1, p3 of the submission,

5 NPWP Consideration

5.1 The Nutritional Products Working Party (NPWP) supported retaining the listing of the new formulations of Locasol for the dietary management of hypercalcaemia of patients under the age of four years (inclusive).

5.2 The NPWP noted that the stated aim of the submission was to request changes to the formulation of Locasol based on new European compositional standards. The NPWP considered that Locasol does not appear to comply with the new European compositional standards for several nutrients, noting that several modifications to nutrients were not required:

- The levels of potassium, chloride, phosphorus, iodine and selenium were reduced; and
- The levels of iodine and selenium were slightly increased.

5.3 The NPWP noted the level for manganese was low compared to Australian adequate intake (AI). 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.

5.4 The NPWP noted the revised formulation had 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 milk powder synthetic low calcium, Locasol, for the dietary management of hypercalcaemia of patients under the age of four years (inclusive), based on new European compositional standards.

6.2 The PBAC noted the NPWP had no concerns that the changes to the formulation would pose a risk to the health and safety of patients.

6.3 The PBAC reaffirmed its previous advice for milk powder synthetic low calcium formula that Nurse Practitioner Prescribing is appropriate and the Early Supply Rule should not apply.

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.