

**14.03(d) AMINO ACID SYNTHETIC FORMULA
SUPPLEMENTED WITH LONG CHAIN
POLYUNSATURATED FATTY ACIDS,
Oral powder 400mg,
Neocate® LCP,
Nutricia Australia Pty Ltd**

**AMINO ACID FORMULA SUPPLEMENTED WITH
PREBIOTICS, PROBIOTICS AND LONG CHAIN
POLYUNSATURATED FATTY ACIDS,
Oral powder 400 mg,
Neocate® Syneo™,
Nutricia Australia Pty Ltd**

1 Purpose of Application

- 1.1 The Committee Secretariat listing requested a change to the formulation of the amino acid formulas Neocate® LCP and Neocate® Syneo™, based on new European compositional standards.

2 Requested listing

- 2.1 The submission did not request changes to existing listings (Neocate® LCP items 2246F, 2560R; 9339M, 9340N and Neocate® Syneo™ items 11331J, 11340W, 11343B).

3 Background

- 3.1 Neocate® LCP was listed on the PBS on 1 August 2007. Neocate Syneo was listed on the PBS on 1 May 2018.
- 3.2 The submission requested a change to the formulation of Neocate® LCP and Neocate® Syneo™ 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.

3.3 There is no change to the level of protein equivalent (PE).

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 Neocate® LCP and Neocate® Syneo™ in meeting the UE compositional standards were:

- changes in the levels of numerous fatty acids;
- decreases in phosphorus folate and manganese in both new formulations,
- increases in the level of Docosahexaenoic acid (DHA) and Arachidonic acid (ARA), monounsaturated fatty acid, selenium, vitamin D, E , folate and choline In both new formulations; and
- a decrease in the level of calcium in Neocate® LCP.

4.5 Key changes to the nutritional profiles are presented in Tables 1 and 2 below.

Public Summary Document – March 2020 PBAC Meeting

Table 1: Levels of essential fatty acids Linoleic Acid (LA), α-Linolenic Acid (ALA), Docosahexaenoic acid, (DHA) and Arachidonic acid (ARA) in the current and new Neocate formulations

	Neocate® LCP		Neocate® Syneo™		IF/FOF Commission Delegated Regulation (EU) 2016/127 [2]
	Current Neocate® LCP	New Neocate® LCP	Current Neocate® Syneo™	New Neocate® Syneo™	
Per 100kcal					
Linoleic Acid (LA) mg	864	681	710	652	500-120
α-Linolenic Acid (ALA) mg	86	68.6	71	65.9	50-100
Ratio LA : ALA	10:1	10:1	10:1	10:1	N/A
Docosahexaenoic acid (DHA) mg	17	25	17	25	20-50
Arachidonic acid (ARA) mg	17	25	17	25	N/A
Ratio DHA : ARA	1:1	1:1	1:1	1:1	N/A

Source: Neocate submission, IF and FOF: infant and follow-on formulae

Table 2: Comparison of the energy, macronutrients & osmolality in current and new Neocate formulations

Nutrient	Neocate® LCP		Neocate Syneo		Neocate® Syneo™ IF/FOF Commission Delegated Regulation (EU) 2016/127 [2]
	Current Neocate® LCP	New Neocate® LCP	Current Neocate® Syneo™	New Neocate® Syneo™	
Energy (kcal/100mL)	67	67	68.2	68	60-70
Protein (g)	2.7	2.7	2.8	2.8	1.86-2.8*
Fat (g)	5.1	5.2	5.0	5.0	4.4-6.0
Carbohydrate (g)	10.9	10.7	10.6	10.6	9-14
Osmolality (mosmol/kg H ₂ O)	340	340	360	360	N/A

Source Neocate submission, *IF/FOF Commission Delegated Regulation (EU) 2016/127

* Infant formula manufactured from protein hydrolysates, except in the case of soya protein hydrolysates where limits are 2.25-2.8g/100kcal

Estimated PBS usage & financial implications

4.6 The submission did not request a price change for the amended listing.

5 NPWP Consideration (and sponsor's further clarification)

5.1 The Nutritional Products Working Party (NPWP) supported retaining the listing of the new formulations of Neocate® LCP and Neocate® Syneo™ for eligible patients with cow's milk allergy, multiple food intolerance and other medical conditions where an

amino acid-based formula is recommended. The NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients.

- 5.2 The NPWP noted the recommended daily quantities on the proposed labels for 2-week-old infants equated to approximately 120 kcal/kg body weight per day, which was higher than the WHO recommended 100 kcal/kg/day and requested the Sponsor consider reviewing its proposed dosage recommendations for this population. The Pre-PBAC Response stated the dosage recommendations were based on those set by international standards, however noted there was some regional variation in recommended energy intakes for different age groups.

For more detail on PBAC's view, see section 7 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended continuing the Restricted Benefit listing of amino acid formulas Neocate® LCP and Neocate® Syneo™, for eligible patients with cow's milk allergy, multiple food intolerance and other medical conditions where an amino acid-based formula is recommended, following its reformulation due to changes in European compositional standards.
- 6.2 The PBAC noted the NPWP supported the proposed listing of Neocate® LCP and Neocate® Syneo™ on the PBS, and noted the Pre-PBAC Response statement that dose recommendations were based on international standards.
- 6.3 The PBAC advised that its previous advice for amino acid formula with vitamins and minerals without phenylalanine 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 because 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.