

**11.01 AMINO ACID FORMULA SUPPLEMENTED WITH  
PREBIOTICS, PROBIOTICS AND LONG CHAIN  
POLYUNSATURATED FATTY ACIDS,  
Oral powder 400 g (Neocate Syneo),  
Neocate® Syneo,  
NUTRICIA AUSTRALIA PTY LIMITED**

**1 Purpose of Submission**

- 1.1 The Committee Secretariat submission requested that the new formulation for amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids (Neocate® Syneo) continue to be listed on the Pharmaceutical Benefits Scheme (PBS) under the same conditions of the existing formulation.
- 1.2 The submission stated that the reason for the change to the Neocate Syneo formula is to increase the similarity of the formula with human milk. This is done by replacing some dried glucose syrup with synthetic human milk oligosaccharide 2'-fucosyllactose (2'-FL), which the submission claimed may provide anti-inflammatory and immune-modulatory effects.

**2 Background**

- 2.1 Neocate Syneo was recommended by the PBAC at its July 2017 meeting and is currently listed on the PBS as Authority Required for the treatment of:
- Cows' milk protein enteropathy
  - Severe cows' milk protein enteropathy with failure to thrive
  - Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
  - Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
  - Cows' milk anaphylaxis
  - Severe intestinal malabsorption including short bowel syndrome
  - Eosinophilic oesophagitis (EOE)
- 2.2 The submission confirmed that the new formulation of Neocate Syneo continues to meet the requirements for Infant Formula Products for Special Dietary Use as set out under *The Australia New Zealand Food Standards Code — Standard 2.9.1: Infant Formula Products*.

2.3 As these products are marketed as nutritional products and not therapeutic goods, they are not registered in the Australian Register of Therapeutic Goods.

### 3 Requested listing

3.1 The submission requested no changes to the existing listings for Neocate Syneo under PBS item codes 11331J, 11340W and 11343B.

## 4 Consideration of the evidence

### *Sponsor hearing*

4.1 There was no hearing for this item.

### *Consumer comments*

4.2 The PBAC noted and welcomed the input from health care professionals (1), medical organisations (2) and consumer groups (1) via the Consumer Comments facility on the PBS website. The PBAC noted submissions from the Australasian Society of Clinical Immunology and Allergy, ausEE Inc and a joint submission from the National Allergy Council and Allergy & Anaphylaxis Australia. The comments described the benefits of treatment with Neocate Syneo including that its probiotic and prebiotic formula supports gut health in infants and children and the variety of flavours and textures of Neocate Syneo enhances compliance, particularly in younger patients. The consumer comments raised concerns about recent supply chain issues and a shrinking range of nutritional products in Australia for the management of cows' milk allergy, EOE, severe intestinal malabsorption and other food allergies and noted the importance of having multiple products available for those people with these indications in addition to the other indications of Neocate Syneo.

### *Nutritional profile*

4.3 A comparison of the new and previous formulation of Neocate Syneo is provided at Table 1.

Table 1: Neocate Syneo reformulation – nutritional comparison

Nutrient	Product nutritional content (per 100 g)		
	Neocate Syneo New	Neocate Syneo Current	New formula to current formula difference
Energy (kcal)	474	464	102%
Energy (kJ)	1985	1941	102%
Protein (g)	13.2	13	102%
Carbohydrate (g)	50.2	49	102%
Of which sugars (g)	4.7	4.6	102%
Fat (g)	23.6	23	103%
Saturates (g)	10.5	9.7	108%
Of which MCT (g)	7.36	7.3	101%
Monounsaturated (g)	9.3	7.8	119%
Polyunsaturated (g)	3.8	4.5	84%

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Nutrient	Product nutritional content (per 100 g)		
	Neocate Syneo New	Neocate Syneo Current	New formula to current formula difference
Of which Linoleic acid (LA) (g)	3.09	3.3	94%
Of which Alpha linolenic acid (ALA) (g)	0.31	0.33	94%
Fibre (g)	4.6	4.5	102%
Minerals			
Sodium (mg)	209	181	115%
Potassium (mg)	520	505	103%
Chloride (mg)	378	370	102%
Calcium (mg)	550	538	102%
Phosphorus (mg)	358	381	94%
Magnesium (mg)	50	49.2	102%
Iron (mg)	7.1	6.9	103%
Zinc (mg)	5.2	5.1	102%
Copper (mg)	0.40	0.39	103%
Iodine (µg)	99.6	95.6	104%
Selenium (µg)	18.0	13.8	130%
Manganese (µg)	47	190	25%
Chromium (µg)	10.4	10.1	103%
Molybdenum (mcg)	10.9	10.7	102%
Vitamins			
Vitamin A (µg RE)	415	390	106%
Vitamin D (µg)	11.4	8.4	136%
Vitamin E (mg TE)	9.48	4.3	220%
Vitamin C (mg)	50.7	49.6	102%
Vitamin K (µg)	42.8	40.8	105%
Thiamin B1 (mg)	0.57	0.54	106%
Riboflavin B2 (mg)	0.57	0.54	106%
Vitamin B6 (mg)	0.46	0.54	85%
Niacin (mg NE)	9.25	10	93%
Folic acid (µg)	66	62.7	105%
Vitamin B12 (µg)	1.33	1.3	102%
Pantothenic acid (mg)	2.94	2.8	105%
Biotin (µg)	18.5	18.1	102%
Inositol (mg)	106	104	102%
Choline (mg)	132	91.9	144%
Others			
Taurine (mg)	30.8	30	103%
L-Carnitine (mg)	9.49	9.5	100%
Bifidobacterium breve M-16V (CFU)	1.00x10 <sup>10</sup>	1.00x10 <sup>10</sup>	100%
Nucleotides (mg)	16.6	23.3	71%

Source: Table 3 Neocate Syneo Update Appendix 1.xlsx. % comparison calculated during the evaluation.

4.4 The submission presented comparisons of the new nutritional profile against the *Australia New Zealand Food Standards Code Standard 2.9.1 Schedule 2* requirements and the *Standard 2.9.5 Schedule 2* requirements as well as adequate intake (AI) and recommended daily intake (RDI) requirements for infants and children between 1 to

20 years. The submission acknowledged the few deviations from AI/RDI values defined by the National Health and Medical Research Council (NHMRC) in certain vitamins and minerals in certain age groups, and noted that none of the deviations were regarded to be of nutritional concern. Overall, the submission claimed the comparisons of the current and new formulation showed general compliance of the new formulation with the standards, AIs and RDIs.

- 4.5 The PBAC considered the new formulation is expected to provide non-inferior clinical effectiveness in comparison to the current formulation.

### ***Estimated PBS usage and financial implications***

- 4.6 The submission did not present economic or financial analyses. The submission requested no change to the current price or PBS restriction of Neocate Syneo. The submission stated the formulation change should have no financial impact to the PBS/RPBS. The Pre-PBAC Response stated there are no anticipated changes to product market growth and service delivery arrangements associated with the formulation change.

## **5 NPWP consideration**

- 5.1 The Nutritional Products Working Party (NPWP) advised that the new formulation of Neocate Syneo is expected to provide non-inferior clinical benefit in comparison to the current formulation for the management of cows' milk protein intolerance.
- 5.2 The NPWP noted that although the manganese was low, it meets the Food Standards Australia New Zealand (FSANZ) standard for infant formula.
- 5.3 The NPWP noted there is a clinical need for nutritional products for the treatment of cows' milk protein intolerance. The NPWP expressed concern that there were a limited number of alternative nutritional products for the treatment of cows' milk protein intolerance on the PBS due to delistings and supply issues. The NPWP considered that it was essential that a variety of products for the treatment of cows' milk protein intolerance be included on the PBS, to ensure adequate supply in the event of individual product shortages and to cater to individual preferences.
- 5.4 The NPWP supported the new formulation of Neocate Syneo continuing to be listed on the PBS under the existing conditions as the existing formulation.

## **6 PBAC Outcome**

- 6.1 The PBAC recommended the new formulation of amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids (Neocate® Syneo) continue to be listed on the PBS under the existing conditions of the current formulation.

- 6.2 The PBAC noted and supported the NPWP advice that the new formulation is expected to provide a non-inferior clinical benefit for the management of cows' milk protein intolerance, cows' milk allergy, EoE and the other indicated conditions.
- 6.3 The PBAC noted there were no changes requested to the circumstances under which the existing listings are available.
- 6.4 The PBAC considered the new formulation is not expected to have impacts on current utilisation of the product or the current costs to Government.
- 6.5 The PBAC noted the concerns raised in the consumer comments and the NPWP advice regarding the clinical need for a variety of products for the treatment of cows' milk protein intolerance be included on the PBS, to ensure adequate supply in the event of individual product shortages and to cater to individual preferences.
- 6.6 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.

## **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.