

**5.10 AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES,
Oral powder 400 g,
Neocate Junior®, Nutricia Australia Pty Ltd.**

1 Purpose of Application

1.1 The minor submission requested an Authority Required listing for the following indications:

- 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;
- Eosinophilic oesophagitis (EoE);
- Cows' milk anaphylaxis; and
- Severe intestinal malabsorption including short bowel syndrome.

2 Requested Listing

2.1 The submission requested that Neocate Junior® be listed for the same indications as the existing listings for Alfamino Junior® with the same restrictions (item codes 10522T and 10527C). No changes to the restrictions were proposed.

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

3 Background

3.1 Neocate Junior® does not require registration with the TGA. The sponsor of Neocate Junior® confirmed that Neocate Junior® meets the requirements for foods that have medical purposes as set out under The Australia New Zealand Food Standards Code — Standard 2.9.5: Food for Special Medical Purposes.

3.2 Neocate Junior® has not been previously considered by the PBAC.

3.3 In March 2015, the PBAC recommended listing Alfamino Junior® as an Authority Required benefit on a cost-minimisation basis against Neocate Advance (Alfamino Junior, March 2015 Public Summary Document).

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

4 Comparator

- 4.1 The minor submission nominated Alfamino Junior® and EleCare® as comparators. The sponsor nominated Alfamino Junior® as the main comparator, as both brands are a flavourless oral liquid powder whereas EleCare® is vanilla flavoured.
- 4.2 Both Alfamino Junior® and EleCare® are also amino acid powdered formulas which are currently PBS-listed for the indications listed in paragraph 1.1.

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

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

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

Clinical trials

- 5.3 As a minor submission, no clinical trials were presented in the submission.
- 5.4 The basis for listing Neocate Junior® presented in the minor submission is that it will meet a clinical need for a hypoallergenic, nutritionally complete, amino acid based powdered formula for the dietary management of children over 1 year of age with cow's milk allergy (CMA), multiple protein food intolerance (MFPI) and other medical conditions where an elemental diet is required (e.g. Eosinophilic Oesophagitis), and continues to persist into childhood.
- 5.5 In consideration of the submission, the NPWP noted that:
- The sponsor provided a suitable comparison against the requirements of the *Australia New Zealand Food Standards Code - Standard 2.9.5: Food for Special Medical Purposes*.
 - The new formulation has a higher protein concentration than other brands of Neocate® listed on the PBS. The NPWP indicated that Neocate® Junior is formulated for older patients who can tolerate the higher concentration.
 - The NPWP considered that the addition of an age restriction was not necessary noting that patients would be under the care of a specialist.
 - The NPWP considered that the nominated comparator of Alfamino Junior® was appropriate.

- The NPWP noted that the listing of this product would be cost neutral to the PBS as it would substitute for currently listed products on an equivalent cost per kilojoule (kJ) basis.

The NPWP supported the Authority Required listing of Neocate Junior® on a cost-minimisation basis against Alfamino Junior® for the dietary management of patients over 1 year of age with CMA, MPFI and other medical conditions where an elemental diet is required.

Estimated PBS usage & financial implications

- 5.6 The submission sought listing at the same DPMQ as Alfamino Junior®.
- 5.7 At the proposed DPMQ for Neocate Junior® (\$352.78) the sponsor claimed that the product costs less per kilojoule (kJ) than the comparator, Alfamino Junior®, as the comparator contains less kJ per maximum quantity than Neocate Junior®.
- 5.8 The minor submission estimated a nil financial impact to the PBS, as the product is expected to partially substitute for Alfamino Junior®, which has the same DPMQ. The minor submission did not estimate any change in script numbers as a result of the higher kJ content. Furthermore, the minor submission estimated that ■% of the current patient population who use Alfamino Junior® will instead use Neocate Junior® over a period of 5 years. The minor submission estimated that there will be no patients switching from the vanilla flavoured Elecare® as it would already be used in preference to the unflavoured amino acid formula variants.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Authority Required listing of Neocate Junior®, 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; eosinophilic oesophagitis (EoE); cows' milk anaphylaxis and; severe intestinal malabsorption including short bowel syndrome; on a cost-minimisation basis to Alfamino Junior® at the price proposed by the submission, noting that this was less than the equivalent cost per kilojoule of energy.
- 6.2 The PBAC noted the advice of the NPWP supported the listing of Neocate Junior® on the PBS.
- 6.3 The PBAC considered that Alfamino Junior® was the appropriate main comparator.
- 6.4 The PBAC noted that the proposed maximum quantity and number of repeats is consistent with the main comparator Alfamino Junior® currently listed on the PBS.

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- 6.5 The PBAC agreed with the NPWP's advice that an age restriction was not necessary as patients would be under the care of a specialist.
- 6.6 The PBAC noted that listing Neocate Junior®, as an Authority Required listing would result in nil financial impact to the PBS.
- 6.7 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC's view that general nutrients be exempt.
- 6.8 The PBAC recommended that Neocate Junior® is suitable for prescribing by nurse practitioners as nutritional products are currently included for prescribing by nurse practitioners.
- 6.9 In accordance with Section 101 (3BA) of the *National Health Act 1953*, the PBAC advised that on the basis of the material available to its March 2017 meeting, Neocate Junior® be treated as interchangeable on an individual patient basis with any other similar nutritional product.
- 6.10 The PBAC noted that this submission was not eligible for an Independent Review, as it had received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES oral liquid: powder for, 400 g	8	5	Neocate Junior®	Nutricia Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required - Emergency <input checked="" type="checkbox"/> Authority Required - Electronic

PBS Indication:	Cows' milk protein enteropathy
Treatment phase:	Initial treatment for up to 6 months
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Clinical criteria:	The condition must not be isolated infant colic or reflux, AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

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PBS Indication:	Severe cows' milk protein enteropathy with failure to thrive
Treatment phase:	Initial treatment for up to 6 months
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Clinical criteria:	The condition must not be isolated infant colic or reflux
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

PBS Indication:	Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment phase:	Initial treatment for up to 6 months
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Clinical criteria:	The condition must not be isolated infant colic or reflux
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

PBS Indication:	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment phase:	Initial treatment for up to 6 months
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Clinical criteria:	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

PBS Indication:	Eosinophilic oesophagitis (EoE)
Treatment phase:	Initial treatment for up to 3 months
Treatment criteria:	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Clinical criteria:	Patient must require an amino acid based formula as a component of a dietary elimination program.
Population criteria:	Patient must be 18 years of age or less.

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Prescribing Instructions	<p>Treatment with oral steroids should not be commenced during the period of initial treatment.</p> <p>Eosinophilic oesophagitis is demonstrated by the following criteria: (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.</p> <p>The date of birth of the patient must be included in the authority application.</p>
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.
PBS Indication:	Cows' milk protein enteropathy
Treatment phase:	Continuing treatment
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.
Clinical criteria:	<p>The condition must not be isolated infant colic or reflux,</p> <p>AND</p> <p>Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.</p>
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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PBS Indication:	Cows' milk protein enteropathy
Treatment phase:	Initial treatment for up to 6 months
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Clinical criteria:	The condition must not be isolated infant colic or reflux, AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.
PBS Indication:	Cows' milk protein enteropathy
Treatment phase:	Continuing treatment
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.
Clinical criteria:	The condition must not be isolated infant colic or reflux, AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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PBS Indication:	Severe cows' milk protein enteropathy with failure to thrive
Treatment phase:	Continuing treatment
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.
Clinical criteria:	The condition must not be isolated infant colic or reflux, AND Patient must have had failure to thrive prior to commencement with initial treatment.
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

PBS Indication:	Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment phase:	Continuing treatment
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.
Clinical criteria:	The condition must not be isolated infant colic or reflux
Population criteria:	Patient must be older than 24 months of age.
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

PBS Indication:	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment phase:	Continuing treatment
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Clinical criteria:	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.
Population criteria:	Patient must be up to the age of 24 months
Prescribing Instructions	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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PBS Indication:	Eosinophilic oesophagitis (EoE)
Treatment phase:	Continuing treatment
Treatment criteria:	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Clinical criteria:	Patient must have responded to an initial course of PBS-subsidised treatment.
Population criteria:	Patient must be 18 years of age or less.
Prescribing Instructions	Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

PBS Indication:	Cows' milk anaphylaxis
Treatment criteria:	Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.
Population criteria:	Patient must be up to the age of 24 months.
Prescribing Instructions	Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

PBS Indication:	Severe intestinal malabsorption including short bowel syndrome.
Clinical criteria:	Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.
Administrative Advice	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

The sponsor had no comment.