

5.27 AMINO ACID SYNTHETIC FORMULA
oral liquid: powder for, 400 g
Alfamino® Junior, Nestle Australia Ltd

1 Purpose of Application

1.1 The minor submission sought listing of a new formulation suitable for children aged 1 year and older for the same indications as the existing Alfamino® product listed on the PBS, as well as for severe intestinal malabsorption including short bowel syndrome.

2 Requested listing

2.1 The submission sought listing for the same PBS indications as Neocate Advance with the exception of the eosinophilic oesophagitis indication. These are summarised as the following:

Name, Restriction, Manner of administration and form	Max. Qty	No.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
AMINO ACID SYNTHETIC FORMULA				
amino acid synthetic formula oral liquid: powder for, 400 g	8	5	\$361.48	Alfamino Junior NT

- Cows' milk protein enteropathy - Initial treatment (for up to 6 months)
- Cows' milk protein enteropathy – Continuing treatment
- Severe cows' milk protein enteropathy with failure to thrive – Initial treatment (for up to 6 months)
- Severe cows' milk protein enteropathy with failure to thrive – Continuing treatment
- Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae - Initial (for up to 6 months)
- Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae – Continuing treatment
- Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein - Initial treatment (for up to 6 months)
- Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein – Continuing treatment
- Cow's milk anaphylaxis – Initial and Continuing treatment
- Severe intestinal malabsorption including short bowel syndrome

3 Background

3.1 Alfamino Junior did not require registration with the TGA. It is classified as a “Food for Special Medical Purpose” regulated under the Australia New Zealand Food Standards Code and complies with this standard.

3.2 Alfamino Junior had not previously been considered by the PBAC.

3.3 In July 2013, the PBAC recommended listing Alfamino as an Authority required benefit for the same indications as those applying to Neocate Gold, on a cost-

minimisation basis compared to Neocate Gold and at an equivalent price per gram of protein.

4 Comparator

4.1 The minor submission nominated Neocate Advance as the main comparator as it is the most similar preparation to Alfamino Junior, containing amino acid synthetic formula and medium chain triglycerides.

4.2 The PBAC noted the following products are listed for the requested indications:

PBS Item	Major components	Label Age Range
Elecare	AAF+MCT	Infants and Children
Elecare LCP	AAF+LCP	Infants and Children
Neocate Advance Vanilla	AAF	12 months+
Neocate Advance	AAF+MCT	12 months+
Neocate LCP	AAF+LCP	0-12 months
Neocate Gold	AAF+LCP+MCT	0-12 months
Alfamino	AAF+LCP+MCT	From birth onwards

Source: Table 5, p11 of the minor submission

LCP=Long chain polyunsaturated fatty acids

MCT=Medium chain triglycerides

AAF=Amino acid synthetic formula

5 Consideration of evidence

5.1 The minor submission did not present any clinical trials.

5.2 The premise of the submission was that the product would fulfil a clinical need for a more nutritionally targeted formula for patients aged 1 year and older, compared to the existing Alfamino product which is suitable for use from birth.

Estimated PBS usage & financial implications

5.3 The submission sought listing at the same price per gram of protein equivalent as Neocate Advance.

5.4 The minor submission therefore claimed that there would be no financial implications to the PBS as the submission expected Alfamino Junior to substitute directly for Neocate Advance, Neocate Advance Vanilla and EleCare[®] in practice.

6 PBAC Outcome

6.1 The PBAC noted advice from the Nutritional Products Working Party and recommended listing Alfamino Junior as an Authority Required benefit for the same indications as Neocate Advance with the exception of eosinophilic oesophagitis on a cost-minimisation basis against Neocate Advance at an equivalent price per gram of protein.

6.2 The PBAC noted the NPWP's support for the listing of Alfamino Junior and advice that Alfamino Junior would provide a more nutritionally targeted product for patients

aged 1 year and older compared to the existing Alfamino product which is suitable for use from birth.

6.3 The PBAC recommended that Alfamino Junior be suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.

6.4 The PBAC recommended that the Safety Net 20 Day Rule should not apply as it has been the PBAC's view that general nutrients be exempt.

Outcome:

Recommended

7 Recommended listing

7.1 Add new items:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
AMINO ACID SYNTHETIC FORMULA			
amino acid synthetic formula oral liquid: powder for, 400 g	8	5	Alfamino Junior NT

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
Episodicity:		-
Severity:		-
Condition:		Cows' milk protein enteropathy
PBS Indication:		Cows' milk protein enteropathy
Treatment phase:		Initial (for up to 6 months)
Restriction Level / Method:		<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
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.

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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.
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> No increase in the maximum quantity or number of units may be authorised. <u>NOTE:</u> No increase in the maximum number of repeats may be authorised.

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
Episodicity:	-
Severity:	-
Condition:	Cows' milk protein enteropathy
PBS Indication:	Cows' milk protein enteropathy
Treatment phase:	Continuing
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
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.
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.
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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

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Episodicity:	-
Severity:	Severe
Condition:	cows' milk protein enteropathy with failure to thrive
PBS Indication:	Severe cows' milk protein enteropathy with failure to thrive
Treatment phase:	Initial (for up to 6 months)
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
Clinical criteria:	The condition must not be isolated infant colic or reflux.
Population criteria:	Patient must be up to the age of 24 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.
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> No increase in the maximum quantity or number of units may be authorised. <u>NOTE:</u> No increase in the maximum number of repeats may be authorised.

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
Episodicity:	-
Severity:	Severe
Condition:	cows' milk protein enteropathy with failure to thrive
PBS Indication:	Severe cows' milk protein enteropathy with failure to thrive
Treatment phase:	Continuing
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined

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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.
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.
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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Episodicity:	-
Severity:	-
Condition:	Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
PBS Indication:	Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment phase:	Initial (for up to 6 months)
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
Clinical criteria:	The condition must not be isolated infant colic or reflux.
Population criteria:	Patient must be older than 24 months of age.
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> No increase in the maximum quantity or number of units may be authorised. <u>NOTE:</u> No increase in the maximum number of repeats may be authorised.

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Episodicity:	-
Severity:	-
Condition:	Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
PBS Indication:	Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment phase:	Continuing
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
Clinical criteria:	The condition must not be isolated infant colic or reflux.
Population criteria:	Patient must be older than 24 months of age.
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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
Episodicity:	-
Severity:	-
Condition:	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
PBS Indication:	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment phase:	Initial (for up to 6 months)
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
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.

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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.
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> No increase in the maximum quantity or number of units may be authorised. <u>NOTE:</u> No increase in the maximum number of repeats may be authorised.

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
Episodicity:	-
Severity:	-
Condition:	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
PBS Indication:	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment phase:	Continuing
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
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.
Treatment criteria:	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Foreword	-
Definitions	-
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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
Episodicity:	-

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Severity:	-
Condition:	Cow's milk anaphylaxis
PBS Indication:	Cow's milk anaphylaxis
Treatment phase:	Initial and Continuing
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
Clinical criteria:	-
Population criteria:	Patient must be up to the age of 24 months.
Treatment criteria:	Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.
Foreword	-
Definitions	Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
Prescriber Instructions:	The name of the specialist and the date of birth of the patient must be included in the authority application.
Administrative Advice:	<u>NOTE:</u> Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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
Episodicity:	-
Severity:	-
Condition:	Severe intestinal malabsorption including short bowel syndrome
PBS Indication:	Severe intestinal malabsorption including short bowel syndrome
Treatment phase:	Initial and Continuing
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.
Treatment criteria:	Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Administrative Advice:	<u>NOTE:</u> Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.
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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.