

4.3 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

oral liquid: powder for, 30 x 36 g sachets;
MSUD Anamix Junior®; Nutricia Australia Pty Ltd

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

oral liquid: powder for, 30 x 36 g sachets;
PKU Anamix Junior®; Nutricia Australia Pty Ltd

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

oral liquid: powder for, 30 x 36 g sachets;
TYR Anamix Junior ®; Nutricia Australia Pty Ltd

1 Purpose of item:

- 1.1 The item provided the PBAC with the additional information requested by the Nutritional Products Working Party (NPWP) for these 3 product types following a deferral from the November 2014 PBAC meeting.

2 Requested Listing:

- 2.1 The minor submissions to the November 2014 sought to notify of a change in the nutritional formula, flavour and pack size from 29 g sachets to 36 g sachets. Apart from these changes, there was no request to change the PBS restrictions.

3 Background

- 3.1 The sponsor submission's notifying of a formulation upgrade, flavour change and pack size increase for the Anamix Junior® range (MSUD, PKU and TYR) were considered at the November 2014 PBAC meeting. The PBAC deferred its recommendation due to incomplete information provided in the sponsor submissions submitted to the November 2014 PBAC meeting.
- 3.2 In the sponsor's pre-PBAC response to the November 2014 PBAC meeting, the sponsor sought to address the deficiencies in its submission as identified in the NPWP's September 2014 teleconference minutes. However, the NPWP was unable to reconvene out of session in the limited time space available to provide further advice to the Committee in November 2014. The PBAC therefore deferred the submissions until such time that advice from the Working Party could be obtained.

4 Summary of additional information provided by the sponsor

- 4.1 The following information was provided by the sponsor:
- Justification for the potentially low levels of the amino acid 'tyrosine' in TYR Anamix Junior.

- A corrected comparison table of the old and new amino acid profile for all three products.
- Advice from the sponsor that it could not identify any clinical trial data on the adequacy of amino acid composition for the MSUD Anamix Junior and PKU Anamix Junior upgraded products.
- In terms of the relatively high vitamin D levels in the upgraded Anamix Junior products, the sponsor's view that the level of intake is well below the National Health and Research Medical Council's recommended upper limit of 80 microgram/day.
- Advice of the sponsor's intent to communicate these formulation changes through healthcare professional letters.

5 PBAC Outcome

- 5.1 The PBAC noted advice from the Nutritional Products Working Party and had no significant concerns over the formulation upgrade for TYR Anamix Junior, MSUD Anamix Junior, PKU Anamix Junior products in terms of the appropriateness of the nutritional content of the products for their intended uses.
- 5.2 The PBAC accepted NPWP advice that it may be helpful for the PBS listings of these products to note the changes in formulation (vitamin D and amino acid composition) through an administrative note for a suggested period of 6 to 12 months.
- 5.3 The PBAC noted that the pack size increase from 29 g to 36 g sachets would result in an increase in the dispensed price for the maximum quantity (DPMQ) if the new formulations are priced on an equivalent gram of protein basis compared to the existing formulations. The submission's provided the reason for the sachet size change as being a result of the sponsor's desire to provide a standardised amount of protein equivalent per product. The submission further claimed the amount of product used by a patient would not change since dosing is by amount of protein/kg of body weight (i.e. although more costly, an initial dispensing would last the patient longer). Whilst the PBAC recommended the listing of the new formulations in 36 g sachet sizes on a cost-minimisation basis with the existing formulations in 29 g sachets at an equivalent cost per gram of protein, the PBAC suggested the Department monitor use and financial expenditure on these products.
- 5.4 The PBAC recommended that the same PBS listing circumstances that apply to the current products apply to the new formulations and pack sizes, with the exception of the additional administrative note.

Outcome:

Recommended

6 Recommended Listing

Add the following new items:

Public Summary Document – March 2015 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
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AMINO ACID FORMULA WITH VITAMINS
AND MINERALS WITHOUT
PHENYLALANINE

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x ~~29-g~~ 36 g sachets 4 4 5 PKU Anamix Junior SB

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:	Phenylketonuria
PBS Indication:	Phenylketonuria
Treatment phase:	-
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Administrative Advice:	<u>NOTE</u> Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
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AMINO ACID FORMULA WITH VITAMINS AND
MINERALS WITHOUT PHENYLALANINE AND
TYROSINE

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x ~~29-g~~ 36 g sachets 4 4 5 TYR Anamix Junior SB

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:	Tyrosinaemia
PBS Indication:	Tyrosinaemia
Treatment phase:	-

Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Administrative Advice:	<u>NOTE</u> Changes in vitamin D levels and other nutrients have occurred with a recent formulation change.

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE				
amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g 36 g sachets	4	4	5	MSUD Anamix Junior SB

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:	Maple syrup urine disease
PBS Indication:	Maple syrup urine disease
Treatment phase:	-
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Administrative Advice:	<u>NOTE</u> Changes in vitamin D levels and other nutrients have occurred with a recent formulation change.

7 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.

8 Sponsor's Comment

The sponsor had no comment.