

14.03 TYROSINE WITH CARBOHYDRATE

Sachets of oral powder 4 g containing 1 g tyrosine, 30

Tyrosine 1000[®], Vitaflo Australia Pty Limited.

1 Purpose of Application

- 1.1 The minor submission sought to amend the listing of Tyrosine 1000 for the dietary management of phenylketonuria (PKU) to include an age restriction to patients aged 3 years and over due to changes in product formulation.

2 Requested listing

- 2.1 The submission requested the addition of the clause 'suitable from 3 years of age onwards' into the current listing.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price Max. Qty	Proprietary Name and Manufacturer	
TYROSINE WITH CARBOHYDRATE					
Sachets of oral powder 4 g containing 1g tyrosine, 30	4	5	\$438.79	Tyrosine 1000 [®]	Vitaflo Australia Pty Limited

Category / Program	Section 85 – General Schedule
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
PBS Indication:	Phenylketonuria
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	<i>This formulation is suitable for patients aged 3 and older.</i>

- 2.2 The Secretariat considered the requested clause should be an administrative advice as it refers to the suitability of the product rather than a strict requirement for prescribing, where determining suitability for patients would be a matter of clinical judgement. Slight wording changes were proposed as outlined in italics.

3 Background

- 3.1 The sponsor of Tyrosine 1000 (Vitaflo Australia Pty Ltd) confirmed the product continues to meet the requirements for foods for medical purposes as set out under *The Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes*.

4 Consideration of the evidence

Sponsor hearing

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

Consumer comments

- 4.2 The PBAC noted there were no consumer comments received for this item.

Change to product formulation

- 4.3 The sponsor advised that the change to the listing was in response to the testing of xanthan gum stabiliser in Tyrosine 1000 which revealed levels of *Cronobacter* bacteria above limits imposed by the manufacturer/sponsor. However, xanthan gum is necessary to maintain solubility of the product.
- 4.4 In 2008, the international Codex Committee on Food Hygiene (CCFH) identified *Cronobacter* species as an important pathogen for infants fed with powdered infant formula¹. In 2016, Food Standards Australia New Zealand (FSANZ) adopted a new *Cronobacter* limit of no bacteria present for powdered infant formulas². Based on this, an age restriction may be appropriate if the absence of *Cronobacter* bacteria cannot be guaranteed.

Estimated PBS usage & financial implications

- 4.5 The submission argued that since the primary-age-market of Tyrosine 1000 is above 3 years, there is unlikely to be a change to PBS utilisation of tyrosine or a cost to the PBS.

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

5 NPWP Consideration

- 5.1 The NPWP noted that the requested addition of an age restriction to the listing of tyrosine with carbohydrate (Tyrosine 1000) was due to the presence of *Cronobacter* bacteria in the xanthan gum stabiliser additive. The NPWP considered that the

¹ In Australia, infant formula is defined for ages 'up to four to six months'.

² Food Standards Australia New Zealand (FSANZ) 2016. Approval Report – Proposal P1039, Microbiological Criteria for Infant Formula. Accessed 7 May 2019, available at <https://www.foodstandards.gov.au/code/proposals/Documents/P1039-MicroReview-AppR.pdf>

requested age restriction to patients aged 3 years and over was acceptable. It noted the age restriction might be overly cautious as limits in regulations for powdered infant formulas are for infants aged up to 6 months. However, the NPWP noted that the use of tyrosine as a standalone product for infants and children is rare and the change was unlikely to affect patients.

6 PBAC Outcome

- 6.1 The PBAC agreed with the changes to the listing of tyrosine with carbohydrate (Tyrosine 1000) processed by the Secretariat to include advice that the product is suitable for patients aged 3 years and over. Noting the NPWP advice, the PBAC agreed the change was unlikely to impact patients as the use of standalone tyrosine in infants and young children is rare.
- 6.2 The PBAC considered that the current arrangements to permit nurse practitioner prescribing and not having the Early Supply Rule apply remained appropriate.
- 6.3 The submission is not eligible for independent review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Amend listing as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price Max. Qty	Proprietary Name and Manufacturer	
TYROSINE WITH CARBOHYDRATE					
Sachets of oral powder 4 g containing 1g tyrosine, 30	4	5	\$438.65	Tyrosine 1000®	Vitaflo Australia Pty Limited

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Administrative Advice	This formulation is suitable for patients aged 3 and older.

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.