

5.23 AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE, oral liquid: powder for, 30 x 130mL cans, PKU Easy Liquid®, Orpharma Pty Ltd.

1 Purpose of Application

1.1 The minor submission requested a restricted benefit listing for phenylketonuria.

2 Requested listing

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Amino acid formula with vitamins and minerals without phenylalanine containing 15 g protein oral liquid: powder, 30 x 130 mL cans	4	5	\$ [REDACTED]	PKU Easy Liquid®	Orpharma 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
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

3 Background

3.1 The sponsor of PKU Easy Liquid®, confirms that it 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 PKU Easy Liquid® has not been considered by PBAC previously.

4 Comparator

4.1 The minor submission nominated PKU Cooler 15®.

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 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted:

- This product has a similar proportion of amino acids to the appropriate comparator, PKU Cooler 15®; but it does not contain choline. There is an RDI level for choline, and patients on a PKU-suitable diet are likely to have low intake of choline. The sponsor was therefore encouraged to consider adding choline to future formulations of the product.
- The product has a similar vitamin and mineral content to the comparator, although slightly lower in calcium, phosphate, and Vitamins A and D.
- In Attachment 3, the biotin RDI for pregnant women aged 14-18 years was incorrectly stated as 3 µg/day, rather than 30 µg/day.

5.5 The NPWP supported the listing of PKU Easy Liquid® as a Restricted Benefit for phenylketonuria on a cost-minimisation basis against PKU Cooler® 15 at an equivalent price per gram of protein.

Estimated PBS usage & financial implications

5.6 The proposed DPMQ (\$██████████) has been calculated based on the same cost per protein equivalent of the comparator.

5.7 The submission assumed ██████████ dispensings per year for this product.

5.8 Based on the DPMQ in the submission, a nil net cost to the PBS was estimated as this product will replace the use of currently PBS listed formulas.

6 PBAC Outcome

6.1 The PBAC recommended the listing of PKU Easy Liquid® as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis against PKU Cooler 15® listing at the same price per gram of protein.

- 6.2 The PBAC noted the advice from Nutritional Products Working Party's (NPWP) view that this product has a similar proportion of amino acids to the appropriate comparator, PKU Cooler 15[®] but it does not contain choline.
- 6.3 The PBAC noted that the submission estimated a nil cost to the PBS as it expected to replace existing products.
- 6.4 In accordance with subsection 101(3BA) of the Act the PBAC advised that, on the basis of the material available to its November 2015 meeting, PKU Easy Liquid[®] should not be treated as interchangeable on an individual patient basis with any other drugs.
- 6.5 The PBAC recommended that PKU Easy Liquid[®] is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
- 6.6 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 item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Amino acid formula with vitamins and minerals without phenylalanine containing 15 g protein oral liquid: powder, 30 x 130 mL cans	4	5	PKU Easy Liquid®	Orpharma Pty Ltd

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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 thanks the PBAC for their considerations.