

5.21 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, 15g protein equivalent oral liquid: powder, 30 x 34 g bottles, PKU Easy Shake & Go®, 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, 34g bottles	4	5	\$ [REDACTED]	PKU Easy Shake & Go®	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 PKU Easy Shake & Go® does not require registration with the TGA. The sponsor 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 Shake & Go® has not been considered by the PBAC previously.

4 Comparator

- 4.1 The minor submission nominates PKU Express-15® as the main comparator. It is also a powder to be made into an oral liquid formulation and contains the same 15g protein equivalent per dosing and per PBS maximum quantity.
- 4.2 The submission also nominates replacement of other similar products by PKU Easy Shake & Go®, containing different amounts of protein equivalent (PE), such as PKU Express-20® (20g PE), Lophlex® (20g PE) or PKU Anamix® Junior (8.4g PE).

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 No clinical trials have been provided, for PKU Easy Shake & Go®, in the submission.
- 5.4 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted:
- This product will likely substitute currently listed products for a very small number of patients and/or may improve compliance. The submission estimated that listing would be cost neutral to the PBS.
 - This product has a similar proportion of amino acids to the comparator, PKU Express 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 slightly lower vitamin and mineral content than the comparator, but the clinical significance is uncertain.
 - The manufacturer recommends this product for children aged three years and over. For children under three years, most Nutrient Reference Values (NRVs) are insufficient, however this is similar to the comparator. A recommendation for use in children aged three years and over was made by the NPWP. However, the NPWP considered a specific age restriction in the listing was not required for these products, as this decision should remain a clinical judgement for the prescriber.
 - 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 Shake & Go® as a Restricted Benefit for phenylketonuria on a cost-minimisation basis against PKU Express 15® at an equivalent price per gram of protein.

Estimated PBS usage & financial implications

- 5.6 The submission assumes [REDACTED] dispensing per year for this product. Estimated nil cost to PBS as the submission expects PKU Easy Shake & Go[®] to only replace the use of other PBS-listed products for phenylketonuria.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of PKU Easy Shake & Go[®] as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis against PKU Express-15[®] listing at the same price per gram of protein.
- 6.2 The PBAC noted that the advice of the NPWP that supported listing of PKU Easy Shake & Go[®] on the PBS.
- 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 Shake & Go[®] should not be treated as interchangeable on an individual patient basis with any other drugs.
- 6.5 The PBAC recommended that PKU Easy Shake & Go[®] 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 Manufacturer	Name and
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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.