

**6.06 AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS and TRACE ELEMENTS without PHENYLALANINE**  
**Bottles containing oral powder 34 g, 30**  
**PKU Easy Shake & Go®**

**AMINO ACID FORMULA with FAT, CARBOHYDRATE without PHENYLALANINE**  
**Tablet: modified release, 70.8 g protein per 100g, 110 g, 4**  
**PKU Easy Microtabs®**

**PROTEIN FORMULA with AMINO ACIDS, CARBOHYDRATES, VITAMINS and MINERALS without PHENYLALANINE, and SUPPLEMENTED with DOCOSAHEXAENOIC ACID**  
**Oral liquid 130 mL, 30**  
**PKU Easy®,**

**Orpharma Pty Ltd**

**1 Purpose of Application**

1.1 The minor submission requested an amendment to the current PBS listings of phenylketonuria (PKU) to increase the maximum quantity for all forms listed in the submission.

**2 Requested Listing**

2.1 The submission requested the following changes to the existing listing:

2.2 No changes to the proposed listing were suggested by the Secretariat

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
PROTEIN FORMULA with AMINO ACIDS, CARBOHYDRATES, VITAMINS and MINERALS without PHENYLALANINE, and supplemented with DOCOSAHEXAENOIC ACID Oral liquid, 30 x 130 mL pouches	5	5	\$ [REDACTED]	PKU Easy®	Orpharma Pty Ltd

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<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Phenylketonuria
<b>PBS Indication:</b>	Phenylketonuria
<b>Restriction Level / Method:</b>	<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

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AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE Tablet: modified release, 4 x 110 g	7	5	\$ [REDACTED]	PKU Easy Microtabs®	Orpharma Pty Ltd

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AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE oral liquid: powder for, 30 x 34 g bottles	5	5	\$ [REDACTED]	PKU Easy Shake & Go®	Orpharma Pty Ltd

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### 3 Background

- 3.1 In the original submission of November 2015, the sponsor of PKU Easy<sup>®</sup>, PKU Easy Microtabs<sup>®</sup>, and PKU Easy Shake & Go<sup>®</sup> confirmed 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 The sponsor stated that the request to increase the products' maximum quantity was initiated by independent clinicians who prescribe the PKU products to adult patients. The clinicians stated that the increase would avoid additional prescriptions. The subsequent protein content of the maximum quantities would be equivalent to the current maximum quantities of other PKU products on the PBS, such as PKU Anamix<sup>®</sup> or PKU Air<sup>®</sup>, which contain 20 g of protein equivalent (PE).
- 3.3 The submission stated that under the current MQ for PKU Easy and PKU Easy Shake & Go, adult patients with PKU require more than the 4 units of 30 pouches or bottles to meet their monthly protein requirements.
- 3.4 The sponsor stated that adult patients with PKU require over 70-80 g of supplemented protein per day, or 2,100 – 2,400 g protein per month. Some other formulations for PKU provide 20 g PE per individual serving, while the sponsor's PKU products contain 15 g PE. Under the current MQ of 4 packs of 30 bottles or pouches, the sponsor's formulations contain 1,800 g PE, which the sponsor stated does not meet the monthly requirements of adult PKU patients. However, due to a higher PE of 20 g per individual serve, other formulations meet the requirements under the same MQ.
- 3.5 PKU Easy Microtabs<sup>®</sup> are similarly below the monthly protein requirements when dispensed at the current MQ. The sponsor claimed that increasing the MQ from 5 to 7 packs will provide a full month's supplemented protein requirements.
- 3.6 PKU Easy<sup>®</sup>, PKU Easy Microtabs<sup>®</sup>, and PKU Easy Shake & Go<sup>®</sup> were recommended for PBS listing by the PBAC at the November 2015 meeting.
- 3.7 The PBAC recommended the listing of PKU Easy Microtabs<sup>®</sup> as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis against Phlexy-10<sup>®</sup> listing at the same price per gram of protein.
- 3.8 The PBAC recommended the listing of PKU Easy Shake & Go<sup>®</sup> as a Restricted

Benefit for the treatment of phenylketonuria on a cost-minimisation basis against PKU Express-15<sup>®</sup> listing at the same price per gram of protein.

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

#### **4 Comparator**

- 4.1 The clinician who initiated the sponsor's request compared the PKU Easy products to similar PBS-listed PKU formulations, such as PKU air<sup>®</sup>, PKU Squeeze<sup>®</sup>, PKU Express<sup>®</sup> and PKU Anamix<sup>®</sup> or Phlexy-10<sup>®</sup> products. The comparators are currently listed on the PBS at the same MQ as the PKU products in this submission.
- 4.2 The comparator brands contain 20g PE and have similar formulations to each PKU product, such as tablets (Phlexy-10<sup>®</sup>), oral liquid powder (PKU Anamix Junior<sup>®</sup>), and oral liquid pouches (PKU Air<sup>®</sup>).

*For more detail on PBAC's view, see section 7 "PBAC outcome"*

#### **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 that:
- The request to increase the maximum quantity (MQ) for the three brands was appropriate, as the resulting grams of protein equivalent (PE) will be the recommended level per month. The increased PE will also be at a level that is similar to other PBS-listed PKU products, as other formulations have a higher PE at the same MQ.
  - If the change to listing is recommended, the increased MQ will result in a decrease in patient co-payments. However, the NPWP determined that this cost to the Government would be minimal.

- 5.5 The NPWP supported the change to the listing of PKU Easy Shake & Go®, PKU Easy Microtabs®, and PKU Easy® by increasing the maximum quantity.

***Estimated PBS usage & financial implications***

- 5.6 The sponsor estimated a nil financial cost to the PBS, as all products are listed on the same price per PE as their comparators.
- 5.7 The increased MQ could potentially lead to fewer patient co-payments, but the sponsor stated that this contributes to less than 1% of the DPMQ.

*For more detail on PBAC's view, see section 7 "PBAC outcome"*

**6 PBAC Outcome**

- 6.1 The PBAC recommended the proposed increase to the maximum quantities of PKU Easy®, PKU Easy Shake & Go®, and PKU Easy Microtabs® for the treatment of phenylketonuria.
- 6.2 The PBAC noted the advice of the Nutritional Products Working Party (NPWP) that supported the changes to the listing of PKU Easy®, PKU Easy Shake & Go®, and PKU Easy Microtabs®.
- 6.3 The PBAC noted that the change to listing will result in decreased patient co-payments, but determined a minimal cost to the PBS.
- 6.4 The PBAC advised that, based on the maximum grams of protein equivalent per maximum quantity, the revised DPMQ should align with similar PKU products on the PBS.
- 6.5 The PBAC noted that this submission is not eligible for an Independent Review, as this is not a submission for a new indication or a major new subgroup.

**Outcome:**

Recommended

**7 Recommended listing**

- 7.1 Amend the existing listings as follows:

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oral liquid: powder for, 30 x 34 g bottles

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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 accepting this request.