

**4.2 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE
oral liquid, 30 x 130 mL & 30 x 174 mL pouch;
PKU Air®; Vitaflo Australia**

1 Purpose of Item

1.1 The item provided the PBAC with the requested further information as outlined in the Nutritional Products Working Party’s (NPWP) September 2014 advice to the PBAC’s November 2014 meeting following the PBAC’s deferral of a submission to list this new product. In particular, the information provided by the sponsor sought to clarify:
1) Whether PKU Air is exactly the same as PKU Cooler “Low Calorie” green and gold flavours and that it is simply a trade product name change; and
2) The correct vitamins and amino acid profile contained in the new PKU Air product.

2 Requested listing

2.1 The submission’s requested listing is shown below:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE				
amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouch	4	5	\$ [REDACTED]	PKU Air 15 Vitaflo
amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouch	4	5	\$ [REDACTED]	PKU Air 20 Vitaflo

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 Air was considered at the November 2014 PBAC meeting. The PBAC deferred its recommendation due to incomplete information provided in the original submission with respect to the vitamin and amino acid content.
- 3.2 The NPWP had identified the following issues with the proposed new product:
- Whether PKU Air is the same product as PKU Cooler ‘green’ and ‘gold’;
 - Clarification on the comparative vitamin content and amino acid compositions between PKU Air and PKU Cooler. Several values appeared to be abnormal.
- 3.3 The sponsor provided the requested information as outlined in the NPWP’s September 2014 teleconference minutes to the PBAC in the November 2014 pre-PBAC Response. However, the NPWP was unable to reconvene to provide further advice on this information provided by the sponsor so the PBAC deferred the submission until such time that further advice from the NPW could be sought.

4 Summary of further information provided by the sponsor

- 4.1 The sponsor clarified that PKU Air is exactly the same as PKU Cooler ‘Low Calorie’ green and gold flavours and that a change had occurred in the trade product name.
- 4.2 The sponsor provided corrections with respect to Appendix 1 of the November 2014 submission to the PBAC to address the errors identified by the NPWP.
- 4.3 In addition, the sponsor provided the amino acid composition of both the PKU Air and PKU Cooler per 100 mL to demonstrate that the products are identical.

Estimated PBS usage & financial implications

- 4.4 The minor submission estimated there to be no financial implications to the PBS as the submission claimed that PKU Air would only substitute for PKU Cooler and possibly for PKU Lophlex LQ and PKU Express products. Since the PKU Cooler is currently listed on the PBS and the submission did not request a change in price, the submission estimated no net financial implications to the PBS.

5 PBAC Outcome

- 5.1 The PBAC noted advice from the NPWP and recommended the listing of PKU Air[®] as a Restricted Benefit for the management of phenylketonuria on a cost-minimisation basis with the existing PKU Cooler listings at the same price per gram of protein.
- 5.2 The PBAC recommended that PKU Air[®] is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
- 5.3 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

6 Recommended listing

6.1 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 oral liquid, 30 x 130 mL pouch <i>[description subject to Australian Medicines Terminology conventions]</i>	4	5	PKU Air 15	Vitaflo
amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouch <i>[description subject to Australian Medicines Terminology conventions]</i>	4	5	PKU Air 20	Vitaflo

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

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.