

**5.13 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 Application

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

2 Requested listing

2.1 The requested listing has been reformatted for compatibility with PharmCIS:

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	4	5	Vitaflo PKU Air 15
amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouch	4	5	PKU Air 20

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 does not require registration with the TGA. It is classified as a “Food for Special Medical Purpose” regulated under the Australia New Zealand Food Standards Code and complies with this standard.

3.2 PKU Air had not been considered by the PBAC previously.

4 Comparator

4.1 The minor submission nominated PKU Cooler as the main comparator, as PKU Cooler resembles PKU air in nutritional composition and presentation. It stated that PKU Air is also similar to PKU Lophlex LQ and PKU Express.

5 Consideration of evidence

5.1 The submission stated that it is difficult to undertake comparative randomised trials in a group of patients when the key management is strict avoidance of the phenylalanine containing foods and avoidance of the substitute formula, as this would result in severe growth retardation and other possible medical complications.

5.2 In the absence of randomised trials, the submission presented a comparison between nutrient compositions of PKU Air to PKU Cooler, PKU Lophlex LQ and PKU Express.

5.3 The submission stated that there is little therapeutic difference between the products and outlined the key differences between PKU Air and PKU Cooler as below.

- PKU Air has 21% less calories per gram of protein. The submission stated that the reduction in calories may assist in weight control for the overweight or obese patients with PKU.
- PKU air is exchangeable with PKU Express 15 on per 15g foil pouch basis, as they have the same calorie content per foil pouch.
- PKU air is available in two new flavours. PKU is available in green with lemon and lime flavoured and in gold with coffee mocha flavoured.

5.4 Based on the presented data, the Nutritional Products Working Party (NPWP) questioned whether PKU Air is identical in nutritional profile to PKU Cooler “green” and “gold”, the low calorie versions of PKU Cooler, which is currently listed on the PBS, and requested further clarification on the differences (if any) between PKU Air and PKU Cooler be provided.

5.5 The NPWP noted that Appendix 1 (p.16) of the submission appeared incomplete, in that it omitted to provide an amino acid composition comparison and that for nearly all of the vitamins (with the exception of choline and inositol), the amount of vitamins contained in PKU Air appeared to be significantly less (approximately four-fold) than that in PKU Cooler.

5.6 The NPWP, therefore, deferred its consideration of this submission until further information could be provided on the following issues:

- 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.

- 5.7 The PBAC noted that the sponsor provided the requested information in its Pre-PBAC Response, however it was not possible in the available time for the NPWP to fully evaluate the information prior to the PBAC meeting.

6 PBAC Outcome

- 6.1 The PBAC deferred its recommendation until further advice could be provided by the NPWP on this submission in view of the additional information that was received from the sponsor.

Outcome:

Deferred

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.