

5.24 CITRULLINE
1 g tablet, 300,
Citrulline Easy Tablets®, Orpharma Pty Ltd.

1 Purpose of Application

1.1 The minor submission requested a Restricted Benefit listing for urea cycle disorders.

2 Requested listing

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
CITRULLINE Citrulline tablets, containing 1g citrulline, 300 tablets per bottle	1	5	\$ [REDACTED]	Citrulline Easy Tablets®	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
PBS Indication:	Urea Cycle Disorders
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
Clinical criteria:	-
Cautions	Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

3 Background

3.1 The sponsor of Citrulline Easy Tablets® 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 Citrulline Easy Tablets® have not been considered by PBAC previously.

4 Comparator

4.1 The minor submission nominated Citrulline 1000® powder sachets as the comparator. This product has lower amounts of carbohydrates and energy than the comparator.

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 citrulline with carbohydrate (Citrulline 1000®) was the appropriate comparator.
- One tablet of Citrulline Easy Tablets® and one 4 gram sachet of Citrulline 1000® contains 1 gram of citrulline.
- The maximum quantity proposed in the submission provides 300 tablets while the maximum quantity for the current listing of Citrulline 1000® provides 120 sachets.
- The tablet form of this product may be preferred by adolescents and adults.
- This product has slightly lower energy and carbohydrate levels than the comparator, but this was not considered clinically relevant.

5.5 The NPWP supported the listing of Citrulline Easy Tablets® as a Restricted Benefit for urea cycle disorders on a cost-minimisation basis against Citrulline 1000® powder sachets at an equivalent price per gram of citrulline.

Estimated PBS usage & financial implications

5.6 The DPMQ is based on calculation of equivalent cost per gram of citrulline with the comparator.

5.7 The submission assumes [REDACTED] dispensings per year for this product.

5.8 Based on the DPMQ in the submission, a nil cost to the PBS was estimated due to direct substitution of the comparator with this product.

6 PBAC Outcome

6.1 The PBAC recommended the listing of Citrulline Easy Tablets® as a Restricted Benefit for the treatment of urea cycle disorders on a cost-minimisation basis against Citrulline 1000® powder sachets at an equivalent price per gram of citrulline.

6.2 The PBAC noted that the advice from Nutritional Products Working Party. The PBAC considered that the wording of restrictions for this product and Citrulline 1000® powder sachets should be same.

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- 6.3 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, Citrulline Easy Tablets® should not be treated as interchangeable on an individual drug.
- 6.4 The PBAC noted that a nil cost to the PBS was estimated due to direct substitution of the comparator with this product.
- 6.5 The PBAC recommended that Citrulline Easy Tablets® 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	
CITRULLINE Citrulline tablets, containing 1g citrulline, 1 300 tablets per bottle	1	5	Citrulline Easy Tablets®	Orphama 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
PBS Indication:	Urea Cycle Disorders
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
Clinical criteria:	The treatment must be for preventing low plasma arginine or citrulline levels.
Cautions	Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

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.