

14.03 TRIGLYCERIDES MEDIUM CHAIN FORMULA, oral liquid: powder for, 400 g, Monogen®, Nutricia Australia Pty Ltd.

1 Purpose of Application

1.1 To advise of an upgrade in the nutritional formula of Monogen®.

2 Requested listing

2.1 No changes to the existing listing were proposed by the sponsor.

3 Background

3.1 Monogen® is currently listed on the PBS for Hyperlipoproteinaemia type 1, Long chain fatty acid oxidation disorders, Chylous ascites and Chylothorax.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

4.2 The PBAC noted that no consumer comments were received for this item.

Estimated PBS usage & financial implications

4.3 The submission proposed no changes to current pricing arrangements and is cost-neutral to the PBS.

5 PBAC Outcome

5.1 The PBAC noted the Nutritional Products Working Party (NPWP) had no objection to the formulation change to Monogen® and accepted the changes as requested, noting that there was no change to the current PBS listing for this product.

5.2 The PBAC noted the formulation upgrade of the current product such as change in long chain fatty acid profile, addition of docosahexaenoic acid and arachidonic acid for use in fatty acid oxidation disorders and chylothorax.

5.3 The PBAC also noted significant increase in choline, Vitamin D, iron, iodine and calcium in the formulation.

5.4 The PBAC noted the vitamin and mineral content was relatively high in the Nutrient Reference Values (NRV) comparison, however the product continues to be appropriately compliant with “Australia New Zealand Food Standards Code - Standard 2.9.1 - Infant Formula Products”, except for Vitamin D which is only marginally higher.

5.5 The PBAC agreed with the NPWP advice that sponsors should notify patients and health care professionals of the change to a different scoop weight and formulation, to avoid the potential for inaccurate preparation of the product.

Outcome:

Recommended

6 Recommended listing

6.1 No change to the existing listing.

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.