

6.18 TRIGLYCERIDES MEDIUM CHAIN FORMULA Oral Powder, 400 g (Monogen), Monogen[®], Nutricia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission sought to amend the current Restricted Benefit listing by updating the nutritional profile of Monogen[®].

2 Requested Listing

- 2.1 The submission proposed no changes to the existing listing.

3 Background

- 3.1 Monogen[®] is currently listed on the PBS for the dietary management of conditions requiring a source of medium chain triglycerides, hyperlipoproteinaemia type 1, long chain fatty acid oxidation disorders, chylous ascites and chylothorax.
- 3.2 The nutritional adjustments to Monogen[®] due to a recipe adjustment include:
- Reduction in the amino acid L-Cysteine (116mg to 28 mg per 100 mL formula). The sponsor claimed that the reduction in L-Cysteine has not changed the protein content of Monogen[®] (2.9 g per 100 kcal) and therefore, is of no nutritional concern.
 - Osmolality has increased (235 mOsm/kg to 240 mOsm/kg). The sponsor claimed that <400 mOsm/kg H₂O is better tolerated in malabsorptive states and therefore an increase to 240 mOsm/kg is of no nutritional concern.
 - In the list of ingredients, the order of L-Tryptophan and L-Ascorbic acid have been swapped, and L-Isoleucine has been removed.
- 3.3 The minor submission stated that the overall nutritional profile of Monogen[®], including energy, macronutrients, vitamins, minerals and trace elements, remains the same.

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.

Clinical trials

4.3 As a minor submission, no clinical trials were presented in the submission.

4.4 In consideration of the submission, the NPWP noted that:

- The sponsor provided a suitable comparison against the requirements of the *Australia New Zealand Food Standards Code - Standard 2.9.5: Food for Special Medical Purposes*.
- According to the Australia New Zealand Food Standards Code – Schedule 29 – Special purpose foods, the minimum amount of cysteine per 100kJ that must be present in infant and follow-on formula is 6 mg. The NPWP noted that the reduction of cysteine in the new formula results in 8.9 mg of cysteine per 100 kJ and considered that though this amount was just above the minimum requirements, further reductions may result in Monogen® not meeting this requirement.
- The submission did not present a nutritional comparison of mg amino acids per 100 kJ and advised that future submissions should include a nutritional comparison in this format.

The NPWP supported the amendment of the formulation of the currently listed Monogen®. The NPWP noted that the level of cysteine was reduced in the new formulation, which was just above the minimum requirements according the Australia New Zealand Food Standards Code.

Estimated PBS usage & financial implications

- 4.5 The minor submission stated that the requested change in nutritional formulation for Monogen® will have no effect on the current PBS listing, clinical indications, prescription or pricing of the product.
- 4.6 The minor submission claimed no change to the current usage of Monogen®; the estimated number of patients is approximately 66 users per given year.
- 4.7 No changes to the DPMQ for Monogen® (\$394.46) were proposed.

For more detail on PBAC's view, see section 5 "PBAC outcome."

5 PBAC Outcome

- 5.1 The PBAC recommended the continued listing of Monogen® with the above change in nutritional profile for the dietary management of conditions requiring a source of medium chain triglycerides. The PBAC noted that no price change was requested by the sponsor and therefore there were nil financial consequences.
- 5.2 The PBAC noted that the NPWP raised some concerns about the reduced amounts of cysteine. However, it was considered that this change was of minimal clinical concern as it is still above the minimum requirements according to the Australian New Zealand Food Standards Code.
- 5.3 The PBAC noted that the submission did not present a nutritional comparison of mg amino acids per 100 kJ and agreed with the NPWP's advice that any future submissions should include a nutritional comparison in this format.
- 5.4 The PBAC noted that this submission does not meet the criteria for an Independent Review. Independent Review is not available in response to a request to modify or extend an existing listing.

Outcome:

Recommended

6 Recommended listing

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.