

14.03a TRIGLYCERIDES MEDIUM CHAIN FORMULA
Oral powder 400 g,
Lipistart[®],
Vitaflo Australia Pty Ltd

1 Purpose of Application

- 1.1 The Committee Secretariat submission requested a formulation change to Lipistart[®]. Lipistart is PBS listed for the dietary management of:
- Patients with fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders; and
 - Hyperlipoproteinaemia type 1, long chain fatty acid oxidation disorders, chylous ascites and chylothorax.

2 Background

- 2.1 Lipistart was listed on the PBS on 1 August 2012.
- 2.2 In this submission, the sponsor of Lipistart indicated the product met the requirements for Infant formulas and Foods for Special Medical Purposes as set out under *The Australia New Zealand Food Standards Code — Standards 2.9.1 (Infant formulas and 2.9.5 (Food for Special Medical Purposes)*.
- 2.3 The submission requested a change to the formulation of Lipistart to comply with the compositional standards specified for foods for special medical purposes for infants in the European Union and CODEX Guidelines. The submission did not explicitly state which EU Standards necessitated the change in formulation. European Commission Delegated Regulations 2016/127 and 2016/128 were recently updated, necessitating a change in a number of nutritional product formulations.

3 Requested listing

- 3.1 The submission proposed no changes to the existing listings (PBS item code 1938B and 10155L).

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a Committee Secretariat submission.

Consumer comments

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

Clinical trials

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

Other relevant matters

4.4 The new formulation of Lipistart includes a range of changes to the nutritional profile, including protein, carbohydrate and fatty acid content, as well as to the vitamin, mineral and micronutrient profile.

4.5 A selection of changes to the formulation of Lipistart are presented in Table 1.

Table 1: Brief overview of Lipistart formulation changes

Type of change/parameter (grams per 100kcal)	Old formulation	New formulation	Comparator (Monogen)
Energy (kcal/100mL)	69	70	75
Protein	3.0	2.6	2.9
Fats (total)	4.5	4.5	2.9
- Medium chain triglycerides (MCT)	2.48	2.34	1.85
- Long chain triglycerides (LCT)	0.57	0.66	0.35
- Docosahexaenoic acid (DHA)	15	15	10.1
- Arachidonic acid (ARA)	30	15	10.1
- Linoleic acid	259	221	151
- α-linoleic acid	36	35	28.6

Source: Changes to the nutritional composition of Lipistart. Minor Submission 'Lipistart CSL Appendices 1-4', Appendix 1a.

4.6 The main changes to the nutritional profile proposed in the submission relate to the fat contents and fatty acid profiles.

Estimated PBS usage & financial implications

4.7 The submission did not request a change of the price of Lipistart.

4.8 The Committee Secretariat submission estimated there to be no financial implications to the PBS/changes in PBS usage as the submission did not expect the reformulation would change the existing patient population.

5 NPWP Consideration

- 5.1 The NPWP noted the requested change to formulation for Lipistart to meet international guidelines and standards for nutritional content of supplementary products for children and infants.
- 5.2 The NPWP noted the revised formulation had included a range of changes to the nutritional profile, including protein, carbohydrate and fatty acid content, as well as to the vitamin mineral and micronutrient profile. The NPWP considered that the nutritional values spreadsheets included in the submission were informative and agreed it would be useful for submissions to continue to present information in this format.
- 5.3 The NPWP accepted the request to change the formulation and noted it had no other concerns that the changes would pose a risk to the health and safety of patients.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended continuing the Restricted Benefit listing of triglycerides medium chain formula, Lipistart, for the dietary management of patients with fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders, and patients with hyperlipoproteinaemia type 1, long chain fatty acid oxidation disorders, chylous ascites and chylothorax, following its reformulation due to changes in European compositional standards.
- 6.2 The PBAC noted the NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients.
- 6.3 The PBAC advised that its previous advice for triglycerides medium chain formula regarding Nurse Practitioner Prescribing, the Early Supply Rule and interchangeability advice under Section 101(3BA) of the *National Health Act 1953* remained appropriate.
- 6.4 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended.

7 Recommended listing

- 7.1 No change to the existing listing.

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.