

**14.03f TRIGLYCERIDES, MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER**  
**Oral powder 400g,**  
**Duocal<sup>®</sup>,**  
**Nutricia Australia Pty Ltd**

**1 Purpose of Application**

- 1.1 The Committee Secretariat submission requested a change to the formulation of the triglyceride medium and long chain with glucose polymer formula, Duocal<sup>®</sup>, based on new European compositional standards.

**2 Background**

- 2.1 Duocal was listed on the PBS on 1 April 1994.
- 2.2 The submission requested a change to the formulation of Duocal to meet new European Commission Delegated Regulations on Food for Special Medical Purposes (FSMP) intended to satisfy the nutritional requirements of infants [Commission Delegated Regulation (EU) 2016/128]. Regulation 2016/128 sets out new maximum and minimum levels of vitamin and mineral substances for products that will provide a sole source of nutrition, and new maximum levels of vitamins and minerals for products that are not a sole source of nutrition. This regulation also requires additional nutrient declarations on the packaging with the intent guarantee appropriate use of the product. Further information on the compositional changes are presented in Section 5.

**3 Requested listing**

- 3.1 The submission proposed no change to the current listing of Duocal (PBS item 3136C).

**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 main changes to the nutritional profile proposed in the submission relate to the fatty acid profile. These changes as well as other changes are presented in Table 1.

Table 1: Summary of changes to Duocal

Type of change/parameter	Old formulation	New formulation
<b>General profile</b>		
Sodium chloride	Not declared	<0.05g/100g
Label claims	Phenylalanine free, gluten free, lactose free, sucrose free, fructose free	Removed from label/not declared
Vitamin E	Not declared	2.9 mg a-TE*
<b>Fatty acid profile</b>		
Fatty Acid (FA) Profile (common name):	Amount as g/100g of FA	Amount as g/100g of FA
C10 (capric acid)	14.08	16.41
C12 (lauric acid)	0.03	1.08
C14 (myristic acid)	0.02	0.40
C16:0 (palmitic acid)	3.16	5.17
C16:1 (palmitoleic acid)	0.13	0.11
C18:0 (stearic acid)	1.24	2.69
C18:1 (oleic acid)	44.92	39.57
C18:2 (linoleic acid)	11.48	10.90
C18:3 (γ-linolenic acid)	2.92	2.30
C20:0 (arachidic acid)	0.45	0.30
C20:1 (gondoic acid)	0.60	0.39
C22:0 (behenic acid)	0.45	0.13
C22:1 (erucic acid)	0.26	0.07

Table 1. Changes to the claims and nutritional composition of Duocal; Minor submission page 3.

\* Vitamin E measured in mg of α-tocopherol equivalence (mg a-TE)

- 4.5 The submission stated there would also be changes to the preparation and administration advice in the product information. A key change included advice that Duocal should be consumed immediately after reconstitution rather than up to 24 hours after reconstitution.

## 5 NPWP Consideration

- 5.1 The NPWP noted the requested change to formulation for Duocal, due to new European compositional standards. The NPWP noted that the majority of changes were to the fatty acid profile.
- 5.2 The NPWP were concerned that the dosing instructions for reconstitution in infant formula on the new labelling may be too open-ended. In particular the NPWP were concerned that the scaling up of doses for infant formula may lead to inappropriate dosing. The NPWP requested the Sponsor agree to engage with health care providers to counsel people who will be preparing the formula on appropriate dosing and/or amend the labelling to be clearer.
- 5.3 The NPWP noted changes to the label removed reference to ingredients such as lactose, gluten and sucrose, with no explanation as to why this had happened. The

Sponsor clarified that the reference to lack of ingredients had not previously been stated on the label, only on the product documentation sheet, and as they are not present in any of the ingredients, the claim has been removed from the documentation sheet. The NPWP was satisfied with this response.

- 5.4 The NPWP approved of the request to change the formulation of Duocal, but reiterated its request for the Sponsor to engage with health care providers to ensure patients (or their caregivers) are able to appropriately prepare the formula, or to amend the product labelling to provide clearer dosing instructions.
- 5.5 The pre-PBAC response stated that due to Duocal being marketed worldwide they are unable to make changes to the label, however agreed to provide fact sheets and engage with health care professionals to ensure caregivers were appropriately preparing the formula for patients and indicated a willingness engage with healthcare professionals to ensure caregivers were educated in preparing the formula appropriately.

*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 and long chain, Duocal, for the dietary management of proven inborn errors of protein metabolism, following its reformulation due to changes in European compositional standards.
- 6.2 The PBAC noted the NPWP were concerned that the dosing instructions for reconstitution in infant formula on the new labelling may be too open-ended, and also noted and supported the commitment from the Sponsor to engage with health care professionals to ensure caregivers are educated to prepare the formula appropriately.
- 6.3 The PBAC advised that its previous advice for triglycerides medium chain and long 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.