

**14.03 HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g;  
KetoCal 4:1®, Nutricia Australia Pty Limited.**

**1 Purpose of Application**

1.1 To advise of an upgrade in the nutritional formula.

**2 Requested listing**

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

**3 Background**

3.1 Ketocal 4:1® is listed on the PBS for patients with:

- intractable seizures requiring treatment with a ketogenic diet; OR
- a glucose transport protein defect; OR
- pyruvate dehydrogenase deficiency.

3.2 The submission states that the main difference between the previous formulation and the new formulation are the adjustments to some of the micro nutrient levels to more adequately meet global recommendations for nutritional reference intakes. In addition, the new formula replaces aspartame with sucralose.

**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 formulation upgrade of the current product and minor changes to micronutrients and trace elements, with the exception of vitamin D which had doubled from 5.2 micrograms/100g to 10.5 micrograms/100 g, which was more than double the recommended dietary intake in all age groups.
- 5.2 The PBAC noted the Nutritional Products Working Party had no objection to the formulation change to KetoCal® and accept the changes as requested, noting that there was no change to the current PBS listing for this 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.