

5.21 GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Sachets containing oral powder 40 g, 30 (Camino Pro Bettermilk)

Camino Pro[®] Bettermilk

Oral liquid 250 mL, 30 (PKU Glytactin RTD 15)

PKU Glytactin[®] RTD 15

Cortex Health Pty Ltd

1 Purpose of Submission

- 1.1 The Category 3 submission requested that glycomacropeptide and essential amino acids with vitamins and minerals (Camino Pro[®] Bettermilk; PKU Glytactin[®] RTD 15) with new formulations continue to be listed on the Pharmaceutical Benefits Scheme (PBS) under the existing conditions.
- 1.2 The submission also requested a new pack size for Camino Pro Bettermilk of 30 x 40 g sachets.

2 Background

- 2.1 Camino Pro Bettermilk was recommended by the PBAC at its July 2012 meeting and is currently listed on the PBS as a Restricted Benefit listing for phenylketonuria (PKU).
- 2.2 PKU Glytactin RTD 15 was recommended by the PBAC at its March 2015 meeting and is currently listed on the PBS as a Restricted Benefit listing for PKU.
- 2.3 The submission stated that the new formulations of Camino Pro Bettermilk and PKU Glytactin RTD 15 meet the requirements for foods that have special medical purposes as set out under the *Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes*.
- 2.4 As these products are marketed as nutritional products and not therapeutic goods, they are not registered in the Australian Register of Therapeutic Goods.

3 Requested listing

- 3.1 The submission requested no restriction changes to the existing listing of PKU Glytactin RTD 15.
- 3.2 The submission requested the listing of the following new pack size for Camino Pro Bettermilk. No other changes to restrictions were requested.

Additions are in italics and deletions are in strikethrough.

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No.of Rpts | Available brands |
|---|--|----------------------|----------------------|---------------|-----------------------------------|
| GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS | | | | | |
| glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 49 g sachets | 10652P | 4 | 4 | 5 | Camino Pro® Bettermilk |
| <i>glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 40 g sachets</i> | <i>NEW</i> | 4 | 4 | 5 | <i>Camino Pro® Bettermilk</i> |
| Restriction Summary / Treatment of Concept: | | | | | |
| Concept ID (for internal Dept. use) | Category / Program: GENERAL – General Schedule (Code GE) | | | | |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners | | | | |
| | Restriction type: <input checked="" type="checkbox"/> Restricted benefit | | | | |
| | Indication: Phenylketonuria | | | | |

- 3.3 The submission advised the new 30 x 40 g sachet pack size will be supplied to market in place of the existing 30 x 49 g sachet form. The sponsor has submitted a delisting request for the 30 x 49 g sachet form which will also be considered at the March 2023 PBAC meeting.

For more detail on PBAC's view, see section 7 PBAC outcome.

4 Comparator

- 4.1 The submission did not nominate a comparator.
- 4.2 For Camino Pro Bettermilk, the PBAC advised that Camino Pro Bettermilk (current 49 g form) is an appropriate comparator and that the alternative comparators identified by the NPWP for the treatment of PKU would be appropriate alternate therapies. The NPWP identified the following alternative comparators:
- PKU Glytactin RTD 15
 - PKU Build
- 4.3 Camino Pro products were originally recommended at an equivalent price per gram of protein as the comparators, XP Maxamum and XP Maxamaid. These were not identified as alternate comparators by the NPWP in relation to the current submission.

For more detail on PBAC's view, see section 7 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

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

Nutritional profile

5.3 The nutritional profile comparison of PKY Glytactin RTD is presented in Table 1 below.

Table 1: PKU Glytactin RTD (chocolate) reformulation

| Nutrient | Product nutritional content (per 250 mL carton) | | |
|---|---|------------------------------|---|
| | PKU Glytactin RTD 15 new | PKU Glytactin RTD 15 current | New formula / current formula nutritional content |
| Protein (g) | 15 | 15 | 100% |
| Energy (kcal) | 199 | 200 | 100% |
| Total Fat (g) | 5.3 | 5 | 106% |
| Saturated fat (g) | 1 | 2 | 50% |
| Cholesterol (mg) | 0.19 | 0 | - |
| DHA (mg) | 75 | 0 | - |
| Total Carbohydrate (g) | 22 | 24 | 92% |
| Dietary fibre (g) | 2.1 | 1 | 210% |
| Total sugar (g) | 5 | 19 | 26% |
| Added sugar (g) | 4.1 | 19 | 22% |
| Vitamins & Minerals | | | |
| Riboflavin (mg) | 0.4 | 0.4 | 100% |
| Niacin (mg) | 12 | 5.0 | 240% |
| Vitamin B6 (mg) | 0.5 | 0.4 | 125% |
| Vitamin B12 (mcg) | 0.89 | 0.8 | 111% |
| Biotin (mcg) | 8 | 8 | 100% |
| Pantothenic acid (mg) | 2 | 1.8 | 111% |
| Vitamin A (mcg retinol equivalents) | 272 | 270 | 101% |
| Vitamin D (mcg of cholecalciferol) | 7 | 6.3 | 111% |
| Vitamin E (mg a-tocopherol equivalents) | 3 | 2.30 | 130% |
| Vitamin K (mcg) | 30 | 30 | 100% |
| Vitamin K1 (mcg) | 15 | 30 | 50% |
| Vitamin K2 (MK-7) (mcg) | 15 | 0 | - |
| Thiamin (mg) | 0.4 | 0.4 | 100% |
| Vitamin C (mg) | 28 | 28 | 100% |
| Folate, DFE (mcg) | 140 | 238 | 59% |
| Folic acid (mcg) | 82 | 140 | 59% |
| Choline (mg) | 205 | 206 | 100% |
| Sodium (mg) | 307 | 240 | 128% |
| Calcium (mg) | 367 | 350 | 105% |
| Phosphorous (mg) | 300 | 315 | 95% |
| Magnesium (mg) | 78 | 120 | 65% |
| Potassium (mg) | 420 | 340 | 124% |
| Iron (mg) | 4.8 | 4.5 | 107% |
| Copper (mg) | 0.2 | 0.2 | 100% |
| Zinc (mg) | 3.0 | 3.3 | 91% |
| Manganese (mg) | 0.8 | 0.8 | 100% |

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| Nutrient | Product nutritional content (per 250 mL carton) | | |
|--------------------|---|------------------------------|---|
| | PKU Glytactin RTD 15 new | PKU Glytactin RTD 15 current | New formula / current formula nutritional content |
| Iodine (mcg) | 60 | 57 | 105% |
| Molybdenum (mcg) | 15 | 15 | 100% |
| Selenium (mcg) | 20 | 20 | 100% |
| Chromium (mcg) | 13 | 13 | 100% |
| Amino acids | | | |
| Aspartic acid (g) | 0.61 | 0.8 | 76% |
| Leucine (g) | 1.8 | 3 | 60% |
| Glutamine (g) | 1.5 | 2 | 75% |
| Lysine (g) | 0.435 | 0.65 | 67% |
| Valine (g) | 0.68 | 0.849 | 80% |
| Isoleucine (g) | 0.79 | 0.97 | 81% |
| Arginine (g) | 1.65 | 1.56 | 106% |
| Glycine (g) | 1.42 | 0.107 | 1327% |
| Proline (g) | 0.87 | 1.29 | 67% |
| Phenylalanine (g) | 0.015 | 0.027 | 56% |
| Tyrosine (g) | 1.17 | 1.15 | 102% |
| Serine (g) | 0.49 | 0.56 | 88% |
| Threonine (g) | 1.23 | 1.62 | 76% |
| Histidine (g) | 0.42 | 0.333 | 126% |
| Alanine (g) | 0.465 | 0.56 | 83% |
| Cystine (g) | 0.0075 | 0.0105 | 71% |
| Tryptophan (g) | 0.375 | 0.234 | 160% |
| Taurine (mg) | 0 | 38.4 | 0% |
| Carnitine (mg) | 0 | 0 | - |
| Methionine (g) | 0.135 | 0.152 | 89% |

Source: submission main body pp5-8

AI: average intake; DFE: dietary folate equivalent; DHA: Docosahexaenoic Acid; GMP: glycomacropeptide; NRV: nutrient reference values; PE: protein equivalent; Phe: phenylalanine; RDI: recommended daily intake; RTD: ready-to-drink; WHO: World Health Organisation; UL: upper limit.

5.4 The nutritional profile comparison of Camino Pro Bettermilk is presented in Table 2.

Table 2: Camino Pro Bettermilk reformulation

| Nutrient | Product nutritional content | | |
|---|---|---|--|
| | Camino Pro BetterMilk new (40 g sachet) | Camino Pro BetterMilk current (49 g sachet) | New formula/ current formula nutritional content |
| Protein (g) | 15 | 15 | 100% |
| Energy kcals | 160 | 160 | 100% |
| Total Fat (g) | 4.5 | 4.5 | 100% |
| Saturated fat (g) | 1.8 | 0.5 | 360% |
| Trans fat (g) | 0 | 0 | - |
| Cholesterol (mg) | 0.2 | 0 | - |
| DHA (mg) | 77 | 32 | 241% |
| Total Carbohydrate (g) | 15 | 23 | 65% |
| Dietary fibre (g) | 0 | 0 | - |
| Total sugar (g) | 4.8 | 9 | 53% |
| Added sugar (g) | 4.3 | 9 | 48% |
| Sugar alcohols (g) | 0 | 7 | 0% |
| Vitamins & minerals | | | |
| Riboflavin (mg) | 0.6 | 0.5 | 120% |
| Niacin (mg) | 11.0 | 4.5 | 244% |
| Vitamin B6 (mg) | 0.6 | 0.4 | 150% |
| Vitamin B12 (mcg) | 1.1 | 1.2 | 92% |
| Biotin (mcg) | 9.5 | 9 | 106% |
| Pantothenic acid (mg) | 2.3 | 1.5 | 153% |
| Vitamin A (mcg retinol equivalents) | 283 | 202 | 140% |
| Vitamin D (mcg of cholecalciferol) | 14 | 3.4 | 412% |
| Vitamin E (mg α-tocopherol equivalents) | 4.8 | 2.30 | 209% |
| Vitamin K (mcg) | 32 | 22 | 145% |
| Vitamin K1 (mcg) | 16 | 22 | 73% |
| Vitamin K2 (MK-7) (mcg) | 16 | 0 | - |
| Thiamin (mg) | 0.6 | 0.3 | 200% |
| Vitamin C (mg) | 33 | 24 | 138% |
| Folate, DFE (mcg) | 135 | 228 | 59% |
| Folic acid (mcg) | 79 | 134 | 59% |
| Choline (mg) | 150 | 134 | 112% |
| Sodium (mg) | 291 | 300 | 97% |
| Calcium (mg) | 541 | 400 | 135% |
| Phosphorous (mg) | 436 | 245 | 178% |
| Magnesium (mg) | 67 | 105 | 64% |
| Potassium (mg) | 491 | 480 | 102% |
| Iron (mg) | 6.4 | 4.5 | 142% |
| Copper (mg) | 0.38 | 0.2 | 190% |
| Zinc (mg) | 3 | 2.8 | 107% |
| Manganese (mg) | 0.9 | 0.5 | 180% |
| Iodine (mcg) | 65 | 45 | 144% |
| Molybdenum (mcg) | 18 | 12 | 150% |
| Selenium (mcg) | 18 | 18 | 100% |
| Chromium (mcg) | 13 | 9.7 | 134% |

| Nutrient | Product nutritional content | | |
|--------------------|---|---|--|
| | Camino Pro BetterMilk new (40 g sachet) | Camino Pro BetterMilk current (49 g sachet) | New formula/ current formula nutritional content |
| Amino acids | | | |
| Aspartic acid (g) | 0.615 | 0.89 | 69% |
| Leucine (g) | 1.575 | 2.89 | 54% |
| Glutamine (g) | 1.5 | 1.9 | 79% |
| Lysine (g) | 1.335 | 0.62 | 215% |
| Valine (g) | 0.675 | 0.904 | 75% |
| Isoleucine (g) | 0.788 | 1.094 | 72% |
| Arginine (g) | 1.53 | 1.3 | 118% |
| Glycine (g) | 0.983 | 0.11 | 894% |
| Proline (g) | 0.87 | 1.2 | 73% |
| Phenylalanine (g) | 0.015 | 0.023 | 65% |
| Tyrosine (g) | 1.17 | 1.34 | 87% |
| Serine (g) | 0.488 | 0.66 | 74% |
| Threonine (g) | 1.23 | 1.71 | 72% |
| Histidine (g) | 0.345 | 0.38 | 91% |
| Alanine (g) | 0.465 | 0.61 | 76% |
| Cystine (g) | 0.0075 | 0.01 | 75% |
| Tryptophan (g) | 0.378 | 0.22 | 172% |
| Taurine (mg) | 0 | 0 | - |
| Carnitine (mg) | 0 | 0 | - |
| Methionine (g) | 0.18 | 0.23 | 78% |

Source: submission main body pp9-12

AI: average intake; DFE: dietary folate equivalent; DHA: Docosahexaenoic Acid; GMP: glycomacropeptide; NRV: nutrient reference values; PE: protein equivalent; Phe: phenylalanine; RDI: recommended daily intake; RTD: ready-to-drink; WHO: World Health Organisation; UL: upper limit.

- 5.5 The submission provided dietetic assessment of the formulation changes in Tables 1 and 2 of the main body.
- 5.6 The submission also made claims throughout the main body relating to potential additional benefits of the reformulations over the comparator. As the submission presented a cost-minimisation analysis with claim of therapeutic equivalence/ non-inferiority, the PBAC did not provide advice on the claimed potential benefits.
- 5.7 The PBAC advised that the new formulations are expected to provide non-inferior clinical benefits for the management of PKU in comparison to the current formulations or any other appropriate comparator.

Estimated PBS usage and financial implications

- 5.8 The submission did not present economic or financial evaluations. The submission requested no changes to the current pricing arrangements.
- 5.9 The submission considered the formulation changes and new pack size listed will have nil financial impact to Government as they would be expected to substitute into the market for the existing products at an equivalent AEMP.

- 5.10 The PBAC advised that the listing of the new formulation of Camino Pro Bettermilk is not expected to increase utilisation.
- 5.11 As a Category 3 submission, the financial estimates analysis has not been independently evaluated.

For more detail on PBAC's view, see section 7 PBAC outcome.

6 NPWP consideration

- 6.1 The Nutritional Products Working Party (NPWP) supported the General Schedule Restricted Benefit listing of a new pack size (30 x 40 g) of Camino Pro Bettermilk on the PBS.
- 6.2 The NPWP advised that the reduction in carbohydrate content does not change the clinical effectiveness of Camino Pro Bettermilk.
- 6.3 The NPWP considered that the appropriate comparator for Camino Pro Bettermilk (30 x 40 g) is the currently listed Camino Pro Bettermilk (30 x 49 g), as it is the only PBS-listed product that is glycomacropeptide-based and suitable for toddlers from 1 year of age.
- 6.4 The NPWP advised that PKU Build[®] and PKU Glytactin RTD 15[®] may also be considered alternate therapies for Camino Pro Bettermilk.
- 6.5 The NPWP advised that the new formulations of Camino Pro Bettermilk and PKU Glytactin RTD 15 are expected to provide non-inferior clinical benefit for the treatment of PKU.
- 6.6 The NPWP noted that the utilisation and financial impacts are difficult to estimate in this population. The NPWP considered it possible the new formulations with less phenylalanine may increase utilisation due to improved adherence but that this would be offset by a reduction in wastage. On balance the NPWP advised the listing of these products was unlikely to result in a substantial financial impact.
- 6.7 The NPWP supported that Camino Pro Bettermilk new formulation be listed on the PBS under the same conditions as the existing Camino Pro Bettermilk and PKU Glytactin RTD 15 with new formulation continue to be listed on the PBS under the existing conditions.

7 PBAC Outcome

PKU Glytactin RTD 15

- 7.1 The PBAC recommended that the new formulation of glycomacropeptide and essential amino acids with vitamins and minerals (PKU Glytactin RTD 15) continue to be listed on the PBS under the existing conditions of the current formulation.
- 7.2 The PBAC noted and supported the NPWP advice that the new formulation is expected to provide non-inferior clinical benefit for the management of PKU.

- 7.3 The PBAC noted there were no changes requested to the circumstances under which the existing listings are available.
- 7.4 The PBAC considered the new formulation would not substantially affect the utilisation and cost to Government.

Camino Pro Bettermilk

- 7.5 The PBAC recommended the General Schedule Restricted Benefit listing of a new form of glycomacropeptide and essential amino acids with vitamins and minerals (Camino Pro Bettermilk) for the treatment of PKU. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Camino Pro Bettermilk in pack size 30 x 40 g would be acceptable if it were cost-minimised to the currently listed Camino Pro Bettermilk in pack size 30 x 49 g comparators on a cost per gram of protein equivalent (PE) basis.
- 7.6 The PBAC noted and supported the NPWP advice that the new formulation is expected to provide non-inferior clinical benefit for the management of PKU.
- 7.7 The PBAC noted there was no changes requested to the circumstances under which the existing listings are available.
- 7.8 The PBAC agreed with the NPWP advice that the new formulation is unlikely to result in a significant change to utilisation or financial impact to Government.
- 7.9 The PBAC noted it was asked to consider a concurrent delisting request for the 30 x 49 g pack size at its March 2023 meeting.
- 7.10 The PBAC noted that its recommendation for Camino Pro Bettermilk was on a cost-minimisation basis and advised that, because the new pack size is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over current pack size, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 7.11 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

8 Recommended listing

PKU Glytactin RTD 15

- 8.1 No change to the existing listing

Camino Pro Bettermilk

- 8.2 Add new medicinal product pack (pack size):

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No.of Rpts | Available brands |
|---|--|----------------------|----------------------|---------------|-----------------------------------|
| GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS | | | | | |
| glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 49 g sachets | 10652P | 4 | 4 | 5 | Camino Pro® Bettermilk |
| <i>glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 40 g sachets</i> | <i>NEW</i> | 4 | 4 | 5 | <i>Camino Pro® Bettermilk</i> |
| Restriction Summary / Treatment of Concept: | | | | | |
| Concept ID (for internal Dept. use) | Category / Program: GENERAL – General Schedule (Code GE) | | | | |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners | | | | |
| | Restriction type: <input checked="" type="checkbox"/> Restricted benefit | | | | |
| | Indication: Phenylketonuria | | | | |

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

9 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.

10 Sponsor's Comment

The sponsor had no comment.