

24th July 2024

Dear Healthcare Professional,

PRODUCT UPDATE: NEW RECIPE Alfamino® 400g with HMOs

We wish to inform you that Alfamino[®] infant formula has a new recipe, with the addition of two $\underline{\underline{\mathbf{M}}}$ infant formula has a new recipe, with the addition of two $\underline{\underline{\mathbf{M}}}$ infant formula has a new recipe, with the addition of two $\underline{\underline{\mathbf{M}}}$ in $\underline{\underline{\mathbf{M}}$ in $\underline{\underline{\mathbf{M}}}$ in $\underline{\underline{\mathbf{M}}$ in $\underline{\underline{\mathbf{M}}$ in $\underline{\underline{\mathbf{M}}}$ in $\underline{\underline{\mathbf{M}}$ in $\underline{\mathbf{M}$ in $\underline{\underline{\mathbf{M}}$ in $\underline{\mathbf{M}$ in $\underline{\underline{\mathbf{M}}$ in $\underline{\underline{\mathbf{M}}$ in $\underline{\underline{\mathbf{M}}$ in $\underline{\underline{\mathbf{M}}$ in

Alfamino® is specially formulated for formula-fed infants with Cow's Milk Protein Allergy. The new recipe Alfamino® will be the first amino acid based infant formula in Australia and New Zealand to contain HMOs. The new recipe Alfamino® continues to be an amino acid based infant formula listed on the PBS and Pharmac, specifically formulated for infants (0-12 months) with severe cow's milk protein allergy, eosinophilic oesophagitis, intestinal malabsorption and/or multiple food intolerances.

The new recipe Alfamino® will be listed on Pharmac as of 1 August 2024.

HMOs in breastmilk

Breast milk is best for babies and provides ideal nutrition. The HMOs, 2'-Fucosyllactose (2'-FL) and Lacto-*N*-neotetraose (LNnT) are 2 of the most abundant HMOs found in breast milk. HMOs in breast milk support the immune system in 4 main ways³⁻¹⁰:

- Promote growth of beneficial gut bacteria
- Help eliminate pathogens from the gut
- Strengthen the gut barrier
- Educate the immune system

HMOs in new Alfamino® recipe

The HMOs in the new Alfamino® recipe are structurally identical to the HMOs 2'-FL and LNnT found in breast milk. Research shows that inclusion of these HMOs in infant formula products supports safe growth in formula-fed babies and that they are well tolerated¹¹⁻¹⁴

Furthermore, additional studies* show growing evidence that infants, who consumed infant formula products containing the HMOs 2'-FL and LNnT, including those with and without cow's milk protein allergy, have:

- Selective growth of beneficial gut microbiota^{11,13}
- A reduction in infection 11,14
- A reduction in infants requiring antibiotic and antipyretic medication over 12 months^{11,14}

The addition of 2'-Fucosyllactose and Lacto-N-neotetraose in the new Alfamino® recipe will be shown on the **back of pack only**, featuring in both the ingredient list and the nutrition information panel (NIP).

^{*}Some studies show secondary outcomes^{11,14}

Non-detectable Lactose in new Alfamino® recipe

Every batch of the new Alfamino® recipe is tested for lactose. Lactose is not detectable in the final product, which means it is lower than the detection limit for lactose (LoD: 0.05g/100g). The lactose content of the new Alfamino® recipe, when made up, is below 0.007g/100mL.

The label of the new Alfamino® recipe includes lactose in the ingredient list to comply with AU/NZ food labelling regulations, because the two HMO, 2'-FL and LNnT, are derived from a microbial fermentation process which uses lactose. Lactose is a substrate that is consumed during the microbial fermentation, followed by a series of purification and isolation steps to generate the final high-purity 2'-FL and LNnT. Alfamino® with the addition of two HMOs is well tolerated by infants with moderate-to-severe CMPA and has an excellent safety profile¹³

There are no other dairy ingredients, or milk derivatives, used in the preparation of Alfamino[®], making this product suitable for the dietary management of infants with CMPA, severe allergy and/or food intolerance.

Product transition and product availability

We recognise that with any recipe update, advice on transitioning will be important for parents. Whenever an infant is moved from one formulation to another, an infant may require some time to adjust. Gradually introducing the new formulation may help ease the transition. The new Alfamino® formulation will be listed on Pharmac as of 1 August 2024. Both formulations will be listed on Pharmac for a few months to assist with availability while supply changes from Alfamino® to Alfamino® with the inclusion of HMOs. This will also allow time for infants to transition to the new formulation.

What will change?

In line with the new recipe introduction, please note that there will be changes to the following:

- 1. Pack ingredient list and nutritional information panel
- 2. EAN barcode change

All these details are summarised in the table below and compared against the current Alfamino[®].

Should you require further information or clarification, please contact your Nestlé Health Science Account Specialist or call Consumer Services on 0800607662.

We thank you for your ongoing support,

Jennifer Nethery

Head of Institutional Sales Nestle Health Science

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ALFAMINO® is an infant formula product for special dietary use and must be used under medical supervision. It is not suitable for general use.

BREAST MILK IS BEST FOR BABIES Information for Healthcare Professionals only

REFERENCES: 1. Glycom A/S Application for the Approval of 2'-O-Fucosyllactose (2'-FL) and Lacto-N-neotetraose (LNnT) Under Standard 1.5.1 (Novel Foods) of the Australia and New Zealand Food Standards Code Appendix IV; 2. FSANZ (2018) Safety, technical and health effects assessment – Application A1155 2'-FL and LNnT in infant formula and other products; 3. Zivkovic AM, et al. Proc Natl Acad Sci 2011; 108 (Suppl 1): 4653-8 4. Zivkovic AM, et al. Funct Food Rev 2013; 5(1): 3-123. 5. Bode L. Early Hum De 2015; 91(11): 619-224. 6. Donovan SM, et al. Ann Nutr Metab 2016;69(Suppl 2): 42-515. 7. Bode L. Glycobiology 2012; 22(9): 1147-626. 8. Walsh C, et al. J Funct Foods 2020; 72: 1040747. 9. Jantscher-Krenn E, Bode L. Minerva Pediatr. 2012; 64: 83-998. 10. Smilowitz JT. et al. Annu Rev Nutr. 2014; 34: 143-69 11. Puccio,G. et al. JPGN 2017; 64: 624-631; 12. Berger, B. et al. 2020; 11(2): e03196-19 13. Gold et al. 2022 Nutrients May 30;14(11):229 14. Vandenplas et al. 2022. Nutrients. Jan 26;14(3):530

IMPORTANT NOTICE: Breast milk is best for babies and provides ideal nutrition. Good maternal nutrition is important for the preparation and maintenance of breastfeeding. Introducing partial bottle feeding could negatively affect breastfeeding and reversing a decision not to breastfeed is difficult. Professional advice should be followed on infant feeding. Infant formula should be prepared and used exactly as directed or it could pose a health hazard. The preparation requirements and weekly cost of providing infant formula until 12 months of age should be considered before making a decision to formula feed. Mothers should be encouraged to continue breastfeeding even when their infants have cow's milk protein allergy. If a decision to use an infant formula for special dietary use is taken, it must be used under medical supervision.

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Please see below a summary of all of the changes between the existing Alfamino® and the new Alfamino® with two Human Milk Oligosaccharides (HMOs) - 2'-Fucosyllactose (2'-FL) and Lacto-N-neotetraose (LNnT)

| | EXISTING | NEW |
|--------------------------------|--|--|
| Product Description | Alfamino® x 400g Can | Alfamino® x 400g Can |
| Nestle Product Number | 12456301 | 12534747 |
| GTIN Unit | 7613287096630 | 8445290533081 |
| GTIN Outer (Case) | 7613287096647 | 8445290533074 |
| Units per case | 6 x 400g | 6 x 400g |
| Formulation change | N/A | Addition of two structurally identical HMOs to that of breast milk: 2'-FL (1.0g/L) and LNnT (0.5g/L) |
| Pharmacode | 2632187 | 2657953 |
| Pharmac Special Authority Code | SA2092 | SA2092 |
| Pharmac Category | Amino Acid Formula | Amino Acid Formula |
| Front of pack | Nestle Alfamino No No No No No No No No No | Nestle Alfamino Nestle Alfa |



| | EXISTING | NEW |
|---|--|---|
| Ingredients | Ingredients Corn Syrup Solids, Vegetable Oil (Sunflower, Canola, Esterified Palm), Amino Acids (L-arginine-L-aspartate, L-lysine acetate, L-leucine, L-proline, L-glutamine, L-valine, Glycine, L-isoleucine, L-threonine, L-serine, L-phenylalanine, L-tyrosine, L-histidine, L-alanine, L-cystine, L-tryptophan, magnesium L-aspartate, L-methionine), Medium Chain Triglycerides, Potato Starch, Minerals (Calcium Glycerophosphate, Potassium Chloride, Calcium Citrate, Sodium Citrate, Potassium Citrate, Sodium Phosphate, Magnesium Oxide, Ferrous Sulphate, Zinc Sulphate, Copper Sulphate, Potassium Iodide, Manganese Sulphate, Sodium Selenate), Emulsifier (472c), Crypthecodinium Cohii Oil (Rich in OHA), Mortierella Alpina Oil (Rich in ARA), Vitamins (C, E, Niacin, Pantothenic Acid, B2, A, B1, B6, Folic Acid, D3, K1, B12, Biotin), Choline Bitartrate, Acidity Regulator (330), Taurine, Inositol, L-Carnitine. | Ingredients Corn Syrup Solids, Vegetable Oil [Sunflower, Canola, Esterified Palm], Amino Acids (L-tysine acetate, L-leucine, L-proline, L-glutamine, L-arginine, L-valine, L-isoleucine, Glycine, L-threonine, L-serine, L-phenylalanine, L-tyrosine, L-aspartic acid, L-histidine, L-alanine, L-cystine, magnesium L-aspartate, L-tryptophan, L-methionine), Medium Chain Triglycerides, Potato Starch, Minerals [Calcium Glycerophosphate, Potassium Chloride, Sodium Citrate, Calcium Citrate, Potassium Citrate, Sodium Phosphate, Magnesium Oxide, Ferrous Sulphate, Zinc Sulphate, Copper Sulphate, Manganese Sulphate, Potassium Iodide, Sodium Selenate), Emulsifier [472cl, Oligosaccharides [2'-Fucosyllactose, Lacto-N-neotetraose] [lactose], Mortivella alpina oit (ARA), Schizochytrium sp. oit [DHA), Vitamins (C. E. Niacin, Pantothenic Acid, B2, A, B1, B6, Folic Acid, K1, Biotin, O3, B12), Choline Bitartrate, Acidity Regulator (330), Inositol, Taurine, L-Carnitine. |
| Nutrition Information Panel (NIP) | NUTRIENT Section Protein P | NUTRIENT Energy kJ / kcal 2085 / 498 277 / 66 Protein** (11% kcal) g 13.3 1.8 Fat (14% kcal) g 24.6 3.3 3.8 Fat (14% kcal) g 5.4 0.72 - 10 |