



“Scientific and  
factual?”

A further review of breastmilk  
substitute advertising to  
healthcare professionals



## **'Scientific and factual'? A further review of breastmilk substitute advertising to healthcare professionals.**

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'Scientific and factual'? A review of breastmilk substitute advertising to healthcare professionals.

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### **Disclaimer**

The opinions given in this resource are those of the authors. We strongly recommend that health professionals review for themselves the evidence provided by manufacturers, and make up their own minds about whether the statements and claims made about the products are scientific and accurate.

This report is provided for information only and individual advice on diet and health should always be sought from appropriate health professionals.

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### **Photo resources**

For information about photo resources for different age groups of children and young people, see the website

[www.firststepsnutrition.org](http://www.firststepsnutrition.org)

### **First Steps Nutrition Trust**

First Steps Nutrition Trust is a charity which provides evidence-based and independent information and support for good nutrition from pre-conception to five years of age.

First Steps Nutrition Trust

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# 1 Introduction

International, EU and national regulations allow manufacturers of breastmilk substitutes to advertise their products to healthcare professionals providing the information is 'scientific and factual'. There is, however, no mechanism to challenge whether adverts are in fact 'scientific and factual' in their content and presentation. Manufacturers of breastmilk substitutes advertise their products to healthcare professionals in magazines, through company representatives' information, healthcare professional websites, at study days and via helplines. Many of the claims made by manufacturers are, however, not accepted by scientific bodies, the evidence may be weak or non-existent and it may relate to a product other than that being advertised. We believe that this misleads healthcare professionals.

In 2016 we published a resource *Scientific and Factual? A Review of Breastmilk Substitute Advertising to Healthcare Professionals*, which highlighted nine adverts for the following breastmilk substitutes, placed in magazines and journals aimed at healthcare professionals in 2015/2016:

- *Aptamil Profutura Follow On Milk*
- *Cow & Gate Comfort milk*
- *HiPP Organic Combiotic First Infant Milk*
- *NANNYcare*
- *Nutramigen Hypoallergenic Formula with LGG*
- *Similac Alimentum*
- *SMA H.A. Infant Milk*
- *SMA PRO First Infant Milk* (short and long adverts).

In that resource, we challenged whether those adverts were indeed scientific or factual. The nine adverts reviewed in that resource are shown in the Appendix on page 41. To access a copy of the resource, go to [www.firststepsnutrition.org/working-within-the-who-code](http://www.firststepsnutrition.org/working-within-the-who-code)

Since then, some of the manufacturers have made changes to their adverts, perhaps as a result of the review, but we believe misleading information is still being given. This further review, published in 2019, unpacks a further set of adverts that have been placed in publications aimed at healthcare professionals, to show why we believe continued vigilance is needed before accepting the claims and information provided by manufacturers about their products.

We hope that the editors and proprietors of journals and magazines will seriously consider whether it is helpful to allow breastmilk substitute adverts in their publications. We are pleased that, in March 2019, the BMJ group of publications made a decision to no longer take adverts for breastmilk substitutes, and we hope that other publications will do the same.

## 2 Background

### 2.1 Regulations relating to advertising of infant formula and follow-on formula to health professionals

The compositional requirements for infant formula and follow-on formula are currently determined by the Infant Formula and Follow-on Formula Regulations (2007) and any amendments to these regulations<sup>1</sup>. New regulations relating to the composition, labelling and marketing of infant formula and follow-on formula are due to come into force across the EU in February 2020. For more information on UK regulation of infant milks see [www.bflg-uk.org](http://www.bflg-uk.org)

Below we summarise some of the key points that relate to the advertising of infant formula and follow-on formula in publications for health professionals.

- 1 Advertising is permitted in publications to health professionals, but must be 'scientific and factual' in nature. The only claims that can be made are those included in the list of permitted claims in Annex IV of the EU Directive. All other nutrition and health claims are prohibited. From 2020, if new regulations are adopted in the UK, health claims on infant formula will not be allowed.
  - 'Nutrition claim' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties.
  - 'Health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.
- 2 Annex IV of the EU Directive allows for nutrition claims related to lactose content, added LCP, taurine, fructo-oligosaccharides and galacto-oligosaccharides and nucleotides. However, these components are considered 'unnecessary' additions to infant formula and follow-on formula by EFSA (European Food Safety Authority, 2014). Claims can also be made related to products which are designed for those with an allergy to milk protein. However, there are a number of conditions that must be fulfilled before a health claim can be made. These include providing "objective and scientifically verified data as proof to the claimed properties".

- 3 Claims are regulated wherever they appear on the labelling, on a website or in advertising or presentations. It is not the case that statements constitute claims only when they appear in headings or banners.

### 2.2 UK Guidance Notes on the Infant Formula and Follow-on Formula Regulations

In the UK there are Guidance Notes from the Department of Health (relevant to all four health departments of the UK) which explain how the regulations should be interpreted. These Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 were last published in 2013 and can be accessed at: [www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/204314/Infant\\_formula\\_guidance\\_2013\\_-\\_final\\_6\\_March.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/204314/Infant_formula_guidance_2013_-_final_6_March.pdf). We would expect new guidance notes to accompany regulatory change in 2020.

#### Restrictions on advertising infant formula (Regulation 21)

Infant formula can be advertised in scientific publications and trade publications.

Advertisements should:

- only contain information of a scientific and factual nature
- not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding.

From: Appendix IV *Guidance on scientific publications and information of a scientific or factual nature*:

Regulation 21 only allows infant formula to be advertised in scientific publications and trade publications and puts in place controls on the content of such advertisements. On the next page is Department of Health guidance on what constitutes a scientific publication and also guidance on the nature of the information that can be included in advertisements for infant formula.

<sup>1</sup> [http://www.legislation.gov.uk/uk/si/2007/3521/pdfs/uk/si\\_20073521\\_en.pdf](http://www.legislation.gov.uk/uk/si/2007/3521/pdfs/uk/si_20073521_en.pdf). Similar regulations are in place in Scotland, Wales and Northern Ireland.

## Scientific publications

“Scientific publications are usually published periodically (at regular or irregular intervals) and aimed at academic and/or professionals in a scientific field, such as GPs, nurses and midwives. They consist of an aggregation of original articles by different authors published under an umbrella title. Articles include those that report new scientific research or review existing scientific research. They may also include editorials, opinion pieces and book or other reviews dealing with a scientific theme.

In addition, they

- are static, rather than dynamic (i.e. the core content is fixed at the time of publication),
- may have been assigned an ISSN.”

## Content of infant formula advertisements

“Advertisements for infant formula can only include information that is of a scientific and factual nature (regulation 21(2)). Where that information constitutes a nutrition or health claim, it must be listed in the first column of Annex IV and the product must meet the conditions specified in the second column. All other nutrition and health claims are prohibited. Paragraphs 32-35 provide information on what constitutes a nutrition or health claim.

*In the Departments view, to comply with this requirement, it must be possible to support any further information provided, that is not a nutrition or a health claim, with an article from a peer-reviewed scientific journal.”*

## 2.3 Regulations relating to milks marketed for special medical purposes

Whilst infant formula and follow-on formula have legislation regulating the labelling and marketing of products, specialised infant milks which currently fall under the regulations for foods for special medical purposes currently do not. Rules on advertising may be strengthened if new EU regulations relating to foods for special medical purposes due to come into force in February 2020 are adopted in the UK. These infant milks can currently be marketed to health professionals without any restrictions.

## 2.4 Why do breastmilk substitute manufacturers advertise?

Companies expect advertising to produce returns in terms of increased product sales, so the best advertisements use images and stories to focus attention on the ‘brand’. The primary mission of any company is to generate profit and increase shareholder value, and breastmilk substitute companies use a range of techniques from direct advertising to more subtle approaches via study days, helplines, representative visits and conference marketing to promote their products. Where a product is linked into healthcare systems where advice and recommendations may be made to consumers by healthcare professionals, companies will attempt to impact healthcare professionals’ decision-making and recommendations.

Advertisements for company representatives to promote breastmilk substitute brands highlight that this role is to “*stimulate retail sales through the promotion of infant formulas to gain Healthcare Professionals recommendations*”<sup>2</sup>.

Being able to advertise products directly to health professionals through advertisements in magazines and journals that aim to professionally inform and update gives manufacturers the opportunity both to promote their brand and to make a series of claims that appear evidence-based and believable.

### What do we already know about advertising of breastmilk substitutes to health professionals?

A survey on the marketing, advertising and distribution of infant formula and follow-on formula conducted by the Food Safety Authority Ireland (2007) reported that, where adverts for infant formula were found in health professional publications, they were found not to comply with legislation. This was either because they included a picture of an infant, or implied equivalence of their product with breastmilk, or because some of the information provided was not factual. Interestingly in this study, while all advertisements found in non-specialist magazines were fully compliant with the legislation, *all* infant formula advertisements found in Irish health professional publications were found to be in breach of the regulations.

<sup>2</sup> Quote from an advertisement for a company representative for a formula company seen in 2015.

## How do health professionals perceive scientific advertisements?

Health professionals may have the skills to investigate advertisement claims, but are unlikely to have the time and resources to do so for every advert they see. The references provided by manufacturers are often in an extremely small typeface and positioned at the bottom of the advert, the aim being that the statements, pictures, graphs and images 'do the talking'.

Studies have examined how those with a heightened awareness of science (such as health professionals) perceive advertising claims which purport to be based on science (Dodds et al, 2008). It was found that advertisements that tapped into current advice and thinking were largely believed uncritically. Science- or health-based claims for food products that were clear and that did not contradict prior knowledge and belief were deemed credible. This suggests that many people will take science and health claims at face value. Most health professionals in this study wanted simple, easy-to-understand messages they could relate to their own scientific knowledge. Infant formula manufacturers use this concept to constantly promote the same claims and ideas over time, even when these are not agreed by expert committees. The constant promotion of prebiotics (fructo- and galacto-oligosaccharides) in infant formula as a means of protecting infant health is a good example. Despite the European Food Safety Authority refusing all health claims for infant formula based on the addition of prebiotics, manufacturers continue to make these claims and many people believe this must therefore be based on agreed scientific evidence.

Health professionals want simplicity in relation to both the visual imagery and the level of detail in advertisements (Dodds et al, 2008) and manufacturers support this by offering adverts for the same product (often in the same publication) – one which is simple and visual, and one which provides apparently much more scientific data. The health professional can then view the simpler advert but be reassured, by a more complex-looking advert, that the information they are being provided with is true.

## Using graphs and images to imply scientific credibility

A study by Tal and Wansink (2014) considered how information that has the appearance of being scientific can increase persuasiveness. In a review for a journal on the public understanding of science, they found that even trivial cues can create an appearance of 'a scientific basis'. Simple elements such as graphs or a chemical formula increased belief in a product's efficacy. This appears to be due to the association of such elements with science, rather than this making the information more comprehensible. People who have a belief in science are more likely to be persuaded by information given in graphs, and are more affected by the presence of graphs in information provided to them. The authors concluded that, even when evidence was not scientifically correct or objective, trivial visual elements can increase persuasion of efficacy. Many adverts for breastmilk substitutes use graphs and diagrams to give an impression of scientific validity. Often the scales on the charts are manipulated to make differences look more impressive than they are, and sometimes the data are not referenced at all.

We believe more investigation is needed to consider how health professionals view adverts for breastmilk substitutes, and how this may potentially influence their practice.

## References

- Dodds RE, Tseñlon E, Weitkamp ELC (2008). Making sense of scientific claims in advertising. A study of scientifically aware consumers. *Public Understanding of Science*, 17 (2), 211-230.
- European Food Safety Authority (2014). Scientific opinion on the essential composition of infant and follow-on formulae. *EFSA Journal*, 12 (7), 3760. Available at <http://www.efsa.europa.eu/en/efsajournal/doc/3760.pdf>
- Food Safety Authority Ireland (2007). A survey on the marketing, advertising and distribution of infant formula and follow-on formula. Accessed at <https://www.fsai.ie/WorkArea/DownloadAsset.aspx?id=774>
- Tal A, Wansink B (2014). Blinded with science: Trivial graphs and formulas increase ad persuasiveness and belief in product efficacy. *Public Understanding of Science*, 25 (1): 117-125.

### 3 Adverts reviewed in this resource

The adverts for breastmilk substitutes that we have looked at in this resource have appeared in journals and magazines aimed at health professionals during 2018/2019. We have considered adverts for the following products:

- Aptamil 2 Follow On Milk
- Aptamil Anti-reflux
- Aptamil Pepti
- Cow & Gate Nutriprem
- Neocate Syneo
- Nutramigen Hypoallergenic Formula with LGG, and
- SMA Althéra.

For each advert we have reviewed the claims and statements made in light of the evidence presented (or not presented) and current expert advice.



**Advert for:** Aptamil 2 Follow On Milk (Danone Nutricia)

**Advert seen in:** *Journal of Health Visiting*, September 2018

**NUTRICIA** Early Life Nutrition [www.efn.nutricia.co.uk](http://www.efn.nutricia.co.uk) **BRINGING SCIENCE TO EARLY LIFE**

FOR HEALTHCARE PROFESSIONAL USE ONLY

# NEW Aptamil Follow On Milk with Pronutra™ - ADVANCE



**PATENTED NEXT GENERATION FORMULATION**

With vitamin D to support the normal function of the immune system

**FOLLOW ON MILK 6-12 months** **2**

Optimal preparation instructions for new formulation: **shake vigorously and vertically for 10 seconds**

## OUR NEW PATENTED FORMULATION COMBINING **PREBIOTICS** AND **POSTBIOTICS**

- ✓ Gut and immune markers closer to breast-fed infants<sup>1,2</sup>
- ✓ Stool patterns closer to breast-fed infants<sup>3</sup>
- ✓ Supports adequate growth<sup>4</sup>

**IMPORTANT NOTICE:** Breastfeeding is best for babies. Follow-on Milk is only for babies over 6 months, as part of a mixed diet and should not be used as a breastmilk substitute before 6 months. We advise that all formula milks be used on the advice of a doctor, midwife, health visitor, public health nurse, dietitian, pharmacist or other professional responsible for maternal and child care, based on baby's individual needs.

**Raise them Ready**  
Aptamil follow on milk

FOR HEALTHCARE PROFESSIONAL USE ONLY

## PREBIOTICS AND POSTBIOTICS SUPPORT THE IMMUNE SYSTEM THROUGH THE GUT<sup>5-7</sup>

### PREBIOTICS



### POSTBIOTICS

**PREBIOTICS** are non-digestible oligosaccharides that pass intact to the lower part of the gut where they act as food for beneficial bacteria stimulating their growth and activity<sup>8</sup>

- ✓ Support healthy gut microbiota<sup>9</sup>
- ✓ Direct effect on immune cells<sup>10</sup>

Nutricia was the first company to introduce a patented prebiotic mixture scGOS/lcFOS(9:1) into formula milks

**30**

clinical studies

**55**

publications

**POSTBIOTICS** are bioactive components produced by beneficial bacteria<sup>11,12</sup>

- ✓ Stimulate healthy gut microbiota, immune functioning and development<sup>13</sup>
- ✓ Support intestinal immunity<sup>14</sup>

Nutricia's unique process involves adding two types of beneficial bacteria to transform the formulation through a fermentation process, producing postbiotics<sup>11</sup>

Supported by clinical data

### FAVOURABLE GUT ENVIRONMENT

- **LOWERS pH** of the gut<sup>1,2</sup> to encourage growth of beneficial bacteria<sup>1</sup>
- **MAINTAINS** soft stools<sup>1</sup>

### MICROBIOTA COMPOSITION

- **INCREASES** beneficial bacteria (bifidobacteria)<sup>1,2</sup>
- **DECREASES** harmful bacteria (c difficile)<sup>1</sup>

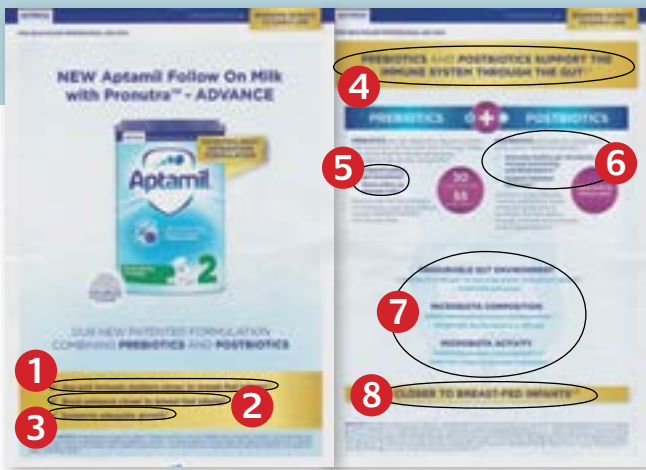
### MICROBIOTA ACTIVITY

- **INCREASES** secretory immunoglobulin A<sup>1,2</sup>
- **IMPROVES** number of microbial metabolites<sup>1,2</sup>

## CLOSER TO BREAST-FED INFANTS<sup>1-3</sup>

**References:** 1. Rodriguez-Herrera A et al. Accepted for oral presentation at the ESPGHAN conference, 9-12 May, 2018 in Geneva, Switzerland. 2. Tims et al. Accepted for poster presentation at the ESPGHAN conference, 9-12 May, 2018 in Geneva, Switzerland. 3. Herrera AJR et al. *J Pediatr Gastroenterol Nutr*. 2015;61:536-537. 4. Rodriguez-Herrera A et al. *J Pediatr Gastroenterol Nutr*. 2016;62:Abstract N-O-010 (p.658-659). 5. Wopener H et al. *Pediatr Allergy Immunol*. 2014;25:428-438. 6. Martin R et al. *Benef Microbes*. 2010;1:367-382. 7. Aguilar-Torale JE et al. *Trends Food Sci Technol*. 2018;75:105-114. 8. Gibson GR et al. *Nat Rev Gastroenterol Hepatol*. 2007;14(3):491-502. 9. Walker WA et al. *Pediatr Res*. 2015;77:220-228. 10. Erwegger T et al. *Pediatr Res*. 2004;56(4):536. 11. Patel R et al. *Clin Perinatol*. 2013;40(1):11-25. 12. Tsilingiri K et al. *Beneficial Microbes*. 2013;4:101-107. 13. Muller C et al. *Pediatr Res*. 2004;56:791-795. 14. Thibault H et al. *J Pediatr Gastroenterol Nutr*. 2004;39(2):147-152. 15. Knol J et al. *J Pediatr Gastroenterol Nutr*. 2005;40:36-42.

## Advert for: Aptamil 2 Follow On Milk (Danone Nutricia)



### Summary of advert

This advert for Aptamil 2 Follow On Milk introduces a new formulation. The advert appeared as a two-sided A4 advert on glossy paper substantially thicker than the other text pages in the journal. The first page provides an image of the new product with the title “NEW Aptamil Follow On Milk with Pronutra – ADVANCE” and a banner overlapping the product emphasising that this is a “PATENTED NEXT GENERATION FORMULATION”. The picture of the front-of-pack of the product states “6-12 months,” “Pronutra ADVANCE – OUR UNIQUE PROCESS” and “With vitamin D to support the normal function of the immune system”. Text overlapping the product image describes a new method of preparation. This first page of the advert states that the new formulation combines prebiotics and postbiotics, but offers no further explanation of the new formulation. Three claims are made at the bottom of the advert “Gut and immune markers closer to breast-fed infants”, “Stool patterns closer to breast-fed infants”, and “Supports adequate growth”.

On the second page of the advert (reverse side) there are no product images but the advert carries the manufacturer’s logo in the top left of the page and it is obviously aligned by design to the previous page. The text contains a series of statements about prebiotics and postbiotics and Nutricia’s “unique process”. At the top of the page a banner states that “PREBIOTICS AND POSTBIOTICS SUPPORT THE IMMUNE SYSTEM THROUGH THE GUT”, claims are made that prebiotics support healthy gut microbiota and have a direct effect on immune cells, and that postbiotics are bioactive components produced by beneficial bacteria, stimulate healthy gut microbiota, immune functioning and development, and support intestinal immunity. Bubbles of text stating “30 clinical studies. 55 publications” and “Supported by clinical data” also appear on this page. There is also a series of statements related to prebiotics and postbiotics, claiming that the product leads to a favourable gut environment and changes the microbiota composition and activity. At the bottom of the page another banner states “CLOSER TO BREAST-FED INFANTS”, followed by the references.

### Claims made, and evidence given to support them

- 1 “Gut and immune markers closer to breast-fed infants”

#### Evidence given to support this claim

Two references are provided to support this claim. The first is given in the advert as Rodriguez-Herrera et al (2018). The reference given in the advert is to an oral presentation at the ESPGHAN conference in 2018, but the relevant reference is cited there as ‘Tims et al, 2018’. This was an oral presentation at a conference, using data from a study that examined the faecal microbiota of infants consuming a test formula with prebiotics and 30% fermented milk, or a control formula without prebiotics or fermented milk. There was a breastfed reference group. The authors reported that, in contrast to the infants consuming the control product, the infants consuming the test formula showed a saccharolytic fermentation profile (lower pH, higher level of acetic acid, and higher level of the antibody secretory IgA). The authors also reported that the levels of some faecal bacterial groups were consistently different between the test and control formula, with levels in the test arm closer to levels detected in the breastfed reference group. Metabolomic data showed differences in metabolites between the study groups. The study that these data were taken from has not been published in a peer-reviewed journal and the composition of the test formula in this study is not the same as that for the product advertised.

The second reference was for a conference poster presentation (Tims et al, 2018a) and presented data from a different study which looked at the effect of partly fermented experimental formula using three different ratios of fermented formula in base powder – 15%, 30% and 50% – and prebiotics GOS/FOS (9:1) on infant gut microbiota composition. These were compared to three control products: formula with prebiotics only, formula with fermented addition only, and a formula without either. A breastfed reference group was included. The authors reported that the faeces of infants consuming one of the experimental products showed a similar saccharolytic fermentation profile to infants consuming the control formula with prebiotics and to the breastfed infants (lower pH, higher level of acetic acid, higher level of sIgA) compared to those consuming formula without prebiotics. There was no dose-response effect noted for the fermented formulae. Again, the product for which

this evidence is provided is not the same as the product in the article, and only data from a poster presentation were given here as evidence.

## 2 “Stool patterns closer to breast-fed infants”

### Evidence given to support this claim

One reference is given to support this claim. Herrera et al (2015) reported that the stool consistency of infants fed a formula with prebiotics and 30% fermented milk (data taken from the same study as used for claim 1 above) was closer to the breastfed reference group, and stools were significantly softer than those of infants fed standard formula without prebiotics or fermented milk. The results were based on parental reports of stool consistency and frequency. This evidence again comes from an abstract rather than from an article from a peer-reviewed journal.

## 3 “Supports adequate growth”

### Evidence given to support this claim

One reference is given to support this claim – an abstract by Rodriguez-Herrera et al (2016), which provides information from the same study as above on growth and safety related to formula use. It reported adequate growth in all test formula groups, which is to be expected if the test formula meets compositional recommendations.

## 4 “PREBIOTICS AND POSTBIOTICS SUPPORT THE IMMUNE SYSTEM THROUGH THE GUT”

### Evidence given to support this claim

This statement is supported by three review articles, two of which were products of Danone Research (Nutricia), and the third of which was produced by a dairy biotechnology company. Although this statement is generally accepted as true for prebiotics in breastmilk, it does not relate to the addition of commercially produced pre- and postbiotics to formula milks.

The first study referenced – Wopereis et al (2014) – is a review article from Danone Research. It gives an account of the role of prebiotics in immunity and then refers to Nutricia-sponsored clinical trials of infant milks with prebiotics. It does not provide evidence related to postbiotics. The second reference – Martin et al (2010) – is also a review article from Danone Research. It gives an account of the development of immunity and the microbiota and then refers to Nutricia-sponsored clinical

trials examining the effect of pre-, pro- and synbiotics in infant milks on necrotising enterocolitis (NEC) and allergy. This again provides no evidence on postbiotics. The third study – referenced Aguilar-Toalá et al (2018) and produced by a Mexican dairy biotechnology company – offers perspectives on postbiotics and their applications for use in foods and pharmaceuticals. The article defines postbiotics as “soluble factors (products or metabolic byproducts), secreted by live bacteria, or released after bacterial lysis, such as enzymes, peptides, teichoic acids, peptidoglycan-derived muropeptides, polysaccharides, cell surface proteins, and organic acids”. The review also states: “These properties suggest that postbiotics may contribute, to the improvement of host health by improving specific physiological functions, even though the exact mechanisms have not been entirely elucidated”. The paper provides no evidence of any functional benefit of the use of postbiotics in infant formula.

## 5 “PREBIOTICS ...

- ✓ Support healthy gut microbiota
- ✓ Direct effect on immune cells”

### Evidence given to support these claims

One reference is given to support the healthy gut microbiota claim. This review article by Walker and Iyengar (2015) discusses the beneficial effects of prebiotics in reference to breastmilk oligosaccharides, but not in terms of exogenous, commercially produced prebiotics (GOS/FOS). It states: “This review of the association of breastfeeding with initial colonization and its importance in the infant/child’s health suggests that a critical new protective function for breastfeeding exists and opens up many new areas for investigation for both clinical and research studies.”

Using this review to make claims about prebiotics in follow-on formula is misleading.

One study is also cited to support the claim that prebiotics have a direct effect on immune cells. A study by Eiwegger et al (2004) cultured cord blood cells from healthy newborns with human breastmilk-derived oligosaccharides, and concluded that breastmilk oligosaccharides positively affect cytokine production and activation of cord blood derived T cells *in vitro*. It is again misleading to use this study to support a statement relating to prebiotics in follow-on formula, as the information does not refer to commercially produced GOS/FOS but is based on human milk derived oligosaccharides in an *in vitro* study.

- 6** “POSTBIOTICS are bioactive components produced by beneficial bacteria
- ✓ Stimulate healthy gut microbiota, immune functioning and development
  - ✓ Support intestinal immunity”

### Evidence given to support these claims

The first statement simply states what postbiotics are, but evidence from three review articles is provided for this: Aguilar-Toalá et al (2018), Patel and Denning (2013), and Tsilingiri and Rescigno (2013). Providing a lot of references for statements of fact is commonly done to give the impression of significant evidence being provided, even when this does not relate to any claims made.

One reference is given to support the statement that postbiotics stimulate healthy gut microbiota, immune functioning and development. Mullié et al (2004) investigated whether the size of the intestinal bifidobacterial population can influence the immune response to poliovirus vaccination in infants. Infants in the trial were fed either a fermented infant formula or a standard infant formula from birth to 4 months of age. This small clinical trial (n=30, but only 20 completed) sponsored by Nutricia used a different formula without prebiotics to the one the evidence is being used to support here. In this study the authors reported that cultivable faecal bifidobacteria levels were significantly higher in the group given fermented formula at 4 months. However, faecal immunoglobulin A titres were similar in both groups and did not increase after vaccination with inactivated poliovirus vaccine. A positive correlation between total bifidobacteria and antipoliovirus was observed for the whole population. However, there was no breastfed reference group, and the composition of the milk and the proportion of fermented milk used in the formula were not disclosed.

One reference is given to support the claim that postbiotics support intestinal immunity. The study, by Thibault et al (2004), was a prospective clinical trial of 971 infants aged 4-6 months. It reported reductions in the severity, but not in the incidence, of diarrhoea in infants who consumed a fermented infant formula compared to those who consumed a standard infant formula of the same nutritional composition. The authors concluded that this outcome may be linked to the bifidogenic effects of fermentation products and their interactions with the intestinal immune system and that the mechanism needs to be explored. Outcomes were based on parental report and four visits with a paediatrician. The trial was sponsored by Nutricia. There

was no breastfed reference group and the formula used differed to the product being advertised here. The milk did not contain prebiotics and neither the composition of the milk, nor the proportion of fermented milk used, was disclosed.

- 7** “FAVOURABLE GUT ENVIRONMENT
- LOWERS pH of the gut to encourage growth of beneficial bacteria
  - MAINTAINS soft stools
- MICROBIOTA COMPOSITION
- INCREASES beneficial bacteria (bifidobacteria)
  - DECREASES harmful bacteria (c difficile)
- MICROBIOTA ACTIVITY
- INCREASES secretory immunoglobulin A
  - IMPROVES number of microbial metabolites”

### Evidence given to support these claims

The references given to support these claims are: Tims et al (2018) (given incorrectly in the advert as Rodriguez-Herrera et al (2018) as explained above); Tims et al (2018a); Herrera et al (2015) and Knol et al (2005). The poster and oral presentations at conferences have been discussed previously and do not provide sufficient evidence to make claims, since they are not from peer-reviewed journal papers. We queried this with Danone and they said that the work would be published and therefore felt their inclusion was justified.

The claim that prebiotics and postbiotics encourage the growth of beneficial bacteria is supported with reference to the article by Knol et al (2005). This clinical trial was for a different milk than the one being advertised, as it did not contain postbiotics. It cannot therefore be used to support statements for the benefit of prebiotics and postbiotics which is how the company is using it here.

- 8** “CLOSER TO BREAST-FED INFANTS”

### Evidence given to support this claim

This statement is again supported by references from Tims et al (2018) (given incorrectly in the advert as Rodriguez-Herrera et al (2018) as previously explained); Tims et al (2018a), and Herrera et al (2015), which are all poster or oral presentations at conferences. This statement cannot be justified from the evidence given here and the stand-alone statement does not explain in what way they believe that any outcome from consuming this product provides an outcome closer to a breastfed baby.

## What does current accepted policy/science say?

The European Food Safety Authority (EFSA) in their *Scientific opinion on the essential composition of infant and follow-on formulae* concluded, as have previous EFSA panels considering health claims, that there is no evidence for health benefits from the addition of prebiotic oligosaccharides to infant or follow-on formula (European Food Safety Authority, 2014).

Postbiotics is the name that has been used to describe the metabolites produced by live bacteria during the fermentation process. There are little published data available to support their use. In 2007, the ESPGHAN Committee on Nutrition carried out a systematic review of the literature to assess knowledge on the effects of fermented infant formula without live bacteria. They concluded that *“The published data on the effects of fermented infant formulae without live bacteria are limited and do not allow firm conclusions”* (Agostoni et al, 2007). A more recent systematic review (Szajewska et al, 2016) also concluded that, from the limited available evidence, the use of fermented infant formula without live bacteria, compared with the use of standard infant formula, does not offer clear additional benefit.

## Our conclusion

The advert states, in bold text, that the patented formulation combines prebiotics and postbiotics, but does not offer any explanation of how postbiotics appear in the product nor any clear rationale for their addition. All four references given on the first page of the advert are from oral and poster presentations at conferences. No peer-reviewed data are given to support the claims made, and the products in the studies which are referred to do not appear to be the same as the product advertised. We do not believe that the evidence provided here is sufficiently robust to support the claims made.

The second page of the advert appears to offer greater scientific explanation of the benefits of the product. However, there is again little robust evidence for the claims being made, and the claims are not supported by recent systematic reviews. The advert makes a series of statements about prebiotics and postbiotics and then more statements about the effect of these on the gut microbiota and immune function, implying that these benefits relate to the use of prebiotics and postbiotics in the advertised formula. The advert provides no convincing rationale for the addition of partly fermented milk to the existing product.

A list of 15 references is provided but bubbles of text state that the claims are supported by *“30 clinical studies”* and *“55 publications”* and are *“Supported by clinical data”*, suggesting that these relate to the product advertised even though these publications and clinical outcome data are not included. None of the references provided appears to be a study where the specific product in this advert is used.

We believe that this advert deliberately misleads health workers into thinking that there is agreed scientific evidence for a benefit of this new formulation on infant health, and by doing this, and by making claims that this follow-on formula can produce outcomes *“closer to breast-fed infants”*, it undermines breastfeeding.

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**Advert for:** Aptamil Anti-reflux (Danone Nutricia)

**Advert seen in:** *Complete Nutrition*, October 2018

For formula-fed infants with frequent regurgitation and marked distress

# NICE\*

## RECOMMENDS a stepped-care approach...

**REVIEW**  
the feeding history,

**REDUCE**

the feed volumes by trying smaller, more frequent feeds (while maintaining an appropriate total of daily amount of milk) unless the feeds are already small and frequent,

**TRIAL**

a thickened formula (for example, containing carob bean gum, rice starch or corn starch).



**Aptamil Anti-Reflux** is a specially designed thickened formula that can help you meet recommendations by NICE

- Formulated with carob bean gum, providing greater viscosity on contact with stomach enzymes compared to starch based thickened feeds<sup>1</sup>
- Shown to reduce infant regurgitation by 78%<sup>2</sup>



**AVAILABLE IN MOST RETAIL AND PHARMACY OUTLETS**

\* National Institute for Health and Care Excellence

References: 1. Danone Research (data on file). 2. Wenzl TG et al. Pediatrics 2002;111:e355-5.

**IMPORTANT NOTICE:** Aptamil Anti-Reflux is a food for special medical purposes, for the dietary management of frequent reflux and regurgitation. It should only be used under medical supervision, after full consideration of the feeding options available including breastfeeding. Suitable for use as the sole source of nutrition for infants from birth, and as part of a balanced diet from 6-12 months.

18-1385 June 2018

**FOR HEALTHCARE PROFESSIONAL USE ONLY.**



## Advert for: Aptamil Anti-reflux (Danone Nutricia)



### Summary of advert

This advert for an anti-reflux milk shows a woman dressed in a white lab coat gazing at a calm baby she is holding on her lap, with her hand holding the baby's head

in a very maternal pose. To the left of this image is the word "NICE" in type that dominates all of the remaining text. This is followed by "RECOMMENDS a stepped-care approach ..." in progressively smaller text. Above the word 'NICE', in the smallest font used in the body of the advert, are the words "For formula-fed infants with frequent regurgitation and marked distress". This is followed by a simplified version of the guidance from the National Institute for Health and Care Excellence (NICE) on the management of regurgitation in infants. The advert makes three claims: "Aptamil Anti-Reflux is a specially designed thickened formula that can help you meet recommendations by NICE"; "Formulated with carob bean gum, providing greater viscosity on contact with stomach enzymes compared to starch based thickened feeds"; and "Shown to reduce infant regurgitation by 78%".

### Claims made, and evidence given to support them

- 1 "Aptamil Anti-Reflux is a specially designed thickened formula that can help you meet recommendations by NICE"

#### Evidence given to support this claim

No evidence is given to support this claim. As a thickened formula, Aptamil Anti-reflux only helps health professionals meet NICE guidance by virtue of it being one of several infant milk options available to use as one of the stages of a stepped care approach, where all other recommended treatment options have been tried.

- 2 "Formulated with carob bean gum, providing greater viscosity on contact with stomach enzymes compared to starch based thickened feeds"

#### Evidence given to support this claim

This claim is supported by reference to Danone research, which is held on file by Danone. We have asked to see this data, but to date it has not been shared with us.

- 3 "Shown to reduce infant regurgitation by 78%"

#### Evidence given to support this claim

One reference is given to support this claim, presenting data from a very small placebo-controlled crossover study in 14 healthy infants (Wenzl et al, 2003). The study reported that the frequency and amount of regurgitation were reduced in infants after consuming infant formula thickened with carob bean gum, compared to when the infants were fed the same milk without thickener. There was, however, no significant reduction in the occurrence or duration of acid gastro-oesophageal reflux. The decrease in regurgitation was thought to have resulted from the decrease in the number of non-acid gastro-oesophageal reflux episodes when thickened infant milk was consumed.

This finding is contradicted by data from a more recent larger clinical trial including 60 infants and their carers, designed to evaluate the efficacy of parental reassurance in combination with different types of infant milk. The trial reported that regurgitation frequency was reduced in all of the three groups, and there was no significant difference in regurgitation frequency between groups receiving standard formula milk, infant milk thickened with rice cereal, or infant milk thickened with bean gum. All participating parents were reassured in the same way. The only significant difference between groups was that infants receiving infant milk thickened with bean gum experienced a greater increase in weight during the trial. The authors suggest that this effect may be due to the greater (although not statistically significant) decrease in regurgitation frequency in this group (Hegar et al, 2008).

#### What does current accepted policy/science say?

The use of thickened milks in infants with simple reflux is not supported by the ESPGHAN Committee on Nutrition on the grounds that there is no conclusive information available on the potential effects of thickening agents on the bioavailability of nutrients and growth of children, or on mucosal, metabolic and endocrine responses (Aggett et al, 2002). There is also very little evidence to suggest that these milks confer any benefits with respect to acid exposure of the oesophageal mucosa or bronchopulmonary complications of gastro-oesophageal reflux. It is suggested that, where infants have simple reflux and no complications, parents and carers require advice and information rather than a different type of formula (Aggett et al, 2002).

This is supported by NICE guidance in the UK (National Institute for Health and Care Excellence, 2015, 2016), which outlines how gastro-oesophageal reflux should be diagnosed and managed in infants. The guidance reiterates that regurgitation is a common and normal occurrence in infants and does not usually need any investigation or treatment. Where, rarely, there are significant symptoms of frequent regurgitation with marked distress, thickener added to milk or a thickened infant milk is recommended for trial, only after a review of feeding history, and a reduction in feed volumes where appropriate or an increase in frequency of feeds has been attempted.

## Our conclusion

While this advert does not directly say that NICE recommends Aptamil Anti-reflux, the disingenuous use of the words “NICE RECOMMENDS” in very dominant type, together with the branding and product image, are clearly an attempt to encourage health professionals to associate the product with NICE guidance and imply that NICE endorses the product. Health professionals should note that the NICE guidance is clear that a thickened formula is only recommended when there are significant symptoms of frequent regurgitation.

We believe that, as the product is available openly on the shelves of shops, supermarkets and pharmacies for parents and carers to purchase without necessarily having consulted their primary healthcare provider, it may actually hinder compliance with recommendations for a stepped care approach.

## References

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Advert for: Aptamil Pepti (Danone Nutricia)

Advert seen in: *Dietetics Today*, July/August 2018

FOR HEALTHCARE PROFESSIONAL USE ONLY

Breastfeeding is best for babies



the

step

in the effective  
management of  
**cows' milk allergy**  
is extensively hydrolysed formula†

REASSURE  
WITH THE  
UK'S MOST  
PALATABLE EHF\*\*

**Aptamil Pepti**

HCPs believe palatability  
increases compliance†



†For the management of mild to moderate cows' milk allergy, the (MAP guideline)† recommends an Extensively Hydrolysed Formula (EHF) as the first step for formula feeding or mixed feeding (if symptoms only with introduction of top-up feeds) infants.

References: 1. Caropden BR conducted a blind taste test using a home usage design with a sample of 100 Dietitians and General Practitioners from 16.11.2016 to 09.12.16. Participants rank ordered the extensively hydrolysed formula (EHF) milk samples (Glaxo Aptamil Pepti, Abbott Simlac Alimentum, Nestle SMA Alchera and Mead Johnson Nutramigen LGG) in terms of overall liking and answered a series of attitudinal questions in relation to the impact of EHF's palatability on infants with CMA and their families. The results from the ranking showed that the Danone Aptamil Pepti sample was liked significantly more than all the other three samples tested. 2. Venker C, et al 2012. Better recognition, diagnosis and management of non-IgE-mediated cow's milk allergy in infancy: (MAP - an international interpretation of the MAP (Milk Allergy in Primary Care) guideline. Clin Transl Allergy, August, vol. 2, no. 26.

†A home usage test assessment was carried out between 16/11/16 and 9/12/16 on the 4 products indicated for cows' milk allergy from birth and included 500 UK healthcare professionals.

IMPORTANT NOTICE: Aptamil Pepti 1 & 2 are foods for special medical purposes for the dietary management of cows' milk allergy. They should only be used under medical supervision, after full consideration of the feeding options available including breastfeeding. Aptamil Pepti 1 is suitable for use as the sole source of nutrition for infants from birth, and/or as part of a balanced diet from 6-12 months. Aptamil Pepti 2 is suitable for babies over 6 months as part of a mixed diet.

18-044 (Palatability)†Date of Prep: March 2018  
© Danone Nutricia Early Life Nutrition 2018

**NUTRICIA**  
Early Life Nutrition

Healthcare Professional Helpline: 0800 996 1234 [www.eln.nutricia.co.uk/cma](http://www.eln.nutricia.co.uk/cma)

## Advert for: Aptamil Pepti (Danone Nutricia)



### Summary of advert

This advert is for an extensively hydrolysed (eHF) cows' milk based infant formula. The majority of the page is taken up by the emotive picture of a small baby (in the

first months of life) with a pink face, crying and quite obviously distressed. This picture is visible through a window in the shape of a number '1'. The '1' shaped window is embedded in a statement that reads "The 1st step in the effective management of cows' milk allergy is extensively hydrolysed formula". The 'st' in "step" and the words "cows' milk allergy" are in a more prominent font and/or colour to draw attention to the words "1st" and "cows' milk allergy". At the top of the page, to the right, is a banner with the words "REASSURE WITH THE UK'S MOST PALATABLE EHF", followed by the product name and the claim that "HCPs believe palatability increases compliance". There is a picture of tins of Aptamil Pepti 1 and Aptamil Pepti 2 at the bottom of the page. Below this, in type only marginally larger than the references, is the statement "For the management of mild to moderate cows' milk allergy, the iMAP guideline recommends an Extensively Hydrolysed Formula (EHF) as the first step for formula feeding or mixed feeding (if symptoms only with introduction of top-up feeds) infants."

### Claims made, and evidence given to support them

- 1 "REASSURE WITH THE UK'S MOST PALATABLE EHF"
- 2 "HCPs believe palatability increases compliance"

### Evidence given to support these claims

One reference is given to support both these claims. Whilst the research report given in the reference cited in the advert was unobtainable, a paper by the same authors outlining this work was also published in 2018 (Maslin et al, 2018). This references a taste test carried out on extensively hydrolysed infant milks suitable from birth available on the UK market. These were Aptamil Pepti 1 (Danone Nutricia), Althéra (Nestlé), Similac Alimentum (Abbott) and Nutramigen LGG 1 (Mead Johnson). The product palatability was assessed by 51 dietitians and 49 GPs who all had prior experience of treating an infant with cows' milk allergy (CMA) and who

were recruited in 2016 by market research agencies from their own healthcare professional registers. Fifty-eight per cent of those taking part had previously tasted an eHF and 98% of the participants had prior awareness of Aptamil Pepti 1 and Althéra, with 72% aware of Alimentum and 68% aware of Nutramigen. The participants ranked the whey-based, lactose-containing milks (Pepti and Althéra) above the casein-based milks (Alimentum and Nutramigen LGG) in terms of taste. The study reported that Aptamil Pepti 1 was ranked as most palatable by 77% of participants and Nestlé Althéra by 20% of participants. Participants completed a questionnaire about the impact of formula palatability on infants and their families, but the leading statements they were given allowed only 'yes' or 'no' answers and did not allow participants to have no opinion. The authors reported that the results of the questionnaire showed that healthcare professionals (HCPs) expected that good palatability would result in better acceptance, but acknowledged that this evidence does not prove there is a link between HCP taste preferences of a hypoallergenic formula and child preferences for the same formula. The authors state that the study was funded by Nutricia, and that three of the four authors were paid by Nutricia to write up the study for publication. Participants were paid by the research agency for their time and travel, but the funding for the research agency was provided by Nutricia, and it is not known whether participants were aware of this when taking part. We believe there is considerable conflict of interest in this work.

- 3 "The 1st step in the effective management of cows' milk allergy is extensively hydrolysed formula"

### Evidence given to support this claim

The iMAP (an international interpretation of the Milk Allergy in Primary Care) guideline is used in support of the statement above (Venter et al, 2017). This guideline does not make the statement above but recommends a trial of an eHF only for infants who are formula-fed or mixed-fed. Breastfeeding remains the primary recommendation for infant feeding. The advert clarifies that eHF is the first step only for formula-fed babies in very small text in a position remote from the main statement, and in a font only marginally larger than the references at the bottom of the page.

## What does current accepted policy/science say?

It is well known that all extensively hydrolysed formula have efficacy in treating cows' milk allergy (CMA). However, the first line of treatment, which is clearly stated in UK guidelines (National Institute for Health and Care Excellence, 2015) is to encourage continued breastfeeding for breastfed babies and to advise the mother to exclude cows' milk protein from her diet. "Where infants are mixed fed or exclusively formula fed then an extensively hydrolysed formula (eHF) that is tolerated by the majority of infants and children (90%) with cows' milk protein allergy can be used to replace cows' milk based formula."

The perceived palatability of the formula is not considered in these guidelines, nor is it considered in the iMAP guidelines referenced by Danone to support the claims made. It is generally accepted that the hydrolysis of proteins changes the flavour of milk in eHFs, but there is no evidence to suggest that the subjective flavour preferences of a group of unrelated adults will be the same as those of infants. Evidence has shown that 1-3 months of exposure to eHF before the infant reaches 3.5 months of age is sufficient to result in greater preference for the flavour of this formula compared with cows' milk formula fed infants who did not experience eHF during their first 8.5 months (Mennella and Castor, 2012). They suggest that the window for early acceptance and long-term influences began to close at around 3.5-4.5 months. The infant shown in this advert looks to be in the early months of life. There is also evidence to suggest that the hedonic response to, and acceptance of, different flavours is learned and that it depends on many factors including the mother's diet during pregnancy, whether or not the baby has ever received breastmilk, the timing of first exposure to the new flavour, and the duration of the exposure (Trabulsi and Mennella, 2012).

## Our conclusion

There is no doubt that an infant who is not breastfed and is diagnosed with CMA requires an extensively hydrolysed formula. However, this advert implies brand superiority, that this formula should be the 'first choice' treatment for CMA in any infant because of its preferred taste over other brands, and that this is corroborated by healthcare professionals. The deliberate omission from the main body of the advert of the fact that eHF is only the first line of treatment of CMA in infants who are formula-fed or mixed-fed is misleading and undermines breastfeeding. We do not believe that the taste preferences of unrelated adults (in a study where there may well have been bias due to previous taste experiences) is relevant to how a milk will be accepted by infants. No evidence is presented in support of the implied claim that infants' 'compliance' with their eHF diet will be any better on this formula than any other eHF. The main purpose of the advert is to raise brand awareness. It provides very little in the way of scientific or factual information to aid health professionals in their choice of products.

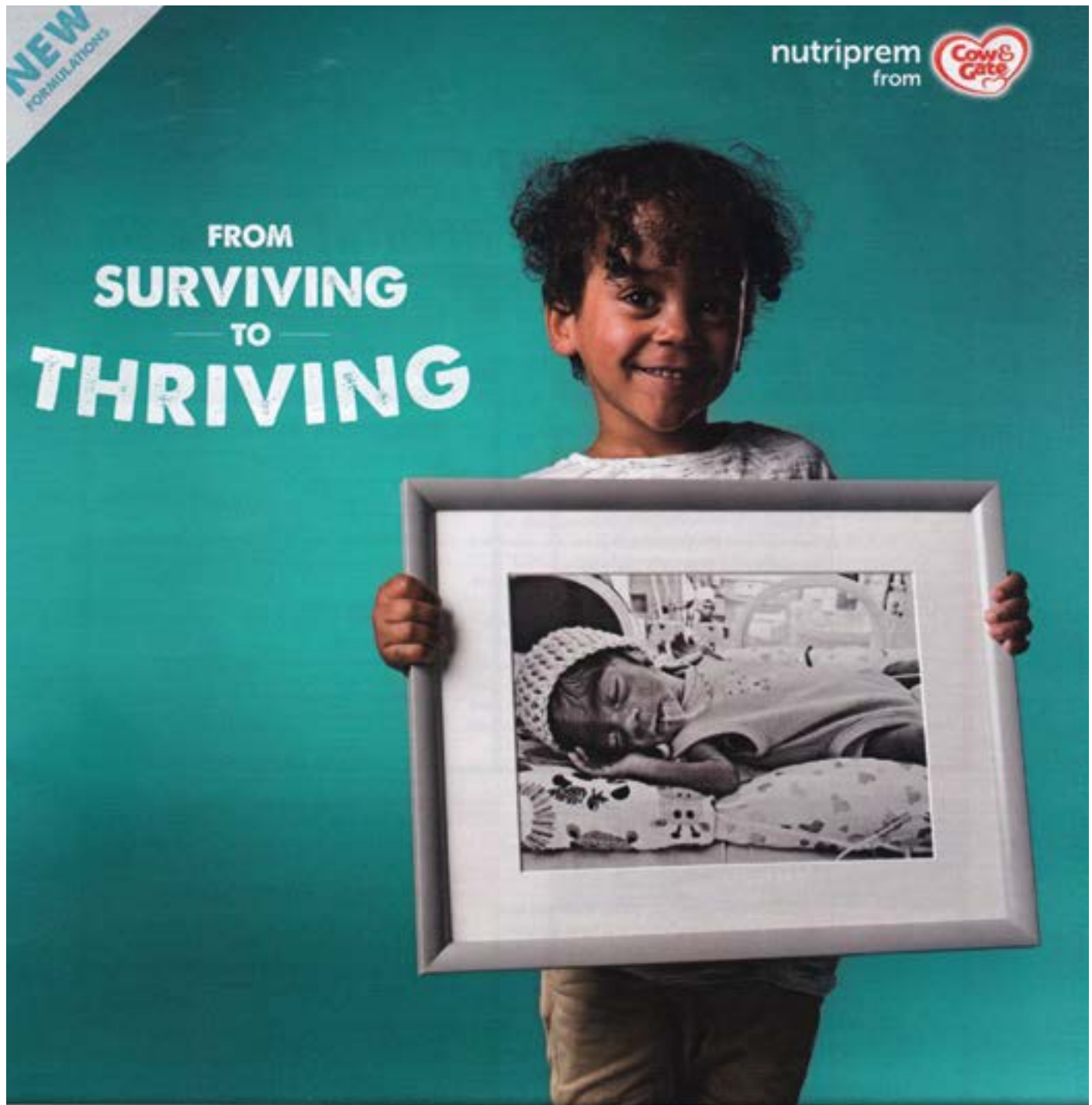
The marketing of Aptamil Pepti 2 product, from 6 to 12 months, will be confusing for families who are told by health professionals in the UK that first infant formula is the only infant formula needed in the first year of life. The *WHO Code of Marketing of Breastmilk Substitutes* and subsequent resolutions are clear that any infant milk marketed for children in the first three years of life is a breastmilk substitute.

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Advert for: Cow & Gate Nutriprem (Danone Nutricia)

Advert seen in: *Dietetics Today*, February 2018



**NEW FORMULATIONS**

nutriprem from 

**FROM SURVIVING TO THRIVING**

## NOW NUTRITIONALLY CLOSER TO BREASTMILK THAN EVER BEFORE<sup>1,2</sup>

Preterm infants deserve the very best chance to thrive into their childhood years and beyond. Inspired by breastmilk, we've introduced our new "best yet" nutriprem formulations, so that we're nutritionally closer to breastmilk than ever before.

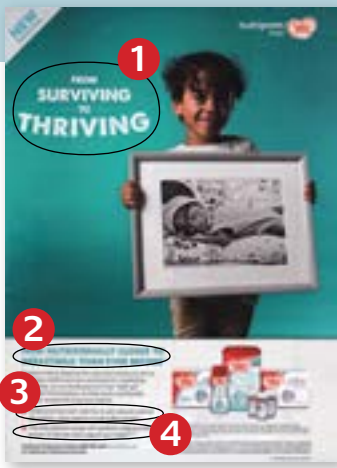
- ✓ NOW enriched with milk fat, to aid calcium and fat absorption, ease digestion and soften stools<sup>3,7</sup>
- ✓ The only preterm range with prebiotic oligosaccharides proven to beneficially support gut health<sup>8,10</sup>

Healthcare Professional Helpline 0800 996 1234 [en.nutricia.co.uk](http://en.nutricia.co.uk)  
For Healthcare Professional Use Only



**Important notice:** Breastmilk is best for babies. Nutriprem human milk fortifier, nutriprem protein supplement, hydrolyzed nutriprem, nutriprem 1 and 2 are foods for special medical purposes. They should only be used under medical supervision, after full consideration of the feeding options available, including breastfeeding. Hydrolyzed nutriprem, nutriprem 1 and 2 are suitable for use as the sole source of nutrition for preterm and low birthweight infants.

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### Summary of advert

This advert is for the entire Nutriprem range of products for premature babies. The focus of the page is an image of a smiling young child holding a large framed photograph

(presumably of himself) as a baby, in an incubator. To the left of this image the text “FROM SURVIVING TO THRIVING” appears prominently in white against a blue background. Text in the top left-hand corner of the advert reads “NEW FORMULATIONS”, and a brand name “Nutriprem” and the Cow & Gate logo appear in the top right corner.

Below the main image are the product details and images of the entire Nutriprem range. The main heading says “NOW NUTRITIONALLY CLOSER TO BREASTMILK THAN EVER BEFORE”, and the text below says these are new “best yet” formulations. Two specific claims are made: “NOW enriched with milk fat, to aid calcium and fat absorption, ease digestion and soften stools”, and “The only preterm range with prebiotic oligosaccharides proven to beneficially support gut health”. The supporting references are printed in very small type below the product images. The advert suggests the claims made apply to all the products in the range.

### Claims implied, and evidence given to support them

There are two strongly implied claims made by the advert:

- 1 An implied link between the use of infant formula and survival, and an implied claim that post-discharge formula is necessary for premature infants to thrive

#### Evidence given to support these implied claims

No evidence is given to support the implied claim that Nutriprem infant milks help an infant survive and thrive.

### What does current accepted policy/science say?

The implied claims are undermined by evidence that supports the use of human milk, not a premature baby formula, as the first line of support for premature babies. A review of human milk feeding in premature infants and risk of necrotising enterocolitis (NEC) reported that an

exclusive human milk diet provides protection against NEC, a neonatal condition which has undisputed high mortality rates (Cacho et al, 2017). Preterm infants are particularly susceptible to NEC due to the immaturity of their gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems (Maffei and Schanler, 2017). Extremely premature infants who receive an exclusive human milk diet have been shown to have a significantly lower dysplasia and retinopathy of prematurity (Hair et al, 2016). A Cochrane review reported that the use of infant formula in premature babies significantly increases the risk of NEC (Quigley and McGuire, 2014). The advert does not make any mention of breastmilk as the most important food for infant survival.

The Nutriprem range also contains a post-discharge formula. A Cochrane review in 2016 (Young et al, 2016) reviewed 16 eligible trials involving 1,251 infants and concluded that there is no evidence to support the use of post-discharge formula for preterm infants after hospital discharge to improve growth and development. A separate Cochrane review investigating growth and development of infants given a nutrient- and energy-dense post-discharge infant milk found little evidence of efficacy at up to 18 months post-term compared with infants given a term infant milk (Henderson et al, 2007). In addition, a study by Rozé et al (2012) looked at a large (almost 3,000 babies) cohort of preterm infants and found that those who were breastfed after discharge grew less well, but had better neurodevelopmental outcomes, which shows that post-discharge formula is not only unnecessary but may have adverse long-term developmental consequences.

### Claims made, and evidence given to support them

- 2 “NOW NUTRITIONALLY CLOSER TO BREASTMILK THAN EVER BEFORE”

#### Evidence given to support this claim

Two references are given to support this claim. The first, Ballard and Morrow (2013), discusses human milk composition and does not provide any evidence that can be related to this formula. The second, Innis et al (1994), suggests that palmitic acid esterified in the sn-2 position in human milk is related to absorption efficiency, but no metabolic significance is suggested for this. This paper again provides no evidence relevant to Nutriprem formula.

The fat content of breastmilk is highly variable depending on the stage of lactation, time of day and the mother's diet, and is extremely complex, providing the primary energy source and having a range of metabolic and physiological functions important for growth and development. It is not possible to artificially recreate the fat profile of human milk. We do not believe that any evidence presented here substantiates a claim that these milks are “*nutritionally closer*” to breastmilk.

**3** “NOW enriched with milk fat, to aid calcium and fat absorption, ease digestion and soften stools”

### Evidence given to support this claim

Five references are given to support this claim. The first, by Bar-Yoseph et al (2013), is a review article written by staff of Enzymotec in Israel – a company that supplies lipid-based bio-functional ingredients and which therefore has a conflict of interest in the reporting of positive evidence on the potential use of structured triglycerides in formula. The review relates to the use of artificially modified vegetable fats with palmitate esterified in the sn-2 position (structured triglycerides) in infant formula, rather than to milk fat. Two further references – Carnielli et al (1996) and Kennedy et al (1999) – both relate to the use of artificially modified vegetable fats with palmitate esterified in the sn-2 position in infant formula. They were also both included in the review by EFSA which concluded that there was no evidence of benefit for the use of palmitate esterified in the sn-2 position in infant formula (European Food Safety Authority, 2014). Interestingly, these studies have previously been used to support claims by Danone that the use of *synthetic* triglycerides made from vegetable fats with a higher proportion of palmitate in the sn-2 position improves fat and calcium absorption and the studies are now being used to support the same claims for the use of milk fat.

The reference by Quinlan et al (1995) considered factors relating to stool hardness in breastfed and formula-fed infants and does not provide any evidence for the products advertised. The final reference – Carnielli et al (1995) – provides evidence from a small crossover study of 12 formula-fed premature infants. Whilst this study reported improvements in absorption of some fatty acids, it was subject to several methodological limitations – including small sample size, lack of wash out period between the test and control formulas, and lack of power calculations – which means it may have been underpowered in relation to some of the outcome measures tested.

**4** “The only preterm range with prebiotic oligosaccharides proven to beneficially support gut health”

### Evidence given to support this claim

This claim appears to be made for all the formula milk in the Nutriprem range, but hydrolysed Nutriprem has no prebiotics present. Evidence given for the claim comes from three small or compromised studies. A study by Mihatsch et al (2006) showed changes to stool viscosity and transit time but provided no evidence of a benefit to the addition of prebiotic oligosaccharides at 1mg/100ml to a feed. Based on the fibre content stated on the manufacturer's datacards, which we believe represents the level of prebiotics present, Nutriprem 1 and 2 contain 0.6mg prebiotic oligosaccharides/100ml. The other two studies – by Boehm et al (2002) and Knol et al (2005) – were funded by Numico and used a test formula supplemented with 1g/100ml oligosaccharides and showed an increase in faecal bifidobacteria. This does not prove a health benefit.

The advert claims that the beneficial effects of prebiotics for gut health are “*proven*”, but the evidence provided is from small, single studies which do not link to health outcomes and which do not provide adequate evidence to support this claim.

### What does current accepted policy/science say?

The European Food Safety Authority (EFSA), in its comprehensive review of the composition of infant formula and follow-on formula (European Food Safety Authority, 2014), reviewed evidence on the potential benefit of altered fatty acid conjugation and concluded there was no convincing evidence for a beneficial effect of the use of palmitic acid predominantly esterified in the sn-2 position in formula milks.

A systematic review and meta-analysis of the safety and efficacy of oligosaccharide supplementation of preterm infant milk – which included the studies by Mihatsch et al (2006) and Boehm et al (2002) – found no decrease in NEC, late onset sepsis or quicker establishment of full enteral feeds (Srinivasjois et al, 2013).

EFSA, in its scientific opinion on the essential composition of infant formula and follow-on formula, clearly states that “*there is insufficient evidence for beneficial effects on infant health of the non-digestible oligosaccharides that have been tested to date in RCTs when added to IF or FOF*”. (European Food Safety Authority, 2014). They have also made it clear that infant formula cannot imitate breastmilk in composition (European Food Safety Authority, 2014).



## Our conclusion

We do not believe that the evidence provided is sufficiently strong to support the claims made. In many of the trials referenced, the test formula contains a higher proportion of the ingredient the claim relates to than the products currently marketed. The claims are made for all the products in the range, even though one of the products does not contain one of the ingredients for which a claim is made.

The suggestion that an infant formula is linked to premature infant survival is misleading and goes against the current evidence that both supports the use of human milk in preventing illness and infection in vulnerable low-birthweight infants, and highlights the risks associated with the use of any formula for premature and low-birthweight babies requiring specialist care. We do not believe any evidence is presented here that would support the claim that this product is “*nutritionally closer to breastmilk than ever before*”.

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Advert for: Cow & Gate Nutriprem (Danone Nutricia)

Advert seen in: Network Health Digest, April 2019

FOR HEALTHCARE PROFESSIONAL USE ONLY

nutriprem from 

# FROM SURVIVING TO THRIVING



**SUPPORTS GUT HEALTH**



**SOFTER STOOLS**



**HALAL CERTIFIED**



**Nutriprem 1 and nutriprem 2** are the **ONLY** preterm products in the UK with **prebiotic oligosaccharides**, proven to support gut health<sup>1,2</sup>

**Nutriprem 1, hydrolysed nutriprem and nutriprem 2** are the **ONLY** preterm products in the UK **enriched with milk fat** to aid calcium and fat absorption, ease digestion and soften stools<sup>4-6</sup>

**Nutriprem 1, hydrolysed nutriprem and nutriprem 2** (90ml and 200ml only) are all **halal certified**



**ESPGHAN compliant<sup>8,10</sup>**

Healthcare professional helpline **0800 996 1234**  
[eln.nutricia.co.uk](http://eln.nutricia.co.uk)  **@NutriciaELNUK**

**Important notice:** Breastmilk is best for babies. Nutriprem human milk fortifier, nutriprem protein supplement, hydrolysed nutriprem, nutriprem 1 and 2 are foods for special medical purposes for the dietary management of preterm and low birthweight infants. They should only be used under medical supervision, after full consideration of the feeding options available, including breastfeeding. Hydrolysed nutriprem, nutriprem 1 and 2 are suitable for use as the sole source of nutrition for preterm and low-birthweight infants.

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### Summary of advert

The new advert retains the main headline – “FROM SURVIVING TO THRIVING” – from the previous advert, this time with a photo of twin girls of about 4

years of age showing pictures of themselves as infants in special baby care. Under this, the advert now makes three claims: “SUPPORTS GUT HEALTH” (with a graphic of a gut); “SOFTER STOOLS” (with a graphic of a nappy); and “HALAL CERTIFIED” (with a ‘tick’ graphic). At the bottom, by a picture of the product range, there is now a circle saying “ESPGHAN compliant”. As in the previous advert, the evidence is provided in extremely small type at the bottom of the page.

### Changes made to claims in the 2018 version of the advert

Following the publication of the advert shown on page 22 in 2018, a complaint was made to Danone Nutricia by 18 individuals and infant feeding organisations asking them to retract the advert as they felt it was misleading and undermined the importance of breastmilk for premature infants. In 2019, this revised advert was seen.

The manufacturers have responded to the complaint that not all the products in the range actually contain prebiotic oligosaccharides, but continue to make the claims that prebiotic oligosaccharides support gut health in two of their products using the same references we have critiqued on page 24 (Boehm et al, 2002<sup>1</sup>, Knol et al, 2005; Mihatsch et al, 2006). No new evidence is presented, despite the fact that the company were given the critique of the evidence provided for these claims.

The claim that these products are enriched with milk fat and that this leads to softer stools, eases digestion and aids fat and calcium absorption, remains the same as in the previous advert, using the same references we have also critiqued on page 24 (Bar-Yoseph et al, 2013; Carnielli et al, 1995; Carnielli et al, 1996; Kennedy et al, 1999; Quinlan et al, 1995). No new evidence is presented, despite the fact that the company were given the critique of the evidence for these claims.

The addition of “ESPGHAN COMPLIANT” here is supported by two new references (Agostoni et al, 2010, Aggett et al, 2006). There are three sets of guidelines (known as

1 The advert does not include the date for this reference, but we assume it to be Boehm et al, 2002.

the Tsang, ESPGHAN and Koletzko guidelines respectively) that have been published on the nutritional requirements of preterm infants (Tsang et al, 2005; Agostoni et al, 2010; Koletzko et al, 2014). The references here relate to two sets of ESPGHAN guidance. Unlike term infants, preterm infants have variable higher growth demands. ESPGHAN guidelines report a higher nutritional requirement for energy, protein, calcium, potassium, sodium, phosphorus and fat-soluble vitamins for pre-term infants, compared to term infants. The guidelines differ in their focus, with ESPGHAN guidelines covering infants with a birthweight of 1.0-1.8kg, although this is not specified in the advert. Any infant milks marketed for premature infants would be expected to meet the latest guidance and this advert fails to mention that the latest ESPGHAN guidance for feeding premature infants says that all preterm infants should receive human milk, and if that is not available, infants should receive donor human milk (Arslanoglu et al, 2013).

### Our conclusion

**It is disappointing that, even when a critical review of the evidence is provided to a company about an advert, claims continue to be made which are unsupported by the evidence provided. The advert undermines clear guidance on the essential feeding of premature infants with breastmilk or donor human milk to protect them from serious and life-threatening infections.**

### References

Most of the references cited in this advert are shown on page 25. Additional references used in the advert are given below.

Aggett P, Agostoni C, Axelsson I et al (2006). Feeding preterm infants after hospital discharge. A commentary by the ESPGHAN Committee on Nutrition. *Journal of Pediatric Gastroenterology and Nutrition*; 42: 596-603.

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Advert for: Neocate Syneo (Danone Nutricia)

Advert seen in: Archives of Disease in Childhood, December 2018



**NEW**

# New Neocate Syneo

Help rebalance gut microbiota dysbiosis in infants with CMA with new **NEOCATE SYNEO**<sup>1,2</sup>

**THE ONLY AAF WITH PRE- AND PROBIOTICS\***  
clinically proven to bring the gut microbiota closer to that of healthy breastfed infants<sup>1</sup>

**NUTRITIONAL MANAGEMENT BEYOND SYMPTOM RESOLUTION**

**Neocate SYNEO**  
6+ months

**Neocate Syneo**  
Hypoallergenic amino acid based infant formula powder  
• optimized composition with 20 essential amino acids, 100% lactose and infant fibers  
• 100% rDNA + Probiotics  
\*Neocate Syneo is not a substitute for breast milk

## Neocate: Fast and effective resolution of CMA symptoms<sup>1,2,3,4</sup>

This information is intended for Healthcare Professionals only.  
Neocate Syneo is a Food for Special Medical Purposes for the dietary management of Cow's Milk Allergy, multiple food protein allergies and other conditions requiring an Amino Acid-based Formula, and must be used under medical supervision after full consideration of all feeding options, including breastfeeding.

\*Accurate at time of publication, October 2018

Probiotic: *Bifidobacterium breve* M-16V and prebiotic scFOS/1cFOS blend

CMA: Cow's Milk Allergy

AAF: Amino Acid-based Formula

**References:** 1. Candy et al. *Pediatr Res*. 2018;83(3):677-686. 2. Burks W, et al. *Pediatr Allergy Immunol* 2015;26:316-322. 3. De Boissieu D, et al. *J Pediatr* 1997; 131(5):744-747. 4. Vanderhoof JA, et al. *J Pediatr* 1997; 131(5):741-744.

Nutricia Advanced Medical Nutrition, White Horse Business Park, Trowbridge, Wiltshire, BA14 0XQ

**NUTRICIA**  
**neocate**  
[www.neocate.co.uk](http://www.neocate.co.uk)

If you would like to order a product sample to be delivered directly to a patient, please visit [www.nutriciaproducts.com/samples](http://www.nutriciaproducts.com/samples)

## Advert for: Neocate Syneo (Danone Nutricia)



### Summary of advert

Neocate Syneo was launched into the UK market in 2018 as an addition to the existing Neocate infant milk product range for infants with cows' milk allergy, and

the advert carries a “NEW” banner and the word “New” is stated in the title. The advert is a picture of a smiling infant with a drawing of his intestines superimposed over his T-shirt, which links to a stylised picture of microbes floating in a circle, intended to represent gut bacteria. The text to the right of the image above and below the graphic of the gut components highlights the product name again and the presence of pre- and probiotics. There is a picture of a can of Neocate Syneo at the bottom of the page and beside it, in a bubble, text that states “NUTRITIONAL MANAGEMENT BEYOND SYMPTOM RESOLUTION”.

Product information and references appear at the bottom of the page along with a brand name reminder and one of the four claims that are made in the advert.

### Claims made, and evidence given to support them

- 1 “Help rebalance gut microbiota dysbiosis in infants with CMA with new NEOCATE SYNEO”

#### Evidence given to support this claim

Two references are given to support the claim that Neocate Syneo can help rebalance the gut microbiota. Both studies referenced were funded by Nutricia, the manufacturer of Neocate Syneo. A study by Candy et al (2018) looked at infants with suspected cows' milk protein allergy, but excluded those who had previously had positive skin prick tests. It was designed to evaluate the effects of the test formula in subjects with non-IgE mediated cows' milk allergy (CMA), but the authors acknowledge that there is no precise test for this diagnosis. The authors also acknowledge that the fact that the majority of subjects in the trial were already receiving a hydrolysed or amino acid-based formula at study entry confounds interpretation of the data. Three groups of infants were included for an eight-week feeding period: a control group (n=36) who were given Neocate LCP; a test group (n=35) who were

given Neocate LCP with synbiotics (added probiotic *Bifidobacterium breve* M-16V and a prebiotic blend of fructo-oligosaccharides); and an exclusively breastfed matched reference group (n=51). Baseline characteristics were similar between the test and control groups although twice as many infants were born by caesarean section in the control group. The breastfed reference groups were age-matched but they were not selected for similar baseline characteristics as the test and control groups. The infants at baseline were anywhere between 1.2 months and 14.2 months of age and were recruited from 11 centres in four countries, and many of the infants would also have been receiving solid food. The milk given to the test group was similar to Neocate Syneo, but not identical. After 11 dropouts from the test and control group, the study reported higher median percentages of faecal bifidobacteria and lower median percentages of *Eubacterium rectale/Clostridium coccooides* in the group fed the test formula with synbiotics compared to the control formula without synbiotics.

Whilst the study showed a shift in the faecal microbiota of infants on the milk containing synbiotics towards that of the breastfed infants, it also reported that there were no statistically significant differences in clinical outcomes between groups. There was, however, a greater reduction in SCORAD scores (Scoring Atopic Dermatitis) for the control group compared to the test group, indicating a greater degree of symptom resolution in the infants fed the formula *without* synbiotics. There was also a greater proportion of children in the control group who were already receiving either an extensively hydrolysed or amino acid-based formula prior to randomisation, potentially masking any reduction in SCORAD scores. Foods consumed by infants who were receiving complementary foods were recorded and the authors reported that this had no effect on outcomes, although data were not presented. The authors pointed out that their study was not primarily designed or powered to show differences in clinical outcomes between groups and their conclusions are that the test formula was tolerated, supported microbiota development and is suitable for dietary management of infants with suspected non-IgE mediated CMA. The need for an amino acid-based formula for infants in this study rather than an extensively hydrolysed formula which is known to be suitable for the majority of infants with CMA is not discussed. The advert does not make it clear that an amino acid-based formula is only likely to be needed by those with complex or multiple food allergies.

The second paper referenced is by Burks et al (2015) and the primary outcome parameter of this study was growth. Infants with IgE or non-IgE mediated cows' milk protein allergy were randomly selected to receive either a milk similar to Neocate Syneo (which includes synbiotics; n=56) or Neocate without synbiotics (n=54) for 16 weeks. Growth was measured as weight, length and head circumference. At 16 weeks the authors found no significant differences in these parameters between groups. Statistically significant differences between the groups were found, with more diarrhoea and fewer infections reported in the test group compared with the control group.

The trial also examined allergic symptoms and stool characteristics. At weeks 4 and 16, faecal samples of the test group had a significantly higher proportion of bifidobacteria compared with the control group, and a higher proportion of *C. histolyticum* and *E. rectale/C. coccooides*. Faecal bacteria are routinely used as a proxy measure of gut microbiota. However, biopsies are rarely taken due to technical difficulties and ethical constraints, so there is very little evidence that faecal bacteria reflect the microbiota. This study did not report on the delivery method of infants included in the study, the use of complementary foods, or the split between IgE and non-IgE mediated allergy between groups, all of which have the potential to confound the results.

The researchers found a similar decrease in symptoms for those in the test and control groups, suggesting that the addition of synbiotics as added ingredients may not have any additional health benefits. It also seems that the milk used in the trials was similar but not the same as that currently advertised. The authors' suggestion that there may be some benefit for the addition of synbiotics is not supported by EFSA's review of ingredients in infant formula (European Food Safety Authority, 2014), which concluded that there was no evidence that synbiotics provided beneficial effects.

**2** "THE ONLY AAF WITH PRE- AND PROBIOTICS clinically proven to bring the gut microbiota closer to that of healthy breastfed infants"

#### Evidence given to support this claim

This claim again refers to the study by Candy et al, 2018 reviewed above. The statement that the infant milk advertised here is "*clinically proven to bring the gut microbiota closer to that of healthy breastfed infants*" is not supported by evidence. Whilst this small study of infants in a wide age range (many of whom also received solids) showed a shift in the faecal microbiota of infants on the milk containing synbiotics towards that of the breastfed infants, it also reported that there were no

statistically significant differences in clinical outcomes between groups. There was, however, a greater reduction in SCORAD scores (Scoring Atopic Dermatitis) for the control group compared to the test group, indicating a greater degree of symptom resolution in the infants fed the formula without synbiotics. The fact that some bacteria species in the stools of infants fed the test formula may be closer to that of breastfed infants than to infants fed the control formula without synbiotics does not mean that this offers any clinical advantages.

**3** "NUTRITIONAL MANAGEMENT BEYOND SYMPTOM RESOLUTION"

#### Evidence given to support this claim

No specific evidence is referenced to support this claim and it is not clear what "NUTRITIONAL MANAGEMENT" means or how this has been measured in order to make this claim.

**4** "Neocate: Fast and effective resolution of CMA symptoms"

#### Evidence given to support this claim

This statement for Neocate is not specific to Neocate Syneo and seems to encompass the full range of Neocate products. The evidence used to support this statement comes from four clinical trials, two of which have already been described above (Candy et al, 2018 and Burks et al, 2015). Neither of these trials compares the speed of symptom resolution with that in infants on any other formula or in those who are still breastfed. Candy et al (2018) relates only to infants with suspected non-IgE mediated CMA and not to non-IgE mediated CMA as confirmed by dietary trial exclusion and reintroduction. The two other trials cited – De Boissieu et al (1997) and Vanderhoof et al (1997) – did not use a milk containing probiotics and therefore it is not clear why these have been used to support any claims for the advertised product. Both trials were small, including 13 and 28 infants respectively. The objective of each was to compare the effectiveness of an amino acid-based formula in infants who showed clinical symptoms of allergy with that of an extensively hydrolysed casein based infant formula. Both studies showed some effectiveness in the relief of symptoms of CMA when amino acid-based formula was consumed. It is not surprising that amino acid-based formula milks were shown to offer effective resolution of symptoms as this type of formula (regardless of the brand) is recommended for children with severe CMA and for those for whom extensively hydrolysed formula is not tolerated or does not lead to symptom resolution (National Institute for Health and Care Excellence, 2015).

## What does current accepted policy/science say?

It is known that amino acid-based formula has efficacy in treating cows' milk allergy (CMA) in infants who are not receiving breastmilk. However, this advert makes efficacy statements based on the addition of synbiotics. The World Allergy Organization (WAO) concluded that "No single probiotic supplement or class of supplements has been demonstrated to efficiently influence the course of any allergic manifestation or long-term disease or to be sufficient to do so." (Fiocchi et al, 2012). Further systematic reviews have reported low-quality evidence on the effect of probiotics on eczema development, and no evidence of an effect on the prevention of other allergies (Cuello-Garcia et al, 2015; Zuccotti et al, 2015). There is also increasing concern that studies looking at the potential benefits of prebiotics, probiotics and synbiotics do not adequately assess harms (Bafeta et al, 2018).

The EFSA 2014 scientific opinion on the essential composition of infant and follow-on formulae notes that the evidence for any benefit of probiotics on infant health comes from single studies and studies with methodological limitations, and concludes that there is no evidence for beneficial effects and that probiotics are not necessary additions to infant formula and follow-on formula (European Food Safety Authority, 2014). The NICE Clinical Knowledge Summary on managing cows' milk protein allergy makes no mention of probiotics in its treatment recommendations (National Institute for Health and Care Excellence, 2015).

### Our conclusion

Both extensively hydrolysed (eHF) and amino acid-based infant milks have efficacy in the management of allergic symptoms in infants who are not breastfed and who are diagnosed with CMA. In the majority of cases an eHF is a suitable treatment choice, but this advert suggests that Neocate is a first line treatment for resolution of CMA. Neocate Syneo is three times more expensive than an eHF marketed by the same company (First Steps Nutrition Trust, 2019).

This advert is unusual in that the claims made do not focus on the efficacy of the product in symptom resolution, but on the addition of an extra ingredient which it claims can modulate the infant gut microbiota. No evidence of any clinical benefits is described or offered. We therefore conclude that this, along with the claim for the whole Neocate range and heavy presence of branding, indicate that this advert is a brand-

awareness exercise and does not help health professionals in their choice of products. Despite the advert claiming "nutritional management beyond symptom resolution", it provides no evidence for any clinical benefits.

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**Advert for:** Nutramigen Hypoallergenic Formula with LGG (Mead Johnson)

**Advert seen in:** *Network Health Digest*, November 2018

This material is for healthcare professionals only.

**DO MORE THAN JUST  
MANAGE COW'S MILK  
ALLERGY: HELP GIVE HER  
THE ABILITY TO PROTECT  
HERSELF FROM  
FUTURE ALLERGIC  
MANIFESTATIONS<sup>1†</sup>**

**ONLY NUTRAMIGEN  
WITH LGG<sup>®</sup> CAN**



**TRANSFORMING THE LIVES OF BABIES  
WITH COW'S MILK ALLERGY**

<sup>†</sup>Versus Nutramigen without LGG<sup>®</sup>

**Reference:** 1. Conani RB et al. *J Allergy Clin Immunol* 2017;139:1906-1913.

Nutramigen with LGG<sup>®</sup> is a food for special medical purposes for the dietary management of cow's milk allergy and must be used under medical supervision. Nutramigen with LGG<sup>®</sup> is not recommended for premature and immunocompromised infants unless directed and supervised by a healthcare professional.

**IMPORTANT NOTICE: Breastfeeding is best for babies.** The decision to discontinue breastfeeding may be difficult to reverse and the introduction of partial bottle-feeding may reduce breast milk supply. The financial benefits of breastfeeding should be considered before bottle-feeding is initiated. Failure to follow preparation instructions carefully may be harmful to your baby's health. Parents should always be advised by an independent healthcare professional regarding infant feeding. Products of Mead Johnson must be used under medical supervision. \*Trademark of Mead Johnson & Company, LLC. © 2018 Mead Johnson & Company, LLC. All rights reserved. LGG<sup>®</sup> and the LGG<sup>®</sup> logo are registered trademarks of Valio Ltd, Finland.

Date of preparation: September 2018 UK/NUT/18/00601

**Nutramigen**

**MeadJohnson**  
Nutrition



This material is for healthcare professionals only.

# DO MORE THAN JUST MANAGE COW'S MILK ALLERGY: HELP GIVE HER THE ABILITY TO ENJOY MILK SOONER<sup>1†</sup>

ONLY<sup>‡</sup> NUTRAMIGEN  
WITH LGG<sup>®</sup> CAN



TRANSFORMING THE LIVES OF BABIES  
WITH COW'S MILK ALLERGY

<sup>1</sup>Versus an eHCF without LGG<sup>®</sup> or formulas based on soy or amino acids.  
<sup>†</sup>The only cow's milk-based formula.

**Reference:** 1. Canani RB et al. *J Pediatr* 2013;163:771-777.

Nutramigen with LGG<sup>®</sup> is a food for special medical purposes for the dietary management of cow's milk allergy and must be used under medical supervision. Nutramigen with LGG<sup>®</sup> is not recommended for premature and immunocompromised infants unless directed and supervised by a healthcare professional.

**IMPORTANT NOTICE: Breastfeeding is best for babies.** The decision to discontinue breastfeeding may be difficult to reverse and the introduction of partial bottle-feeding may reduce breast milk supply. The financial benefits of breastfeeding should be considered before bottle-feeding is initiated. Failure to follow preparation instructions carefully may be harmful to your baby's health. Parents should always be advised by an independent healthcare professional regarding infant feeding. Products of Mead Johnson must be used under medical supervision. \*Trademark of Mead Johnson & Company, LLC. © 2018 Mead Johnson & Company, LLC. All rights reserved. LGG<sup>®</sup> and the LGG<sup>®</sup> logo are registered trademarks of Valio Ltd, Finland.

Date of preparation: September 2018 UK/NUT/18/00601

Nutramigen

MeadJohnson  
Nutrition

## Advert for: Nutramigen Hypoallergenic Formula with LGG (Mead Johnson)



### Summary of adverts

These two adverts have appeared in the same journal often on subsequent pages. Both adverts rely on evidence from the same authors, but make slightly different claims.

The first advert has more than half of the page dedicated to an image of a happy toddler playing with wild flowers in a sunlit field. The text to the left of the image reads “DO MORE THAN JUST MANAGE COW’S MILK ALLERGY: HELP GIVE HER THE ABILITY TO PROTECT HERSELF FROM FUTURE ALLERGIC MANIFESTATIONS”, with a footnote in small type: “Versus Nutramigen without LGG”.

The second advert dedicates more than half of the page to an image of a smiling toddler in a bathrobe with a chocolatey face, reaching out to a very large chocolate cake. The main text to the left reads “DO MORE THAN JUST MANAGE COW’S MILK ALLERGY: HELP GIVE HER THE ABILITY TO ENJOY MILK SOONER”, and in small type a footnote: “Versus an eHCF without LGG or formulas based on soy or amino acids”.

Both adverts make the claim “ONLY NUTRAMIGEN WITH LGG CAN”. Two claims are implied here: the first that Nutramigen with LGG can accelerate tolerance to cows’ milk; and the second that only Nutramigen with LGG can do this. In very small type at the bottom of the page the second advert footnotes the claim made with “The only cow’s milk-based formula”.

Below the picture on each of the adverts there is an image of three cans of formula milk – Nutramigen 1, Nutramigen 2 and Nutramigen 3 and a further claim: “TRANSFORMING THE LIVES OF BABIES WITH COW’S MILK ALLERGY”.

Also, the second advert, in very small type below the reference, states: “Nutramigen with LGG is a food for special medical purposes for the dietary management of cow’s milk allergy and must be used under medical supervision. Nutramigen with LGG is not recommended for premature and immunocompromised infants unless directed and supervised by a healthcare professional.”

### Claims made, and evidence given to support them

- 1 “DO MORE THAN JUST MANAGE COW’S MILK ALLERGY: HELP GIVE HER THE ABILITY TO PROTECT HERSELF FROM FUTURE ALLERGIC MANIFESTATIONS”

### Evidence given to support this claim

This reference is from a clinical trial carried out between 2008 and 2014, and the trial was part sponsored by Mead Johnson (Canani et al, 2017). The babies included in the trial were aged between 1 month and 12 months with a median age of 5 months, and the follow-up period was 36 months. Only infants with IgE mediated CMPA proven by skin prick test (SPT) and double-blinded placebo-controlled food challenge (DBPCFC) were included in the trial. Infants were randomised to receive either Nutramigen extensively hydrolysed formula with no probiotic or Nutramigen extensively hydrolysed formula with the probiotic *Lactobacillus rhamnosus* GG (LGG). Allergic manifestations and other food allergies were recorded at baseline and at 12 months, 24 months and 36 months. SPT and DBPCFC were also performed at these visits to determine tolerance acquisition. The trial reported an absolute risk difference of -0.23 of any allergic manifestation during 36 months for Nutramigen with LGG compared to Nutramigen without probiotic. This means that, compared with eHF without probiotics, four subjects needed to be treated with eHF with probiotic for 36 months to prevent at least one allergic manifestation.

As highlighted previously, this trial relates only to children with IgE mediated cows’ milk allergy. Infants with other food allergies, allergic diseases and conditions were excluded from the study. The study took place between 2008 and 2014 and no details were provided of the infant milks used in the trial except that they were both commercially available in Italy at the time of the study and that they were identical in composition except for the presence of LGG. It is therefore not clear if the Nutramigen milks with LGG currently marketed are those used in the trial. No details of the duration or exclusivity of breastfeeding was provided except for the proportion of babies breastfed for more than two months, and there was no breastfed reference group. Parents were not blinded to the infant milk their child received and they recorded the amount of milk consumed daily. Health problems and allergic symptoms were recorded

by structured interviews with parents. The interviews occurred at 12-month intervals or more frequently in individual children if advised by the GP. Although dietitians were employed to give advice on the exclusion diet, the trial report did not appear to record compliance with the cows' milk exclusion diet.

**2** "DO MORE THAN JUST MANAGE COW'S MILK ALLERGY: HELP GIVE HER THE ABILITY TO ENJOY MILK SOONER"

### Evidence given to support this claim

One reference is given to support this claim based on an earlier study in Italy (Canani et al, 2013). This claim implies that Nutramigen with LGG can accelerate tolerance to cows' milk. The study cited is a prospective non-randomised trial of infants aged 1-12 months with CMPA who were already treated and free of symptoms and who were already receiving one of five different formula types as prescribed by their physician. The study groups were allocated on the basis of the formula they were already receiving, i.e. a non-randomised allocation. Each of the five treatment groups was followed for up to 12 months to look at acquisition of tolerance to cows' milk. Two of the study arms used extensively hydrolysed casein-based formula (eHCF): one of which contained the probiotic *Lactobacillus rhamnosus* GG (LGG). Of the other three, one used soya formula, one amino acid-based formula, and one hydrolysed rice formula. The trial notably lacked a breastfeeding reference group to explore the effect of normal feeding on tolerance to cows' milk. As approximately half of infants with cows' milk allergy (CMA) are known to outgrow this allergy by 12 months of age, this may well confound any conclusions regarding tolerance.

The authors concluded that the rate of acquiring oral tolerance was higher in the groups having either of the extensively hydrolysed formula milks and this was augmented by the addition of LGG. However, the study contains a large number of variables that could have impacted on the outcomes. The duration and exclusivity of breastfeeding between groups was not reported other than the proportion of infants per group breastfed for two months or more. One of the main findings of the study was that infants with IgE mediated CMA were less likely than those with non-IgE mediated allergy to achieve tolerance after 12 months. The group receiving Nutramigen with LGG had the lowest rate of IgE mediated allergy. The authors suggest that the positive trend in the rate of patients acquiring tolerance at the end of the study period observed for children receiving eHF alone compared with children receiving rice, soya or amino acid-based formula could be explained at least in part by the number of patients enrolled in the different

groups, resulting in a lower power to detect differences. There were differences in the brand of infant milk consumed in each of the treatment groups. For example, within the amino acid-based formula group (n=33), three different brands of formula were consumed, but in the largest group (n=71), extensively hydrolysed casein based formula with LGG, only Nutramigen with LGG was consumed. Differences between brands may therefore have been masked, as brands were grouped according to category.

**3** "ONLY NUTRAMIGEN WITH LGG CAN"

Both of the above two claims conclude with the sentence "ONLY NUTRAMIGEN WITH LGG CAN". This implies that Nutramigen with LGG is the only extensively hydrolysed formula that can accelerate tolerance to cows' milk protein. No specific studies are given to support this statement. The study by Canani et al (2017) only compares Nutramigen with LGG to Nutramigen without LGG; it does not compare Nutramigen LGG to all other eHF for the treatment of CMA, nor to breastfeeding, and evidence does not therefore, support the statement that "ONLY NUTRAMIGEN WITH LGG CAN". The study by Canani et al (2013) compares Nutramigen with LGG to Nutramigen without LGG, an amino acid-based formula, a soya protein based formula and a rice protein based formula. It does not compare Nutramigen with LGG to any of the other cows' milk based eHF recommended for the treatment of CMA in formula-fed or mixed-fed infants, nor to breastfeeding. It does not therefore, support the statement that "ONLY NUTRAMIGEN WITH LGG CAN". However, in the second advert this claim carries a footnote in very small text at the bottom of the page: "The only cow's milk-based formula". This footnote is confusing as it could alter the meaning of the sentence to a simple, true statement of fact – that Nutramigen with LGG is the only cows' milk based eHF with LGG, rather than claiming that it is the only brand that can accelerate time to tolerance.

### What does current accepted policy/science say?

A recent Cochrane review by Osborn et al found no evidence to support feeding with a hydrolysed formula to prevent allergic disease in preference to exclusive breastfeeding, and no substantial evidence to support short-term or prolonged feeding with a hydrolysed formula compared with a cows' milk formula for prevention of allergic disease in infants unable to be exclusively breastfed (Osborn et al, 2018).

It is well known that extensively hydrolysed formula have efficacy in treating cows' milk allergy (CMA) in infants who are not receiving breastmilk. However, this advert makes

efficacy statements based on the addition of probiotic to the formula milk. The World Allergy Organization (WAO) concluded that “No single probiotic supplement or class of supplements has been demonstrated to efficiently influence the course of any allergic manifestation or long-term disease or to be sufficient to do so.” (Fiocchi et al, 2012). Further systematic reviews have reported low-quality evidence on the effect of probiotics on eczema development, and no evidence of an effect on the prevention of other allergies (Cuello-Garcia et al, 2015; Zuccotti et al, 2015). There is also increasing concern that studies looking at the potential benefits of prebiotics, probiotics and synbiotics do not adequately assess harms (Bafeta et al, 2018). It was reported in 2018 that the prominent regulatory organisations – the American Academy of Pediatrics, National Institute of Allergy and Infectious Diseases, European Academy of Allergy and Clinical Immunology, European Society for Pediatric Gastroenterology, Hepatology and Nutrition and the FAO of the United Nations/WHO – do not support the use of probiotics for primary prevention of allergic diseases (Sharma and Im, 2018).

The EFSA scientific opinion on the essential composition of infant and follow-on formulae notes that the evidence for any benefit of probiotics on infant health comes from single studies and studies with methodological limitations, and concludes that there is no evidence for beneficial effects and that probiotics are not necessary additions to infant and follow-on formula (European Food Safety Authority, 2014). The NICE Clinical Knowledge Summary on managing cows’ milk protein allergy makes no mention of probiotics in its treatment recommendations (National Institute for Health and Care Excellence, 2015).

## Our conclusion

An infant who is not breastfed and who is diagnosed with CMA is likely to require an extensively hydrolysed formula. However, these adverts imply that Nutramigen LGG is the only hydrolysed formula milk that can protect infants from future allergic manifestations, and that this is due to the inclusion of probiotics. There are currently no agreed scientific reviews or consensus statements that suggest extensively hydrolysed formula milks or probiotics have any influence on the development of food allergy in either infants at high risk of atopy or healthy infants. We do not believe that the evidence provided from the two clinical trials presented adequately supports the claims made.

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Advert for: SMA Althéra (Nestlé)

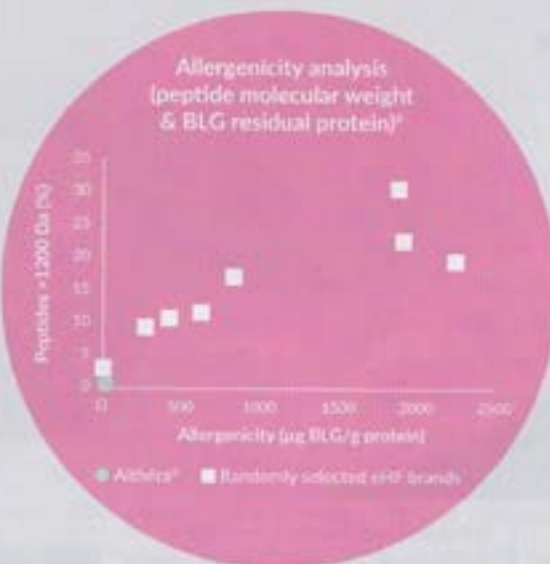
Advert seen in: Complete Nutrition, December 2018/January 2019

## The difference IS IN THE DETAIL

Why might some eHF samples show better clinical outcomes for symptom resolution?<sup>1-4</sup>

Our analyses of eHF samples from manufacturers around the world – which compared peptide size and residual protein content – showed that eHFs may have different allergenic potentials.<sup>4-6</sup>

Althéra® is proven to have a consistent, very low allergenic potential which may make all the difference in the dietary management of your CMA patients.<sup>4-8</sup>



Learn more about our latest research and clinical trials:  
[www.nestlehealthscience.co.uk/althera](http://www.nestlehealthscience.co.uk/althera)

**IMPORTANT NOTICE:** Mothers should be encouraged to continue breastfeeding even when their infants have CMA. This usually requires qualified dietary counselling to completely exclude all sources of cows' milk protein from the mothers' diet. If a decision to use a special formula intended for infants is taken, it is important to give instructions on correct preparation methods, emphasising that unboiled water, unsterilised bottles or incorrect dilution can all lead to illness. Formula for special medical purposes intended for infants must be used under medical supervision. Althéra® and Alfamino® are for complete nutritional support from birth or supplementary feeding from 6 months and up to 3 years of age for the dietary management of CMA and/or multiple food protein allergies. Abbreviations: BLG, β-lactoglobulin; CMA, cows' milk allergy; Da, Daltons; eHF, extensively hydrolysed formula. References: 1. Dupont et al. *BJN*, 2012; 107(3): 325-338. 2. Chauveau et al. *Pediatr Allergy Immunol*, 2016; 27(5): 541-543. 3. Petrus, N.C. et al. *Eur J Pediatr*, 2015; 174(6): 759-765. 4. Kuslys M, et al. *EMJ Allergy and Immunol*, 2017; 2(1): 46-51. 5. Nutten S, et al. *EMJ Allergy and Immunol*, 2018; 3(1): 50-59. 6. Nutten S, et al. Abstract, EAACI Congress, 26-30 May, 2018. 7. Niggemann, B. et al. *Pediatr Allergy Immunol*, 2008; 19(4): 348-354. 8. Data on file. 9. Nowak-Węgrzyn A, et al. *Clin Pediatr (Phila)*, 2015;54(3): 264-272. Version: ALLER50\_August2018. For healthcare professionals only.



Explore the rest of our portfolio: Alfamino® is our non-allergenic amino acid formula for the effective dietary management of severe CMA.\* Learn more: [nestlehealthscience.co.uk/alfamino](http://nestlehealthscience.co.uk/alfamino)



## Advert for: SMA Althéra (Nestlé)



### Summary of advert

The top half of this advert for an extensively hydrolysed formula (eHF) is dominated by a picture of a can of the milk powder sitting on top of a pile of textbooks and folders. The

text to the right of this reads “*The difference IS IN THE DETAIL*”, followed by the question “*Why might some eHFs show better clinical outcomes for symptom resolution?*” In bold is the claim that “*Althera is proven to have a consistent, very low allergenic potential which may make all the difference in the dietary management of your CMA patients.*” In the centre of the advert, a graphic in a large pink circle represents the results of analysis into the “*allergenicity*” of Althéra and other eHF brands. Readers are invited to learn more about this research by visiting a web address which directs them to more claims and references on the manufacturer’s website. References are in small type at the bottom of the page on the left-hand side. At the bottom of the page on the right-hand side is a picture of a different SMA formula – SMA Alfacino – and the words “*Explore the rest of our portfolio: Alfacino is our non-allergenic amino acid formula for the effective dietary management of severe CMA*”.

### Statements and claims made, and evidence given to support them

**1** “Why might some eHFs show better clinical outcomes for symptom resolution?”

#### Evidence given to support this

Whilst this question does not constitute a claim, it strongly implies that the advertised product shows better outcomes for symptom resolution than other brands. Four references are given in support of the question, presumably to provide the answer.

Dupont et al (2012) is a review article which looked at the molecular weight of proteins and residual protein in a range of products from different manufacturers. It emphasised that, for a child with cows’ milk allergy (CMA), the first line of defence is breastfeeding, but that if the child is not breastfed, the first choice is an eHF.

The article also highlights the lack of statistical power of studies available on eHF and that the efficacy rates of those available vary between 40% and 100%. It also states that, whilst the American Academy of Pediatrics (AAP) defines an extensively hydrolysed formula as a formula containing only peptides that have a molecular weight of <3,000 Da, there is no clear evidence that such a threshold would ensure the prevention of allergic reactions in infants and young children with cows’ milk allergy (CMA). The review does not consider a relationship between peptide size, residual protein content and efficacy. Many of the studies included in the review were old (1988-2003) and therefore the formulations are likely to differ from currently marketed products.

The second study cited, by Chauveau et al (2016), was an examination of the protein profile of three eHF products, which found differences in the level of hydrolysis and quantity of residual whey and casein peptides. It did not consider symptom resolution. The third study by Petrus et al (2015) was an observational study which investigated the incidence and predicting variables of treatment failure with a whey-based eHF (weHF) in all children with CMA in the Dutch EuroPrevall Birth Cohort Study. This study reported that half of the children treated with weHF had incomplete symptom resolution. Only symptoms of gastrointestinal discomfort contributed independently to the probability of treatment failure. The final study cited here – Kuslys<sup>1</sup> (2017) – is a presentation made at a Nestlé-sponsored conference (symposium review) and not an article from a peer-reviewed journal. It refers to studies that have reported chemical heterogeneity of eHFs in terms of the degree of hydrolysis and residual peptides including  $\beta$ -lactoglobulin, whey and caseins. It also introduces the findings from a Nestlé research programme which examined the protein profile of eHF available from 11 suppliers across ten different countries.

Together, these references show that differences have been reported in the protein profiles of different eHF marketed for children with CMA. No evidence of differences in symptom resolution between brands is offered, and so these references do not support any suggestion that some eHF products offer better clinical outcomes than others.

1 The advertisement cites this as Kuslys et al (2017), where Kuslys was one of four speakers at a symposium. We reference the specific work by Kuslys within this symposium.

**2** “Althéra is proven to have a consistent, very low allergenic potential which may make all the difference in the dietary management of your CMA patients.”

### Evidence given to support this claim

This claim is supported by five references. The first – Kuslys (2017) as mentioned above is a presentation made at an industry-sponsored conference (symposium review) and is not an article from a peer-reviewed journal. It does not provide evidence related to dietary management of CMPA. The second reference is given as Nutten et al (2018), but this appears to be a presentation made at an industry-sponsored conference just by Sophie Nutten herself, and whilst the reference suggests it is over nine pages, the section from Sophie Nutten is over three pages. We have therefore re-referenced this as Nutten (2018). This is a topic summary and not an article from a peer-reviewed journal. It summarises the analysis carried out by Nestlé on their own and other manufacturers’ products. The analysis examined the molecular weight of peptides and the ‘potential allergenicity’ in terms of the level of residual peptides  $\beta$ -lactoglobulin and casein in a range of eHFs. This analysis found significant variability in the molecular weight of peptides,  $\beta$ -lactoglobulin and casein content of products. Batch-to-batch variation was found both between and within countries. No references to support any of the statements made are given in this topic summary.

The chart on the advert, displaying both peptide size and residual  $\beta$ -lactoglobulin (BLG) content, shows that Nestlé Althéra has the lowest Dalton size (a greater degree of hydrolysis) of all the products compared and also had residual lactose content below the limit of quantification. It erroneously suggests that allergenicity is based on BLG content alone by stating this on the x axis of the chart. It is not clear why the results for residual casein content were not also overlaid onto the chart, nor if Althéra was also free of any residual casein (Nutten et al, 2018). The authors suggest that the degree of hydrolysis correlates with the potential allergenicity of a product on the basis that those with peptides of a smaller Dalton size also appear to have undetectable or low levels of residual  $\beta$ -lactoglobulin. This reference appears to be for a summarised version of the conference presentation described above and therefore does not contribute anything further to the evidence base presented. The fourth reference to support the claim that the lower allergenicity potential can have an impact on dietary management of CMA is by Niggemann et al (2008). This study does not suggest Althéra has a consistent protein profile across batches; it just suggests that it is tolerated

by infants with CMA to the same extent as the amino acid formula tested. It does not therefore support the claim made. The fifth reference is just to “Data on file”.

**3** “Explore the rest of our portfolio: Alfamino is our non-allergenic amino acid formula for the effective dietary management of severe CMA.”

### Evidence given to support this claim

The final sentence in the advert relates to a different product and states “*Explore the rest of our portfolio: Alfamino is our non-allergenic amino acid formula for the effective dietary management of severe CMA*”. This is supported with a reference to Nowak-Węgrzyn et al (2015). This reference refers to a study which showed that this amino acid formula (AAF) met the criteria for the American Academy of Pediatrics’ definition of hypoallergenic.

### What does current accepted policy/science say?

The NICE Clinical Knowledge Summary on cows’ milk protein allergy in children provides guidance on how to manage suspected or diagnosed cows’ milk protein allergy (National Institute for Health and Care Excellence, 2015). The first line of support is to encourage continued breastfeeding for breastfed babies and to advise the mother to exclude cows’ milk protein from her diet. Where infants are mixed-fed or exclusively formula-fed, an extensively hydrolysed formula (eHF) that is tolerated by the majority of infants and children (90%) with cows’ milk allergy can be used to replace cows’ milk-based formula.

The European Commission has limited the content of immunoreactive proteins in hydrolysed formula milks to <1% of total protein and determines the adequacy and safety of these products on the basis of experimental studies in animals and clinical trials showing tolerance in >90% of infants with hypersensitivity to the protein from which the hydrolysate is manufactured (European Commission, 2006). The size of proteins is not specified by this definition, and EFSA in their 2014 scientific opinion on the essential composition of infant and follow-on formulae, states that “*protein hydrolysates are insufficiently characterised by the declared protein content even though they fulfil regulatory criteria concerning amino acid patterns; therefore the safety and suitability of each specific infant and follow-on formula containing protein hydrolysates has to be established by clinical evaluation in the target population*” (European Food Safety Authority, 2014). Peptide size alone is insufficient to characterise extensively hydrolysed formulas.

## Our conclusion

The aim of this advert is to achieve brand awareness and suggest that this product is more effective in the management of CMA than other similar eHF products. The bulk of the evidence presented is not from peer-reviewed journals and relies on theories of relative allergenicity rather than clinical trials.

The basis of the claim is that Althéra will be more effective for the management of infants with CMA than other available products because it has a smaller Dalton size and less residual proteins than other products. The theory is that a smaller peptide Dalton size and very low residual  $\beta$ -lactoglobulin result in a product that is potentially less allergenic than others and therefore suggests that, because Nestlé have shown that their product has a less allergenic profile than others, it may result in better clinical outcomes. The EFSA 2014 scientific opinion on the essential composition of infant and follow-on formulae, states that “*the safety and suitability of each specific infant and follow-on formula containing protein hydrolysates has to be established by clinical evaluation in the target population*” (European Food Safety Authority, 2014).

No clinical trials were used to support this claim and so the evidence used does not support the statement that the product “*may make all the difference in the dietary management of your CMA patients.*” The only evidence given to suggest that there is any consistency between batches of Althéra is from a Nestlé analysis of products and it seems from the limited data available that only two batches of Althéra were tested. We do not therefore believe that the evidence used is sufficiently robust to support the statement that the product has a consistently low allergenic potential.

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# Appendix: Breastmilk substitute adverts reviewed in the first version of this resource (2016)

The following adverts for breastmilk substitutes were placed in magazines and journals in 2015/2016, aimed at healthcare professionals. They were reviewed in the first version of our resource *Scientific and factual? A review of breastmilk substitute advertising to healthcare professionals*. To access the full review, go to: [www.firststepsnutrition.org/working-within-the-who-code](http://www.firststepsnutrition.org/working-within-the-who-code)

**NUTRICIA**  
Early Life Nutrition



INSPIRED BY  
**BREASTMILK RESEARCH**

**NEW Aptamil Profutura Follow On milk** has a composition and structure closer to that of breastmilk\*

- Contains our highest ever levels of Long Chain Polyunsaturated Fatty acids (LCFAs)
- The first zero formulation to include phylogenic-based LCFAs
- Contains milk fat, providing a fatty acid profile closer to that of breastmilk
- Contains our unique blend of Galesara™ and Protera™ (patented) (15057728)

For further information visit: [aptamilprofutura.com/uk](http://aptamilprofutura.com/uk)

**OUR MOST ADVANCED FORMULATION YET.**



\*Based on a comparison of the fatty acid profile of Aptamil Profutura Follow On milk with that of breastmilk. The comparison is based on the fatty acid profile of the milk fat component of the formula, not the total fatty acid profile of the formula. The comparison is based on the fatty acid profile of the milk fat component of the formula, not the total fatty acid profile of the formula. The comparison is based on the fatty acid profile of the milk fat component of the formula, not the total fatty acid profile of the formula.

It's not just  
**BABIES**  
who need relief  
from **COLIC**



**85% of Paediatricians\* reported an improvement in common infant feeding problems with a formula like Cow & Gate Comfort†**

Science shows that partially hydrolysed formula milk containing oligosaccharides (HMOs) improve the symptoms of colic in bottle fed babies. In fact 8 bottles fed baby's colic is more than twice as likely to be managed with partially hydrolysed and digestive care formula like Cow & Gate Comfort.

Learn more about the evidence based management of colic at [inpractice.co.uk](http://inpractice.co.uk)




\*Out of 16 paediatricians  
Reference: 1. Science 7 (2014) Infant Feeding 446-454  
2. Science 7 (2014) Infant Feeding 446-454

Comfort for babies, relief for mums.

**BREASTFEEDING IS BEST FOR BABIES**

**Less is more: the UK's first reduced protein infant milk, now with alpha-lactalbumin**

High protein intake in the first two years of life has been linked with an increased long-term risk of being overweight or obese. Our new infant milk with 1.6g protein/100kcal, and added alpha-lactalbumin, is the first formula in the UK to contain less than 1g protein/100kcal of protein.



**The BeMUM (Belgrade-Munich Infant Milk) study†**

Aim: To prove the safety and suitability of the reduced protein formula for healthy term babies aged 0-4 months and non-intake compared to a standard formula.

**Results**

- Adequate growth for age and no differences in weight gain between formula groups
- Good tolerance and acceptance: both formulas were well accepted and tolerated, the differences in stool consistency and colour, urine, flatulence, regurgitation or vomiting
- Protein intake closer to that of breastfed babies for those on the reduced protein formula (Figure 2)
- Positive influence on safety: no complications, increases in formula intake for babies on the reduced protein formula (in fact) those babies consumed significantly less energy of 10 days and 30 days of age compared to the control fed group. This was significantly lower than frequency which might indicate higher safety.
- Improved energetic efficiency: Weight gain per 100kcal and length gain per 100kcal were significantly higher in the 1st month for the intervention group compared with the control group. This could be due to the improved protein quality of the intervention formula.



**Study design**

- Intervention group: well-reduced protein infant formula, n=42
- Control group: well-standard infant formula, n=42
- Follow-up group with breastfed infants, n=10
- All infants recruited and anthropometrically measured after 30, 45, 60 and 90 days of age.

†The study was registered on ClinicalTrials.gov (NCT01100001).  
\*http://www.clinicaltrials.gov/ct2/show/study?term=NCT01100001

**To find out more, visit [hipp4heps.co.uk](http://hipp4heps.co.uk)**

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**BREASTFEEDING IS BEST FOR BABIES**

**NANNY care**

**Why consider a whole goat milk formula?**

Cow's milk is commonly used to manufacture infant formula, generally because it is the most widely available source.

Goat milk is made from whole goat milk which is more fully regulated and approved for use in infant formula.

**Better digestibility**

The immaturity of a new born infant's digestive tract requires the proteins in formula to be easily digestible. Goat milk proteins are digested more completely than cow's milk proteins.

**NANNYcare First infant milk:**

- Behaves more like breast milk in the infant stomach forming easier, softer and more porous curds than cow's milk formula.
- This aids digestion by allowing easier access by stomach enzymes.
- Nearly 3 fold more beta lactoglobulin is digested in goat milk compared with cow's milk!



**Casein profile**



Goat milk has a smaller proportion of α1-casein than cow's milk and a greater proportion of β-casein, similar to the casein profile of human milk.



These factors contribute to the better digestion of goat milk and suggest why a goat milk formula may be beneficial and may simply suit some babies better than cow's milk formula.

**For more info visit [nannycare.co.uk](http://nannycare.co.uk) or email us [enquiry@nannycare.co.uk](mailto:enquiry@nannycare.co.uk) or call our helpline UK: 0800 328 5836**

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**NEW**  
Introducing  
Nutramigen

**Nutramigen**  
SMA LGG<sup>®</sup>

## The express route to the end of cow's milk allergy

Get the exciting benefits of Nutramigen LGG, with the addition of a probiotic (Lactobacillus GG), for six extra days!

**First step – symptom resolution**

- ✓ Proven to take an average efficacy of 50%\*
- ✓ Faster resolution of (20) symptoms vs standard formula†

**Final destination – oral tolerance to leave CMA behind**

- ✓ The only oral\* clinically proven to accelerate oral tolerance\*\*
- ✓ It's out of 33 infants by 12 months to cow's milk after 33 months of use†

*The healthy looking CMA formula!*

**Mead Johnson**  
Nutrition

Supporting you to support mums

**IMPORTANT NOTICE:** Breast milk is best for babies and breastfeeding should continue for as long as possible. Infant milk should only be used on the advice of a doctor, midwife, health visitor, public health nurse, dietitian or pharmacist, or other professionals responsible for maternal and child care.

FOR HEALTHCARE PROFESSIONALS ONLY

# Especially for Oliver

- ✓ Reduces the risk of developing allergy to cows' milk proteins
- ✓ Easy to digest
- ✓ Omega 3 and 6 LCPs

**Oliver has a family history of allergy.**  
SMA H.A.<sup>®</sup> Infant Milk is a nutritionally complete formula that has been designed to reduce the chances of developing an allergy to cows' milk proteins.

**Supporting you to support mums**

**SMA nutrition** [www.smahcp.co.uk](http://www.smahcp.co.uk)  
SMA Careline: 0800 0 81 81 80

**IMPORTANT NOTICE:** SMA H.A.<sup>®</sup> Infant Milk should NOT be used if a baby has already been diagnosed with allergy to cows' milk proteins or is suspected of already having an allergy to cows' milk protein.

**IMPORTANT NOTICE:** Breast milk is best for babies and breastfeeding should continue for as long as possible. Infant milk should only be used on the advice of a doctor, midwife, health visitor, public health nurse, dietitian or pharmacist, or other professionals responsible for maternal and child care.

FOR HEALTHCARE PROFESSIONALS ONLY  
BREASTFEEDING IS BEST FOR BABIES

## Three good reasons to choose our new SMA<sup>®</sup> PRO First Infant Milk\*

- ✓ Clinically proven\*
- ✓ Made with SMA<sup>®</sup> Nutrition's exclusive protein process
- ✓ Contains Omega 3 & 6 LCPs and GOS/FOS\*\*

Learn more about SMA<sup>®</sup> PRO range at  
[www.smahcp.co.uk](http://www.smahcp.co.uk)  
[www.smahcp.ie](http://www.smahcp.ie)

SMA Careline UK: 0800 0 81 81 80  
ROI: 1800 951 852

**SMA nutrition**  
Supporting you to support parents

**IMPORTANT NOTICE:** Breast milk is best for babies and breastfeeding should continue for as long as possible. Infant milk should only be used on the advice of a doctor, midwife, health visitor, public health nurse, dietitian or pharmacist, or other professionals responsible for maternal and child care.

BREASTFEEDING IS BEST FOR BABIES FOR HEALTHCARE PROFESSIONALS ONLY

## Which First Infant Milk is most in line with expert opinion on growth?

The Department of Health recommends exclusive breastfeeding for the first six months of life.

**SMA PRO First Infant Milk is the only first infant milk clinically proven to achieve a growth rate comparable with a breastfed baby as defined by WHO growth standards†**

**Protein and the importance of slower growth rates**

Because the protein in breast milk is adapted to a baby's needs, a breastfed baby tends to grow more slowly than a formula fed baby. This slower growth rate has shown to have significant long-term health benefits, including a lower risk of obesity, cardiovascular disease and diabetes.\*

**We've responded to expert opinion about proteins in SMA<sup>®</sup> PRO First Infant Milk:**

- 1. SMA PRO First Infant Milk is the only first infant milk clinically proven to achieve a growth rate comparable with a breastfed baby as defined by WHO growth standards†
- 2. SMA PRO First Infant Milk has the lowest protein and protein to energy ratio of any first infant milk.
- 3. SMA PRO First Infant Milk has the lowest levels of whey protein to casein ratio compared with other first infant milks.
- 4. SMA PRO First Infant Milk has the lowest levels of whey protein to casein ratio compared with other first infant milks.

**Setting the right quantity and quality of protein in infant and toddler diets has lifelong health benefits.**  
With SMA PRO First Infant Milk, you can help build a nutritional foundation for life in the first 1000 days.

**IMPORTANT NOTICE:** Breast milk is best for babies and breastfeeding should continue for as long as possible. Infant milk should only be used on the advice of a doctor, midwife, health visitor, public health nurse, dietitian or pharmacist, or other professionals responsible for maternal and child care.



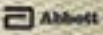
**THIS IS HUGE**

After months of coping with the sleepless, weary and heart-breaking cries of her cow's milk allergy, suddenly, a little moment like this doesn't seem so tiny after all.



- Proven efficacy - hypoallergenic and has been shown to reduce symptoms<sup>1</sup>
- Proven to be well tolerated - 98% of infants tolerated Similac Alimentum<sup>2</sup>
- Palm oil and palm steroles of free supports calcium absorption and bone mineralization<sup>3</sup>

**SIMILAC ALIMENTUM. FOR BIG LITTLE MOMENTS.**

*Appetite for life* 



ISBN:  
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**FIRST STEPS NUTRITION TRUST**

