

**Key points**

- CMA is the most common childhood food allergy affecting 1.9–4.9% of infants<sup>1,2</sup>
- Key clinical guidelines recommend extensively hydrolysed formula (eHF) as first-line management for formula-fed infants with mild-to-moderate CMA<sup>2-4</sup>
- Nutramigen with LGG® has demonstrated short-term (symptom relief),<sup>5</sup> medium-term (accelerated return to milk\*)<sup>6</sup> and long-term (reduced future allergic manifestations\*)<sup>7</sup> benefits.

**Product name**

Nutramigen™ 1, 2 &amp; 3 with LGG®

**Indication**

- Nutramigen with LGG is an eHF with a probiotic (LGG) for dietary management of infants with CMA, providing age-adapted nutrition to support growth<sup>8</sup> and an accelerated return to milk.\*<sup>6</sup>

**Feeding guide**

Age	Nutramigen with LGG	Tins per month
0–6 months	1	9–10
6–12 months	2	5–6
≥1 year	3	5

See tin label for detailed feeding guidance; HCP to determine the formula intake based on the individual situation

**Preparation and storage**

- Wash hands; clean feeding utensils in water (≥10 minutes rolling boil)
- Boil fresh water; as soon as possible cool to room temperature; do not use softened water<sup>9</sup>

**Important notice**

- Breastfeeding provides the best nutrition for babies
- This material is for HCPs only

AAF=amino acid-based formula; CMA=cow's milk allergy; eHF=extensively hydrolysed formula; HCP=healthcare professional; LGG=*Lactobacillus rhamnosus* GG<sup>†</sup> vs Nutramigen without LGG; <sup>†</sup>Efficacy data calculated using data on allergic reactions after oral food challenge with an eHF, from Table 3 of Dupont et al. 2012. As judged by the Committee on Nutrition of the French Society of Paediatrics. Efficacy data was calculated based on studies with Nutramigen before the addition of LGG.

- Feed immediately or cover and store in a refrigerator at 2–4°C for ≤24 hours
- Store tin in a cool, dry place; after opening, keep tightly covered and use within 1 month.

**Precautions**

- Do not freeze prepared formula and do not use if unrefrigerated for >2 hours
- Use formula that has been in contact with baby's mouth within 1 hour and do not refrigerate
- Do not heat prepared formula in a microwave.

**Monitoring**

- Trial formula for up to 4 weeks to allow symptom recovery and formula acceptance<sup>2</sup>
- To confirm diagnosis of non IgE mediated allergy, reintroduce milk and monitor whether symptoms return<sup>2</sup>
- Guidelines recommend eHF for formula-fed infants for up to 2 years or until allergy is outgrown<sup>1</sup>
- ~50% of CMA infants remain allergic at 1 year of age with most reaching oral tolerance by the age of 3 years<sup>10</sup>
- A 'planned reintroduction' by an HCP will determine whether tolerance to milk protein has been acquired.<sup>2</sup>

**About CMA**

- CMA is an adverse immune reaction to cow's milk protein presenting with immediate (IgE mediated) and delayed (non IgE mediated) symptoms<sup>4</sup>
- Prevalence in infants is 1.9–4.9%<sup>1,2</sup>
- Children with CMA have an increased risk of other allergic manifestations.<sup>7</sup>

**Guideline recommendations**

- For formula-fed infants, expert guidelines recommend eHF for first-line management of mild–moderate CMA<sup>2,4</sup>
- eHF is effective for symptom resolution in ~90% of infants with CMA,<sup>1,11</sup> while AAF should be reserved for severe cases (~10%).<sup>2</sup>

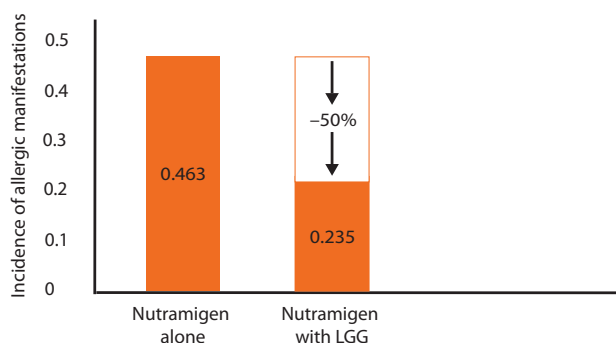
## Evidence for use

- Short-term: effective symptom relief:
  - average clinical efficacy<sup>†</sup> of 99%<sup>3</sup>
- Medium-term: faster oral tolerance acquisition:\*
  - >80% of infants return to milk after 12 months of use<sup>6</sup>
- Long-term: reduction in future allergic manifestations:
  - occurrence of ≥1 other allergic manifestation (asthma, eczema, urticaria, rhinoconjunctivitis) reduced by ~50% as shown in Figure 1.<sup>7</sup>

### Figure 1: Incidence of future allergic manifestations<sup>7</sup>

#### Allergic manifestations combined during a period of 3 years

Adapted from Berni Canani R, Di Costanzo R, Bedogni G et al. 2017.<sup>7</sup> This figure depicts the main study outcome under complete case analysis. Absolute risk difference for Nutramigen with LGG vs Nutramigen alone = -0.23 (95% CI, -0.36 to -0.10; p<0.001).



## Budgetary implications

- Nutramigen with LGG reduced infant healthcare costs over 12-month and 18-month periods compared with AAF or eHF (without LGG).<sup>12-14</sup>

## Cautions

- Not recommended for premature and immunocompromised infants unless directed and supervised by an HCP
- Babies fed eHF may produce frequent loose stools of a greenish colour (not unusual).

## Order and contact information

UK pharmacy PIP order code	Nutramigen with LGG (400 g)	Age	NHS price
019-8861	1 (previously Nutramigen LIPIIL 1)	0-6 months	£11.21
298-7766	2 (previously Nutramigen LIPIIL 2)	6-12 months	£11.21
406-4325	3	≥1 year	£11.21

For queries or milk-free recipes, please call the Mead Johnson Careline 01895 230575 or visit [www.nutramigen.co.uk](http://www.nutramigen.co.uk)

## References

1. Fiocchi A, Brozek J, Schunemann H et al. World Allergy Organization (WAO) diagnosis and rationale for action against cow's milk allergy (DRACMA) guidelines. *World Allergy Organ J* 2010; **3**(4): 57-161.
2. Venter C, Brown T, Meyer R et al. Better recognition, diagnosis and management of non-IgE-mediated cow's milk allergy in infancy: iMAP—an international interpretation of the MAP (Milk Allergy in Primary Care) guideline. *Clin Transl Allergy* 2017; **7**: 26.
3. Dupont C, Chouraqui J, de Boissieu D et al. Dietary treatment of cows' milk protein allergy in childhood: a commentary by the Committee on Nutrition of the French Society of Paediatrics *Br J Nutr* 2012; **107**(3): 325-338.
4. Luyt D, Ball H, Makwana M et al. BSACI guideline for the diagnosis and management of cow's milk allergy. *Clin Exp Allergy* 2014; **44**(5): 642-672.
5. Baldassarre M, LaForgia N, Fanelli M et al. Lactobacillus GG improves recovery in infants with blood in the stools and presumptive allergic colitis compared with extensively hydrolyzed formula alone. *J Pediatr* 2010; **156**(3): 397-401.
6. Berni Canani R, Nocerino R, Terrin G et al. Effect of Lactobacillus GG on tolerance acquisition in infants with cow's milk allergy: a randomized trial. *J Allergy Clin Immunol* 2012; **129**(2): 580-582.
7. Berni Canani R, Di Costanzo R, Bedogni G et al. Extensively hydrolyzed casein formula containing Lactobacillus rhamnosus GG reduces the occurrence of other allergic manifestations in children with cow's milk allergy: 3-year randomized controlled trial. *J Allergy Clin Immunol* 2017; **139**(6): 1906-1913.
8. Scalabrin D, Johnston W, Hoffman D et al. Growth and tolerance of healthy term infants receiving hydrolyzed infant formulas supplemented with Lactobacillus rhamnosus GG: randomized, double-blind, controlled trial. *Clin Pediatr (Phila)* 2009; **48**(7): 734-744.
9. BDA. *Guidelines for the preparation and handling of expressed and donor breast milk and special feeds for infants and children in neonatal and paediatric health care settings*. British Dietetic Association. 2016. Available at: [www.bda.uk.com/regionsgroups/groups/paediatric/sfu\\_guidelines](http://www.bda.uk.com/regionsgroups/groups/paediatric/sfu_guidelines) (accessed November 2018)
10. GIKids. Cow's milk protein intolerance. Factsheet. 2013. Available at: [www.gikids.org/content/103/en/cows-milk-protein-intolerance](http://www.gikids.org/content/103/en/cows-milk-protein-intolerance) (accessed November 2018)
11. Meyer R, Groetch M, Venter C. When should infants with cow's milk protein allergy use an amino acid formula? A practical guide. *J Allergy Clin Immunol Pract* 2018; **6**(2): 383-399.
12. Guest J, Panca M, Ovcinnikova O, Nocerino R. Relative cost-effectiveness of an extensively hydrolyzed casein formula containing the probiotic *Lactobacillus rhamnosus* GG in managing infants with cow's milk allergy in Italy. *Clinicoecon Outcomes Res* 2015; **7**: 325-336.
13. Guest J, Weidlich D, Mascunan Diaz J et al. Relative cost-effectiveness of using an extensively hydrolyzed casein formula containing the probiotic *Lactobacillus rhamnosus* GG in managing infants with cow's milk allergy in Spain. *Clinicoecon Outcomes Res* 2015; **7**: 583-591.
14. Ovcinnikova O, Panca M, Guest J. Cost-effectiveness of using an extensively hydrolyzed casein formula plus the probiotic *Lactobacillus rhamnosus* GG compared to an extensively hydrolyzed formula alone or an amino acid formula as first-line dietary management for cow's milk allergy in the US. *Clinicoecon Outcomes Res* 2015; **7**: 145-152.