



# Hydrolysed Rice Formula in the UK

Case studies in the management of cow's milk allergy



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With the 2025 launch of a hydrolysed rice formula (HRF), UK clinicians now have access to a halal, kosher and plant-based — albeit not vegan, as it contains 2'-fucosyllactose (2'-FL) — human milk oligosaccharide (HMO), hypoallergenic formula for infants with cow's milk allergy (CMA) who cannot be exclusively breastfed. Backed by international guidelines and growing evidence, HRF offers a new alternative to extensively hydrolysed formula (eHF). Soya formula was discontinued in the UK market in 2022, although there was some availability of stock until late 2023.

## What is HRF?

Hydrolysed rice formula is produced by enzymatically breaking down rice protein, reducing its allergenicity and facilitating digestibility.<sup>1</sup> Unlike standard rice drinks or milks HRFs are nutritionally complete and designed to meet infant feeding standards, with added essential amino acids (lysine, threonine, tryptophan), vitamins and minerals. Standard rice drinks or milks are unsuitable for infants under 5-years-old due to the high content of arsenic.

Until recently, HRF was not available on UK prescription. The recent NHS listing of a HRF changes this, aligning UK practice with global standards.

## Recent guideline positioning

DRACMA\* 2024 (World Allergy Organization)<sup>2</sup>

- Recognises HRF as nutritionally adequate and clinically equivalent to eHF.
- Recommends HRF as first-line treatment for CMA in formula-fed infants, alongside eHF, where available.

EAACI\* 2024 (Management of IgE mediated allergies)<sup>3</sup>

- Recommends HRF as first-line treatment for CMA in formula-fed infants, alongside eHF, where available.

ESPGHAN\* 2023 (Consensus paper)<sup>4</sup>

- Endorses HRF as an alternative to eHF.
- Suggests using HRF as a diagnostic tool.

All of these guidelines stress the importance of availability. With HRF now available in the UK for prescription, its role and use is likely set to expand.

Safety & nutritional considerations

- **Arsenic:** Concerns about inorganic arsenic in rice-based drinks are valid, but HRFs on the market are within strict WHO\* and EU\* safety limits.<sup>12, 13</sup>
- **Nutritional completeness:** Modern HRFs are fortified with limiting amino acids and meet the requirements for infant growth and development. They include a slightly higher amount of protein than cow’s milk-based formulas to compensate for the lower bioavailability of these.
- **Palatability:** While taste acceptance varies, HRFs are often better tolerated than eHFs in infants sensitive to taste.

Prescribing HRF in the UK

- There is currently one HRF available on NHS prescription.
- Where necessary, check local formulary inclusion and any restrictions (e.g. second-line after eHF failure).
- Current gaps for prescription indications are a lack of NICE\*, BSACI\* and local guidelines, which should be updated very soon.
- Consider cost implications, as HRF is significantly cheaper than AAF.

Practical uses

Case study 1

Baby A had been diagnosed with non-IgE mediated CMA whilst being exclusively breastfed, and his mum was following a dairy free diet. Baby A had been completely asymptomatic from 8-weeks-old. Mum challenged by introducing milk back in her diet when the baby was around 15-weeks-old, and symptoms returned. Since weaning, Baby A had IgE- mediated reactions to egg; the reason why he was seen in my clinic.

Mum is required to return to work when Baby A is 8-months-old and is unable to keep up with expressing, so she openly asked for a suitable formula for top-ups whilst Baby A is in nursery. Mum was concerned about palatability of formulas available, as her older child was also tried on eHF and AAF with no success.

I therefore provided samples of HRF and advised parents to start offering small amounts in either an open cup or a sippy cup, as it would be detrimental to introduce a teat at this age.

He accepted HRF eventually, although it took a few attempts, both due to open cup technique and taste. I had suggested to also try to express some breastmilk to mix this into the HRF if needed but, in the end, this was not required for acceptance.

Table 1: Growth clinical evidence summary<sup>5-11</sup>

| Study                                                                                 | Length of study | Population                                                            | Age         | Outcome                                                                                                                                                                   |
|---------------------------------------------------------------------------------------|-----------------|-----------------------------------------------------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ramirez-Farias <i>et al.</i> 2024<br>Non-randomised, multi-centre, single-group study | 28 days         | 33 young children were enrolled, 19 Protocol Evaluable, 33 ITT        | 0-90 days   | HRF supported improved growth parameters in infants with CMA, as well as good tolerance and an overall improvement in parental wellbeing                                  |
| D’Auria <i>et al.</i> 2003<br>Randomised pilot study                                  | 6 months        | 16 infants with CMPA (+ atopic dermatitis) confirmed by DBPCFC or OFC | 6-14 months | Growth and protein nutrition status similar between HRF and SF groups**                                                                                                   |
| Agastoni <i>et al.</i> 2007<br>Randomised, prospective, comparative trial             | 6 months        | 125 infants with CMPA confirmed by DBPCFC                             | 6-12 months | Comparable improvements in weight-for-age z-scores between HRF and eHF groups between 6 and 12 months**                                                                   |
| Girardet <i>et al.</i> 2013<br>Prospective, multicentre, open study                   | 5 months        | 78 healthy infants without CMPA                                       | 1-6 months  | HRF supported weight gain and z-scores comparable to the WHO Child Growth Standards**                                                                                     |
| Lasekan <i>et al.</i> 2006<br>Prospective, randomised, double-blind clinical trial    | 16 weeks        | 65 healthy infants without CMPA                                       | 1-4 months  | HRF supported weight, length and head circumference comparable to that of infants fed a standard cow’s milk-based formula**                                               |
| Reche <i>et al.</i> 2010<br>Prospective, open and randomised clinical trial           | 21 months       | 92 infants diagnosed with IgE-mediated CMPA                           | 1-10 months | Weight and length similar between HRF and eHF groups up to 18 months                                                                                                      |
| Vandenplas <i>et al.</i> 2014<br>Prospective study                                    | 6 months        | 42 infants with CMPA                                                  | 0-16 weeks  | HRF allowed a catch-up to normal weight gain in the first month. Normalisation of the weight-for-age, weight-for-length, and BMI z-scores within the 6-month study period |

\*\*Study conducted in Risolac® now called Similac Arize. Rice hydrolysate identical in both formulations. Cow’s milk protein free. ITT = intention to treat; BMI = body mass index; CMPA = cow’s milk protein allergy; DBPCFC = double-blinded, placebo-controlled, food challenge; eHF = extensively hydrolysed formula; HRF = hydrolysed rice formula; OFC = oral food challenge; SF = soy formula; WHO = World Health Organization; IgE = immunoglobulin E.

Table 2: Clinical application: When to consider HRF<sup>2-4</sup>

| Clinical scenario                                           | Preferred formula(s)                                    |
|-------------------------------------------------------------|---------------------------------------------------------|
| Mild-to-moderate CMA (non-IgE or IgE-mediated), formula-fed | eHF or HRF                                              |
| Symptomatic with, or refusing, eHF                          | HRF or amino acid formula (AAF) (depending on severity) |
| Severe CMA (e.g. anaphylaxis, FPIES, faltering growth)      | AAF                                                     |

The family slowly built up the volumes and by the time he commenced nursery at 9 months, he was taking 3 x 5 oz cups throughout the day (15 oz/24 h), which is an age-appropriate volume. Mum continued breastfeeding at night for comfort, which both of them benefitted from.

I explained to the family that they could use HRF to cook with (porridge, cereal, mash), or use fortified milk alternatives for this, but to avoid any rice drinks as these are not suitable for those under 5-years-old. They are due to commence the milk ladder at around his 1st birthday.

## Case study 2

Baby B is a 3-month-old who was formula fed and had a suspected Non-IgE CMA from birth. She had been managed in the community, but we received an Advice&Guidance request from her GP for support.

Baby B's main symptoms were loose, watery stools, alongside eczema and vomiting. They had tried whey-based eHF + lactose 1st line. Her eczema and vomiting had improved, but her stools were still very loose and watery. She was then tried on casein-based eHF as second-line. Her stools had slightly improved to mucousy, rather than watery, but overall were still loose and her improvement was not significant.

At this point, the GP had escalated to AA, but Baby B refused to take this formula. The family had tried titrating the new formula into the old one for acceptance, but she still refused it.

At this point, I advised the GP to arrange a trial of HRF (using the sample service to avoid a further prescription if this was not accepted). I also suggested that the family titrate the HRF into her old formula (introducing 1oz of HRF to 6oz of eHF) and increase the amount of HRF daily. This was well accepted and tolerated, and Baby B's symptoms fully resolved after 7 days of exclusive HRF.

The GP then commenced the prescription, and I reminded them that following 4 weeks of symptom improvement, Baby B will require a challenge to confirm Non-IgE CMA.

## Case study 3

Baby C is a 7-month-old who was admitted to the ward due to faltering growth (weight had dropped from 25th centile to 2nd) and dehydration. Mum explained that he had been breastfed from birth and never had any issues – he thrived on this. Unfortunately,

mum noticed that her supply started reducing quickly, and although initially there was no obvious cause, they then found out that she was pregnant again. At this point, the family introduced standard formula, which caused Baby C lip and eye swelling, hives and vomiting. They attended A&E who recommended starting casein-based eHF, which Baby C refused to take. He was then swapped to whey-based eHF, which he also refused to take, alongside plain water offered by the family.

This was the cause of the admission to the ward, where AAF was trialled, also unsuccessfully, whilst Baby C was rehydrated via IV fluids. It was therefore decided to pass a nasogastric tube (NGT) to commence feeding with AAF, and samples of HRF were sent home for the family to try. I advised to try this in open cups or sippy cups to avoid exposure to a bottle, in case this was bottle aversion.

Baby C did not accept HRF orally, however following a discussion with the family it was agreed to move onto feeding HRF down his NGT. This was well tolerated and caused no gastrointestinal issues. Baby C quickly regained weight, and by the age of 8.5-months his weight was back on the 25th centile.

HRF was continued until he was 11 months old, as he was accepting fortified milk alternatives and water orally and had a good, varied diet, and the risks of continuing NGT feeds for nutritional support whilst having a newborn sibling at home significantly outweighed the benefits of continuing.

## Final word

- HRF represents a viable and evidence-based option in the UK for infants with CMA when breastfeeding is not possible or insufficient.
- The new UK availability of a prescription HRF means the theoretical guideline support (from DRACMA, EAACI, ESPGHAN and other bodies' consensus statements) can start translating into clinical practice.<sup>2-4</sup>
- For many infants with CMA, HRF may now be an acceptable first-line formula, especially where eHF is poorly tolerated or refused, or where families prefer a plant-based, halal and kosher alternative.
- However, in more severe cases (anaphylaxis, faltering growth, FPIES), current guideline consensus remains to favour AAF, and more data will help clarify whether HRF can safely replace these in those settings.

“Hydrolysed rice formula is produced by enzymatically breaking down rice protein, reducing its allergenicity and facilitating digestibility.<sup>1</sup>”

References: 1. Dupont C, *et al.* (2020). Hydrolyzed Rice Protein-Based Formulas, a Vegetal Alternative in Cow's Milk Allergy. *Nutrients*; 12(9): 2654. 2. Bognanni A, *et al.* (2024). World Allergy Organization (WAO) Diagnosis and Rationale for Action against Cow's Milk Allergy (DRACMA) guideline update – XII – Recommendations on milk formula supplements with and without probiotics for infants and toddlers with CMA. *World Allergy Organ J.*; 17(4): 100888. 3. Santos AF, *et al.* (2024). EAACI guidelines on the management of IgE-mediated food allergy. *Allergy*; 80(1): 14–36. 4. Vandenplas Y, *et al.* (2024). An ESPGHAN Position Paper on the Diagnosis, Management, and Prevention of Cow's Milk Allergy. *J Pediatr Gastroenterol Nutr.*; 78(2): 386–413. 5. Ramirez-Farias C, *et al.* (2024). Tolerance of infants fed a hydrolysed rice infant formula with 2'-fucosyllactose (2'-FL) human milk oligosaccharide (HMO). *Nutrients*; 16(12): 1863. 6. D'Auria E, *et al.* (2003). Nutritional value of a Rice-Hydrolysate formula in infants with cows' milk protein allergy: a randomised pilot study. *J Int Med Res.*; 31(3): 215–222. 7. Agostoni C, *et al.* (2007). Growth of infants with IgE-mediated cow's milk allergy fed different formulas in the complementary feeding period. *Pediatr Allergy Immunol.*; 18(7): 599–606. 8. Girardet JP, *et al.* (2013). Growth efficacy and tolerance of an infant formula based on hydrolysed rice proteins. *Arch Pediatr.*; 20(3): 323–328. 9. Lasekan JB, *et al.* (2006). Growth, tolerance and biochemical measures in healthy infants fed a partially hydrolysed rice protein-based formula: a randomised, blinded, prospective trial. *J Am Coll Nutr.*; 25(1): 12–19. 10. Reche M, *et al.* (2010). The effect of a partially hydrolysed formula based on rice protein in the treatment of infants with cow's milk protein allergy. *Pediatr Allergy Immunol.*; 21(4 Pt 1): 577–585. 11. Vandenplas Y, *et al.* (2014). Safety and tolerance of a new extensively hydrolysed rice protein-based formula in the management of infants with cow's milk protein allergy. *Eur J Pediatr.*; 173(9): 1209–1216. 12. FAO/WHO (2010). Chemical safety: arsenic. Accessed online: [www.who.int/docs/default-source/chemical-safety/arsenic/summary72-rev.pdf](http://www.who.int/docs/default-source/chemical-safety/arsenic/summary72-rev.pdf) (Sep 2025). 13. European Food Safety Authority (2014). Dietary exposure to inorganic arsenic in the European population. *EFSA Journal* 2014; 12(3): 3597.

\*DRACMA = Diagnosis and Rationale for Action against Cow's Milk Allergy; EAACI = European Academy of Allergy and Clinical Immunology; ESPGHAN = European Society for Paediatric Gastroenterology, Hepatology and Nutrition; WHO = World Health Organization; EU = European Union; NICE = National Institute for Health and Care Excellence; BSACI = The British Society for Allergy & Clinical Immunology.