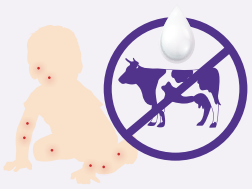
Hypoallergenic formula with synbiotics for the dietary management of cow's milk allergy: new data on the experiences of parents and healthcare professionals

Cow's milk allergy (CMA) is an immune-mediated response to the proteins found in cow's milk. CMA is one of the most common food allergies in early life affecting approximately 1–4% of young children, usually appearing within the first few months and before six months of age.[1] While the exact worldwide prevalence of CMA is unknown, research suggests an increased prevalence over the last 20–30 years.[1,2]



CMA IS ONE OF THE MOST COMMON FOOD ALLERGIES IN EARLY LIFE

Although CMA symptoms are wide ranging, the gastrointestinal (GI) tract is most commonly affected (e.g. vomiting, reflux, diarrhoea, constipation, bloody stool, abdominal pain), followed by the skin (e.g. rashes, swelling of the lips and eyes) and respiratory tract (e.g. wheezing, coughing). CMA is divided into rapid onset (IgE-mediated) where symptoms usually present within an hour after ingestion and delayed onset (non-IgE mediated) where symptoms may take hours or days to present.

The effect of CMA goes beyond clinical symptoms, impacting longer term health and wellbeing, family quality of life (QoL), as well as the wider healthcare system. In fact, studies have shown infants and children with CMA use more healthcare resources, including medication prescriptions, hospital admissions and healthcare contacts (e.g. general practice appointments and consultations with dietitians/other specialists) than infants and children without CMA.[3,4]

Breastfeeding should always be encouraged for infants; the composition of breastmilk is nutritionally rich in macronutrients and micronutrients, as well as including a wide range of bioactive compounds that are essential for infant growth and development.

However, in infants with CMA when breastfeeding is not an option, there is now a progressive **move towards offering hypoallergenic infant formulas which go beyond symptom management of CMA and contain ingredients that mimic the functionality of some of the bioactive compounds present in breastmilk**, including synbiotics – the combination of both pre- and probiotics. **Synbiotics have been linked with favourable shifts in the composition of the gut microbiota and the developing immune system**[5] which has the potential to improve health outcomes, including allergy and atopic disorders.[6] **This new generation of formulas target the infant gut microbiota and are designed to support the developing immune system.**

Summary of evidence from clinical trials

Both Pepti Syneo extensively hydrolysed formula (eHF) and Neocate Syneo amino acid-based formula (AAF) are nutritionally complete hypoallergic formulas which contain a synbiotic blend of both prebiotics and probiotics, specifically selected to support the gut microbiota in infants with CMA.

To date, published research exploring hypoallergenic formulas including Pepti Syneo and Neocate Syneo have shown they have an excellent safety profile, are well tolerated, and support normal growth. In addition, studies have shown that hypoallergenic formulas with synbiotics support the gut microbiota in infants with CMA, prompting favourable shifts in gut microbial composition that are more reflective of the gut microbiota of healthy breastfed infants.[7,8,9] The graphic on the next page summarises the additional clinical and observational findings* with use of eHF and AAF formulas containing synbiotics.

* Based on evaluation of adverse events and safety parameters in studies in infants with CMA receiving a hypoallergenic formula with synbiotics in comparison with a hypoallergenic formula without synbiotics.

Summary of evidence from clinical trials

Medication use

- Reduction of asthma medication at one year follow up.[10]
- Reduced need for medication for functional GI disorders.[8]
- Lower percentage of infants required antibiotics.[7,8]
- Lower use of dermatological medication.[11]
- Lower rates of medication prescriptions, including antibacterials and anti-infectives.[12]

Respiratory

- Lower prevalence of asthma-like symptoms at one year follow-up.[10]

Hospitalisations

- Reduction in hospital visits and medications in the six months follow-up.[14]
- Fewer hospitalisations due to infections.[15]

Dermatological symptoms

- Demonstrated greater improvement of atopic dermatitis.[9]**
- Improvements in atopic symptoms including rhinitis and itchy eyes.[14]
- Improvements in dermatological symptoms (e.g. dryness, erythema).[16]

Infections

- Fewer infections[8] and GI infections.[15]
- Fewer ear infections.[11]
- Lower rates of infections.[12,13]

GI

- Reduction in constipation and dry stools.[9]
- Improvements in severity of abdominal pain, burping, flatulence, constipation.[14]
- Improvements or disappearance in GI symptoms (e.g. stooling, flatulence).[16]
- Improved stool consistency and colour, closer to those of healthy breastfed infants.[17]

Other

- Improvements in caregiver reported QoL.[14]
- Improvement in infant and parent QoL.[16]
- Lower rate of healthcare contacts.[13]
- Potential healthcare cost-savings.[12]

* Based on evaluation of adverse events and safety parameters in studies in infants with CMA receiving a hypoallergenic formula with synbiotics in comparison with a hypoallergenic formula without synbiotics.

** In the subgroup of infants with IgE-associated atopic dermatitis.

KEY

- **Pepti Syneo eHF** with short chain galacto-oligosaccharides/long chain fructo-oligosaccharides and *Bifidobacterium breve*
- **Neocate Syneo AAF** with short chain fructo-oligosaccharides/long chain fructo-oligosaccharides and *Bifidobacterium breve*

User Experience Survey

A global healthcare user experience survey was recently completed by 90 parents and 210 healthcare professionals (HCPs) including Paediatricians, Gastroenterologists, General Practitioners, Dietitians and Allergists, across six countries (Australia, France, Germany, Spain, UK, USA) to gain real-life insights from HCPs and parents about their experiences with Pepti Syneo and Neocate Syneo, and to ascertain whether their experience reflected the evidence from randomised control trials (RCTs) and real-world evidence (RWE) studies. HCPs who completed the survey needed to have experience of, or have used these formulas in their patient population and parents were required to have a child that was currently taking the formula.

Multiple choice Likert scale type questions were used for both HCPs (e.g. always / often / sometimes / rarely / never / not applicable) and parents (e.g. yes / no / I don't know / not applicable). The data on the two different formulas were collated and summarised.

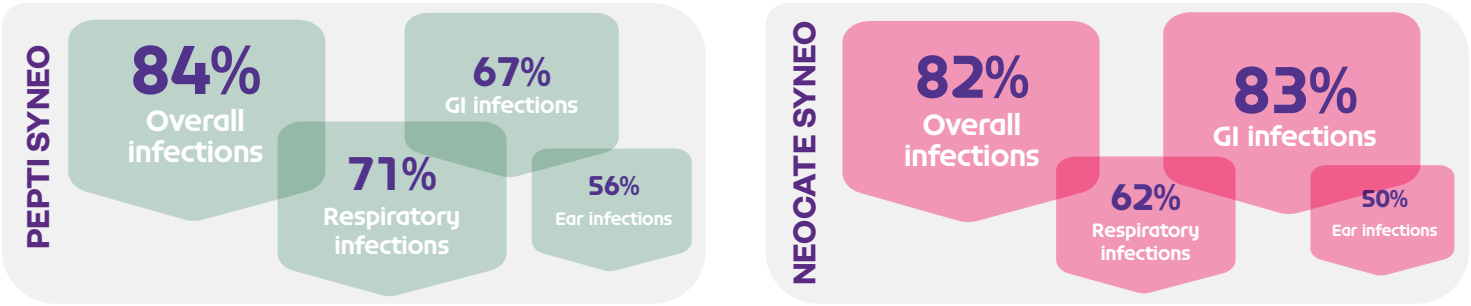
Outcomes

The user experience survey offered first hand, personal insights from users of both formulas, by exploring the effects of formula and management of CMA on the health and wellbeing of the child and their families, as well as the potential impact on the wider health economic burden of CMA.

Both HCPs and parents reported consistent improvements across all outcomes, suggesting that **both formulas can effectively manage the immediate symptom burden of CMA, as well as positively impacting upon longer term health outcomes, QoL and associated reductions in healthcare resources.**

ADVERTORIAL

HCP insights*** Percentage of HCPs observing a reduction in infections



***HCPs reported observing changes sometimes, often or always.

Table 1: Summary of HCPs' observations*** of health-related outcomes in their patients after use of Pepti Syneo or Neocate Syneo.

			Pepti Syneo	Neocate Syneo
	**Medications**	Reduction in need for antibiotics	**63%**	**64%**
		Reduction in need for medications for skin symptoms	**76%**	**55%**
		Reduction in need for medications for GI symptoms	**79%**	**84%**
		Reduction in need for anaphylaxis medications	**42%**	**34%**
	**Healthcare visits**	Reduction in need for visits to the doctor	**72%**	**75%**
		Reduction in need for visits to the hospital	**80%**	**65%**
	**Quality of life**	Improvement in wellbeing of the child	**97%**	**97%**
		Improvement in wellbeing of the parent or family	**95%**	**97%**

***HCPs reported observing changes sometimes, often or always.

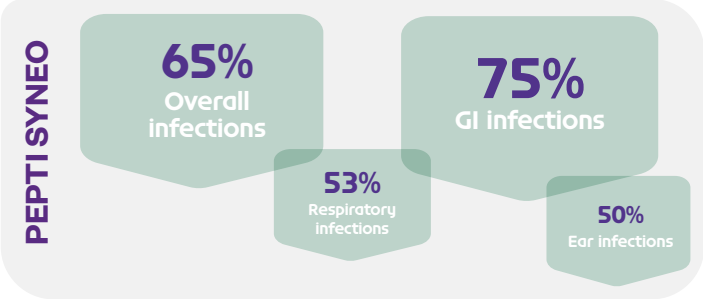
In addition to observing the expected improvements in allergic symptoms, HCPs reported a reduction in the number of infections, medications, and need for medical and healthcare services in their patients being prescribed eHF or AAF containing synbiotics.

- HCPs reported **high levels of acceptability with both formulas** (91%) and would recommend both formulas to other HCPs (95%) for the effective management of CMA.
- The majority of HCPs agreed that **both formulas made CMA management much or a little easier** (85% for Pepti Syneo and 77% for Neocate Syneo) and **they would continue to use both formulas for infants with CMA who require AAF or eHF** (96% for Pepti Syneo and 97% for Neocate Syneo).
- Most HCPs agreed that they would continue to use Pepti Syneo (93%) or Neocate Syneo (88%) as **their first choice for infants with CMA.**

HCP: **"Neocate Syneo enhances the life of infants who have skin symptoms or gastric issues associated with CMA".**

Parents' insights

Percentage of parents observing a reduction in infections



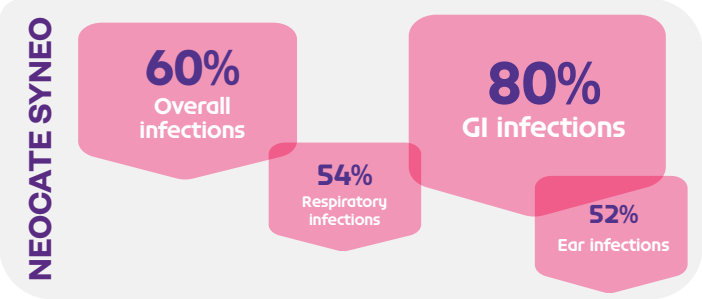


Table 2: Summary of parents reporting health-related outcomes in their children after use of Pepti Syneo or Neocate Syneo

			Pepti Syneo	Neocate Syneo
	Medications	Reduction in need for antibiotics	**63%**	**66%**
		Reduction in need for medications for skin symptoms	**68%**	**66%**
		Reduction in need for medications for GI symptoms	**68%**	**64%**
		Reduction in need for anaphylaxis medications	**45%**	**34%**
	Healthcare visits	Reduction in need for visits to the doctor	**85%**	**86%**
		Reduction in need for visits to the hospital	**77%**	**78%**
	Quality of life	Improvement in wellbeing of the child	**78%**	**90%**
		Improvement in wellbeing of the parent or family	**93%**	**96%**

Parents reported the expected improvement in their child's allergic symptoms. In addition, parents reported an overall improvement in their health, including a reduction in the numbers of infections their child suffers with, and reduction in the need for medication and healthcare services.

- Parents of children taking the formulas reported high levels of acceptability (95%) and **would recommend to other parents (100%) for the effective management of CMA.**
- The majority of parents agreed that **both formulas were easy or very easy to prepare** (80% for Pepti Syneo and 90% for Neocate Syneo).
- Most parents agreed that **both formulas had a positive effect on their child** (88% for Pepti Syneo and 94% for Neocate Syneo) and on the family (83% for Pepti Syneo and 90% for Neocate Syneo).
- Over 95% of parents whose child had originally been taking a different hypoallergenic formula agreed that **the formulas containing synbiotics were preferred to their child's previous formulas.**

Parent of child on Pepti Syneo:

"My child is able to sleep better and her overall mood has improved. It has made her a happier and more settled baby".

Parent of child on Neocate Syneo:

"We worry less, we can sleep better and the day is more pleasant and less stressful".

Conclusion

To date, a number of studies (RCTs and RWE) have been conducted on the hypoallergenic infant formulas including synbiotics. Results from these studies have shown improvements in GI, respiratory, and dermatological symptoms. Furthermore, results have shown reductions in medication use, healthcare resources and hospitalisations, as well as increases in QoL.

This new HCP and parent experience survey complements the data reported in these studies, reporting similar improvements in outcomes including CMA symptoms, QoL and a reduced need for healthcare resources. The data offer further insights (acceptability, ease of use and satisfaction) direct from the users of these products reflecting how this new generation of formula with synbiotics can benefit infants living with CMA.

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