

Prescribing Guidelines of Infant Formula for Infants with Cow's Milk Protein Allergy (CMPA) or Lactose Intolerance

Background information - these guidelines have been produced to aid GPs in prescribing appropriate infant formulas for the management of Cows Milk Protein Allergy (CMPA).

Infant formula for lactose intolerance should be purchased over-the-counter. Breast feeding is promoted as the best form of nutrition for a good start in life.

Adverse reactions to foods, mainly cow's milk protein (CMPA), are most common in the first year of life¹.

- Most infants with cow's milk protein allergy CMPA develop symptoms before 1 month age, often within 1 week after introduction of CMPA based formula².
- CMPA can induce both acute IgE-mediated reactions (within 2 hours) e.g. rash or urticaria, wheeze, vomiting and delayed reactions that may be either non IgE-mediated or mixed (> 2 hours) e.g. mild-moderate eczema, reflux.
- Severe CMPA hypersensitivity symptoms may include anaphylaxis, severe eczema or faltering growth.
- 5 – 15% of infants show symptoms suggestive of reaction to cow's milk protein.
- 16 – 42% of infants with gastro-oesophageal reflux (GOR) have CMPA³.
- A remission rate is expected of 45 – 50% of infants at 1 year, 60 -75% at 2 years and 85 – 90% at 3 years⁴.

Managing CMPA:

- Breast milk remains the ideal choice for the CMPA infant⁵.
- If CMPA symptoms persist in the breast fed infant, a maternal exclusion diet i.e. milk-free diet, is indicated⁵ for a minimum trial of 2 weeks.
- The mother will need a calcium supplement of 1000mg/day e.g. Sandocal 1000, if she follows a milk free diet herself whilst breastfeeding.
- A referral should be made to a paediatric dietitian when suspicion of CMPA is raised and all infants on a cow's milk free diet should be referred to a paediatric dietitian.
- For infants who are not breast fed an appropriate hypoallergenic formula is required⁶ – see *flowchart 1*.

- These formulae vary in palatability – introduce as soon as possible and if possible transition the introduction with incremental mixing of the milks.
- It is advisable to prescribe a smaller amount on a trial basis initially.

Lactose intolerance

- Primary lactose intolerance can occur later in life as we lose the ability to produce lactase. Lactose intolerance can be a congenital condition, due to absence of the lactase enzyme, but this is very rare.
- Secondary lactose intolerance is the commonest form of lactose intolerance and occurs following an infectious gastrointestinal illness. Damage to the small bowel mucosa causes a temporary deficiency in lactase.
- Symptoms include abdominal bloating, increased wind and frothy, loose stools which may in turn cause perianal irritation and redness. Blood or slime in stools is **NOT** a feature of lactose intolerance.
- Diagnosis of lactose intolerance should be suspected in children who have a diarrhoeal illness lasting more than 2 weeks. Resolution of symptoms, usually within 48 hours, when lactose is removed from the diet is the gold standard for diagnosis. Children should be referred if there are any concerns about significant weight loss or if symptoms do not improve.
- Treatment: Infants should be given a lactose-free formula. Secondary lactose intolerance in infants usually lasts 6 – 8 weeks but may last as long as 3 – 6 months, so parents will also need to understand how to follow a low-lactose diet. Referral to a dietitian is recommended if the low-lactose diet is to continue.
- Suitable products, used from birth to maximum 18 months, requirement 4 – 8 tins a month.
SMA LF (SMA)
Enfamil lactose free (Mead Johnson)
- **Parents should be asked to purchase formula for lactose intolerance over the counter.**

Soya-based formula

In 2004 the Chief Medical Officer issued a statement advising against the use of soya-based formula in infants with cow's milk protein sensitivity or lactose intolerance. Soya formula is no longer indicated for infants who are milk intolerant or allergic, due to its phyto-oestrogen content, and the increased risk of sensitisation to soya protein. This is especially important for infants under 6 months of age. 10 to 35% of children with CMPA are also sensitive to soya. Use of soya formula should be limited to exceptional circumstances to ensure adequate nutrition, for example, infants of vegan parents who are not breastfeeding, or infants who find alternatives unacceptable.

Parents wishing to feed their infant on soya-based formula should be advised of the risks and instructed to buy the formula over the counter. Soya-based formula is prescribable for galactosaemia only, on the advice of a consultant.

It may also be prescribed in exceptional cases of CMPA in infants older than 6 months, where extensively hydrolysed formulas and amino acid based formulas are refused. Caution is needed as incidence of soya allergy is high in infants with CMPA

For those infants prescribed soya formula, most should covert to supermarket bought soya or oat calcium-enriched milk when they reach 1 year of age if their diet is adequate and they are growing well. Only children with specific rare medical conditions require a prescribed soya formula after this age.

Box 1 Signs and symptoms of possible food allergy²	
IgE-mediated	Non-IgE-mediated
The Skin	
<ul style="list-style-type: none"> • Pruritus • Erythema • Acute urticaria (localised or generalised) • Acute angioedema (most commonly in the lips and face, and around the eyes) 	<ul style="list-style-type: none"> • Pruritus • Erythema • Atopic eczema
The gastrointestinal system	
<ul style="list-style-type: none"> • Angioedema of the lips, tongue and palate • Oral pruritus • Nausea • Colicky abdominal pain • Vomiting • Diarrhoea 	<ul style="list-style-type: none"> • Gastro-oesophageal reflux disease • Loose or frequent stools • Blood and/or mucus in stools • Abdominal pain • Infantile colic • Food refusal or aversion • Constipation • Perianal redness • Pallor and tiredness • Faltering growth plus one or more gastrointestinal symptoms above (with or without significant atopic eczema)
The respiratory system (usually in combination with one or more of the above symptoms and signs)	
<ul style="list-style-type: none"> • Upper respiratory tract symptoms – nasal itching, sneezing, rhinorrhoea or congestion (with or without conjunctivitis) 	
<ul style="list-style-type: none"> • Lower respiratory tract symptoms (cough, chest tightness, wheezing or shortness of breath) 	
Other	
Signs or symptoms of anaphylaxis or other systemic allergic reactions	
Note: this list is not exhaustive – the absence of these symptoms does not exclude food allergy.	

References

1. Host A., 2001. Primary and secondary dietary prevention. *Pediatr Allergy Immunol*; 12 (suppl 14): 78-84
2. Heine RG, Elsayed S, Hosking CS, Hill DJ. Cow's milk allergy in infancy. *Urr Opin Allergy Clin Immunol* 2002;2: 217-25
3. Sicherer SH, 2003. Clinical aspects of gastrointestinal food allergy in childhood. *Paediatrics*; 111 (6); 1609-1616
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7. *Food Allergy in Children NICE guideline 116 & NICE quick reference guide 2011*

Prescription of infant formula in infants with suspected cow's milk protein (CMP) allergy or lactose intolerance

CMPA Mild to moderate symptoms

One or more of the following symptoms:

- Gastrointestinal:
Frequent regurgitation, vomiting, diarrhoea, constipation, blood in stool, iron deficiency anaemia.

Persistent distress or colic (≥ 3 hrs per day – wailing/irritable), for at least 3 days/week over > 3 weeks
- Dermatological:
Atopic dermatitis, swelling of the lips or eyelids (angio-oedema), urticaria unrelated to acute infections, drug intake or other causes.



Suitable formula / feeding (Prescribed on NHS)

Cow's milk protein free foods if weaning.

Step 1: Breastfeeding

If mum is breastfeeding consider CMP free diet for mum, with calcium supplements, for a minimum trial of 2 weeks. (1000mg/day e.g. Sandocal 1000)

Step 2: Extensively hydrolysed formulas (EHF)

- Casein Based: Nutramigen 1 & 2 (Mead Johnson)
- Whey based:
Peptijunior (Cow and Gate)
Pepti – contains lactose (Aptamil)

Step 3: Amino acid based formulas (AAF)

If symptoms do not improve after 2 weeks or the child persistently refuses EHF then:

- E.g. Neocate LCP or Nutramigen AA
For a minimum trial of 2 weeks

Step 4: Soya Formula

- Can only be used in infants over 6 months who refuse above formulas.
- Use with caution as high incidence of soya allergy in children with CMP allergy.

CMPA Severe symptoms

One or more of the following symptoms:

- Gastrointestinal:
 1. Faltering growth due to chronic diarrhoea and/or regurgitation/vomiting and/ or refusal to eat.
 2. Iron deficiency anaemia due to occult or macroscopic blood loss.
 3. Protein losing enteropathy (hypoalbuminaemia).
 4. Endoscopic/histologically confirmed enteropathy or severe allergic or eosinophilic colitis.
- Dermatological:
Exudative or severe atopic dermatitis with hypoalbuminaemia, or faltering growth iron deficiency anaemia.
- Respiratory:
Acute laryngoedema or bronchial obstruction with difficulty breathing.
- Systemic reactions:
Anaphylactic shock – needs immediate referral to hospital for management.



Suitable formula / feeding (Prescribed on NHS)

Cow's milk protein free foods if weaning

1. **Breastfeeding:**
Consider CMP free diet for mum, with calcium supplements, for a minimum trial of 2 weeks.
2. **Amino acid bases formulas (AAF)**
For a minimum trial of 2 – 4 weeks
 - E.g. Neocate LCP or Nutramigen AA

Lactose Intolerance Symptoms:

Includes:

- Diarrhoea
 - Colic
- Symptoms are usually transient and 2^o to GI insult e.g. : rotavirus infection.

Diagnosis

- Clinical history
- Reducing substances in stool

Treatment (purchased OTC)

- Breastfed babies – lactase drops (e.g. Colief, 4 drops / feed)
- Formula: Low lactose formulas based on CMP e.g.: SMA LF; Enfamil O-Lac
- Weaned children would need to avoid solids containing lactose.

Note: Most children should be able to revert back to normal formula once GI insult has resolved within 4 – 6 weeks

- If symptoms do not improve after two weeks on lactose free diet, consider alternative diagnosis.

Suggested quantities

- 0-6 months 10x400g per month
 - 6-12 months 12x400g per month
- This is based on an average baby's weight and mls/kg requirement and is only a general guide.

Notes:

- Please refer ALL infants on cow's milk protein free diets to a paediatric dietitian
- Prescription for infant formula should not be routinely required beyond the age of 18 months, except on dietetic advice.

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