

Appropriate Prescribing of Specialist Infant Formula Feeds

Purpose of the guidance

These guidelines aim to assist GPs and Health Visitors with information on the appropriate use of infant formula that can be prescribed. The guidelines are targeted at infants 0-12 months. Some of the formula feeds mentioned can be used above this age group and advice on this is included in the guidelines. The guidelines advise on:

- ✓ Initiating prescribing
- ✓ Quantities to prescribe
- ✓ Products to prescribe for different clinical conditions
- ✓ Reviewing and discontinuing prescriptions
- ✓ Onward referral for dietetic advice and/or secondary/specialist care.

What is an allergy

A food allergy is where the immune system recognises a protein in food (or molecule linked to a protein) as foreign to the body and triggers a response against it. Food allergies may be IgE-mediated or non-IgE mediated but mediated by other immune mechanisms. IgE-mediated reactions are acute and usually occur within 2 hours of ingesting the food. Non-IgE mediated reactions tend to be delayed and may occur up to 48 hours after food ingestion. Cow's milk protein allergy is most commonly a combination of both IgE and non-IgE mediated symptoms and usually develops in the first year of life. See appendix table 1 NICE 2011- Food Allergy in Children and Young People.

Food hypersensitivity is a reaction to proteins in foods, without any immune involvement in the reaction.

Lactose intolerance is a non-immune mediated response to the carbohydrate 'lactose' in cow's milk. There are 3 causes of lactose intolerance:

1. Congenital lactose intolerance- congenital deficiency of the lactase enzyme responsible for metabolism of lactose. This is characterised by poor growth and infantile diarrhoea from first exposure to breast milk (which contains lactose).
2. Primary lactose intolerance- low levels of lactase, developed over a period of years but not before the ages of 2-5 years. Foods of lower lactose content will be tolerated.
3. Secondary lactose intolerance- temporary loss of lactase activity due to gastrointestinal illness damaging the small intestine e.g. viral gastroenteritis, giardiasis or coeliac disease. It is reversible by following a lactose free diet to allow the gut to recover for 6-12 weeks. Diagnosis is by clinical history and confirmed by exclusion of lactose-containing foods and subsequent improvement in symptoms.

IgE rAST testing and skin prick testing for Cow's milk protein (CMP) allergy is useful in the diagnosis of type I hypersensitivity reactions (immediate onset urticarial rash/vomiting etc.) to CMP. Bedside or laboratory allergy testing for suspected exacerbation of atopic eczema due to ingestion of cow's milk is not indicated. Such test will often produce false positive

results, leading to an unnecessary diet restriction. If such an allergy is suspected the standard diagnostic procedure is withdrawal and re-challenge with cow's milk, with observation of the severity of the eczema over time, as described in the appendix below.

Symptoms of cow's milk protein allergy (CMPA)

- Usually occur within the 1st year of life
- Atopic dermatitis
- GI symptoms e.g. blood in stools, diarrhoea, vomiting, abdominal distension, colic, constipation
- Recurrent wheeze
- The more of the above symptoms involved the more likely the child is to have a milk allergy, particularly if different organs are affected or if the child has not responded to treatment for atopic eczema, reflux or chronic GI symptoms.
- Breast fed infants can display similar symptoms due to milk protein from the mother's diet passing to the infant.
- If treated effectively most children outgrow the allergy by 2 years.

Treatment of CMPA

- Breast feeding is still the most appropriate choice of feed. The mother should follow a milk free diet and ensure sufficient calcium (1250mg per day), usually via a supplement. Symptoms should resolve within 2 weeks, if not it is unlikely that CMPA is the cause of symptoms.
- Bottle fed infants require a hypoallergenic formula. It is important to introduce as soon as possible as formula vary in palatability. If not accepted initially, introduce by mixing with standard formula and slowly wean onto the hypoallergenic formula. A minimum trial of 3 weeks is recommended, if no improvement in symptoms after this time, the infant is unlikely to have CMPA.
- All infants should be re-challenged with cow's milk within 4 weeks of starting a milk free diet, either by exposing to milk in maternal diet for breastfed infants or with normal cow's milk based formula for formula fed infants. If symptoms reoccur cow's milk protein allergy has been confirmed. If symptoms do not reoccur, cow's milk protein allergy has been excluded and all specialist formula should be stopped and the infant should continue on over the counter first formula and wean onto an appropriate diet containing dairy.
- For those with confirmed cow's milk protein allergy, a milk challenge should take place between 9 and 12 months, depending on the time of diagnosis. Infants will require 6 months symptom free prior to a milk challenge.
- ***All infants with confirmed CMPA must be weaned on a milk free diet and will require referral to the Paediatric Dietitian to advise on this and to assess calcium intake as milk intake reduces.***
- By 2 years, all infants will be recommended to switch to normal cows milk or if not tolerated, a commercially available substitute e.g. calcium enriched oat milk / almond milk / coconut milk /soya milk.
- Hypoallergenic formula should not be prescribed past 2 years unless specifically requested by the Paediatric Dietitian or Paediatrician e.g. in cases of continued milk allergy alongside faltering growth.

Options for formula feed to prescribe

1st line Extensively hydrolysed formula	Age	Product / unit size	Additional information
	From Birth	Althera [®] (Nestle) – 450g tin (£10.68)	May need to mix with standard formula and gradually increase
If above formula refused due to taste			
	From Birth	Similac Alimentum [®] (Abbott) – 400g tin (£9.44)	May need to mix with standard formula and gradually increase
2nd line	If symptoms persist for 4 weeks on extensively hydrolysed formula, an amino acid based formula should be tried for 2 weeks		
	From Birth	Alfamino [®] (Nestle) - 400g tin (£23)	May need to mix with standard formula and gradually increase
If above formula refused due to taste			
	From Birth	Neocate LCP [®] (Nutricia) - 400g tin (£29.56)	May need to mix with standard formula and gradually increase

Indicator for immediate prescription of amino acid based formula:

1. Faltering growth with suspected CMPA
2. Blood in stools
3. Significant symptoms within the first 12 weeks whilst exclusively breast fed
4. Atopic dermatitis

Quantities to prescribe

When any infant formula is prescribed the guide below should be used:

For powdered formula:

Age of child	Number of tins for 28 days
Under 6 months	13 x 400g tins
6-12 months	7-13 x 400g tins
Over 12 months	7 x 400g tins

Review and discontinuation of formula feed on prescription

The need for specialist milk formulas on prescription should be regularly reviewed by GP, Paediatrician or Dietitian.

All children with milk allergy should be challenged with milk at 9-12 months, depending on age of diagnosis. Children will require 6 months symptom free, after initial confirmation of diagnosis, prior to a milk challenge. Milk challenges should be repeated approximately every 6 months. Advice on appropriate foods with which to challenge should be provided by a specialist dietitian. Children should be exposed to low levels of milk initially (using the milk ladder (iMAP) and gradually increased. Cooked milk has a lower allergic risk as the protein is broken down and therefore should be introduced before uncooked milk products.

All specialist formula should be discontinued by 2 years and changed to appropriate over the counter milks e.g. calcium enriched oat milk / almond milk / coconut milk /soya milk.

The Paediatrician or Specialist Dietitian may on occasion request continuing with a specialist formula beyond 2 years in exceptional circumstances e.g. faltering growth alongside evidence of continued milk allergy or multiple food allergies.

Gastro-oesophageal reflux (GOR)

Cow's milk protein may aggravate gastro-oesophageal reflux in some infants. Where reflux is suspected and not responding to anti-reflux treatment, a 3 week trial of an extensively hydrolysed formula may be considered. Where there is no improvement in reflux symptoms within 3 weeks, it is unlikely that milk protein is impacting on reflux and the formula should be stopped.

Where infants with GOR respond to milk free formula, they should be challenged with regular formula after 4 weeks and if symptoms reoccur they will need to be initially weaned onto a milk free diet and referred to a specialist dietitian for support. A milk challenge should be repeated between 9 and 12 months, to be agreed with the dietitian based on clinical symptoms.

References

NICE 2011 Food Allergy in Children and Young People

Food Hypersensitivity- diagnosing and managing food allergies and intolerances (2009), Skypala I, Venter C. Wiley-Blackwell 978-1-4051-7039-9

Clinical Paediatric Dietetics (2007), Shaw V, Lawson M. Blackwell Publishing 978-14051-3493-4

Venter C, Brown T, Shah N, Walsh J, Fox AT. Diagnosis and management of non-IgE-mediated cow's milk allergy in infancy – a UK primary care practical guide [Online]. Clin Transl Allergy 2013;3(1):23. Available at: <http://www.ctajournal.com/content/3/1/23>

The iMAP Guidelines- Milk Allergy in Primary Care February 2017 UK Version.
<https://www.allergyuk.org/health-professionals/mapguideline>

Appendix

Recognition of a food allergy (NICE 2011 Food Allergy in Children and Young People)

Consider the possibility of food allergy in children and young people whose symptoms do not respond adequately to treatment for:

- atopic eczema¹
- gastro-oesophageal reflux disease
- chronic gastrointestinal symptoms, including chronic constipation.

Or has one or more of the signs and symptoms in **Table 1** (pay particular attention to persistent symptoms that involve different organ systems)

Table 1. Signs and symptoms of possible food allergy

Note: this list is not exhaustive. The absence of these symptoms does not exclude food allergy

IgE-mediated	Non-IgE-mediated
The skin	
Pruritus	Pruritus
Erythema	Erythema
Acute urticaria – localised or generalised	Atopic eczema
Acute angioedema – most commonly of the lips, face and around the eyes	
The gastrointestinal system	
Angioedema of the lips, tongue and palate	Gastro-oesophageal reflux disease
Oral pruritus	Loose or frequent stools
Nausea	Blood and/or mucus in stools
Colicky abdominal pain	Abdominal pain
Vomiting	Infantile colic
Diarrhoea	Food refusal or aversion
	Constipation
	Perianal redness
	Pallor and tiredness
	Faltering growth in conjunction with at least 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)	
Upper respiratory tract symptoms (nasal itching, sneezing, rhinorrhoea or congestion [with or without conjunctivitis])	
Lower respiratory tract symptoms (cough, chest tightness, wheezing or shortness of breath)	
Other	
Signs or symptoms of anaphylaxis or other systemic allergic reactions	

¹ For information about treatment for atopic eczema see 'Atopic eczema in children' (NICE clinical guideline 57)