



Prescribing of specialist infant formula in primary care

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The guidelines are targeted at infants aged 0-12 months. However, some of the items mentioned here can be used past this age. Prescribing advice on this is included.

Whilst these guidelines advise on appropriate prescribing of specialist infant formula, breast milk remains the optimal milk for infants. This should be promoted and encouraged where it is clinically safe to do so and the mother is in agreement.

Referrals to Nutrition and Dietetic Service

All patients should be referred to Dietetics except for those started on a special infant formula for Secondary lactose intolerance. They should be referred if symptoms do not resolve once standard formula is recommenced (usually within 8 weeks).

Any patient that requires a dietetic referral should have the referral discussed with the parents/carers of the infant and the referral should contain the following information (in addition to standard patient information).

- Reason for referral for dietary advice / assessment
- Relevant social history, including if the child is a 'child in need' or on a child protection plan
- Relevant biochemical and weight measurements including weight history, head circumference and length
- Relevant dietary history
- Language requirements / need for interpreter

Dietetic Teams:

Coventry 02476 966161

Nuneaton 02476 865098

Warwick 01926 495321 (Ext 4258)

Where appropriate please refer to the Coventry and Warwickshire Pathology Services document on the Investigation of suspected lactose or milk-protein Intolerance in infants available on the Coventry and Warwickshire APC website.

Quantities of formula 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	or	12 x 450g tins	or	6 x 900g tins
6-12 months	7-13 x 400g/450g			or	3-6 x 900g tins
Over 12 months	7 x 400g tins	or	6 x 450g tins		3 x 900g tins

These amounts are based on:

- Infants under 6 months being exclusively formula fed and drinking 150ml/kg/day of a normal concentration formula.
- Infants 6-12 months requiring less formula as solid food intake increases.
- Children over 12 months drinking the 600ml of milk or milk substitute per day recommended by the Department of Health.

For liquid high energy formula:

Prescribe an equivalent volume of formula to the child's usual intake until an assessment has been performed and recommendations made by a paediatrician or paediatric dietitian.

N.B. Some children may require more, e.g. those with faltering growth. Review recent correspondence from the paediatrician or paediatric dietitian.

Recommendations

DO	Promote and encourage breast-feeding where it is clinically safe and the mother is in agreement. Provide information on local services available to support this.
	Advise about a maternal milk free diet for infants with cows' milk protein allergy (CMPA) who are breast fed.
	Check any formula prescribed is appropriate for the age of the infant.
	Check the amount of formula prescribed is appropriate for the age of the infant and/or refer to the most recent correspondence from the paediatric dietitian.
	Review any prescription where the child is over two years old, the formula has been prescribed for more than one year, or greater amounts of formula are being prescribed than would be expected.
	Review the prescription if the patient is prescribed a formula for CMPA but able to eat or drink any dairy containing foods such as cow's milk, cheese, yogurt, ice cream, custard, chocolate, cakes, cream, butter, margarine, ghee (list is non-exhaustive).
	Prescribe only two to four tins/bottles initially until compliance/patient acceptability is established to avoid waste.
	Remind parents to follow the advice given by the formula manufacturer regarding safe storage of the feed once mixed or opened.

DO NOT	Add infant formula to the repeat prescribing template in primary care, unless a review process is established to ensure the correct product and quantity is prescribed for the age of the infant.
	Prescribe NON - ACBS approved infant formulas. They should be purchased.
	Prescribe lactose free formula (SMA LF [®] , Enfamil O-Lac [®]) for infants with CMPA.
	Routinely prescribe soya formula (SMA Wysoy [®]) for those with CMPA or secondary lactose intolerance. It should not be prescribed at all in those under six months due to high phyto-oestrogen content.
	Suggest goat's milk and formula made from it, sheep's milk or other mammalian milks for those with CMPA or secondary lactose intolerance.
	Suggest rice milk for those under five years due to high arsenic content.
	Prescribe Nutriprem 2 Liquid [®] or SMA Gold Prem 2 Liquid [®] unless there is a clinical need.
	Formula that thicken in the stomach should not be used in conjunction with separate thickeners or in conjunction with medication such as antacids, ranitidine, or proton pump inhibitors, since the formula need stomach acids to thicken and reduce reflux.
	Pre-thickened formula should not be used along with other thickening agents, e.g. Gaviscon [®] , Carobel [®] to avoid over thickening of the stomach contents.
	Suggest Infant Gaviscon [®] more than six times in 24 hours or where the infant has diarrhoea or a fever, due to its sodium content.
Prescribe low lactose/lactose free formula in children with secondary lactose intolerance over one year old who previously tolerated cow's milk, since they can use lactose free products (e.g. Lactofree [®]) from supermarket.	

Cow's milk protein allergy (CMPA)

Symptoms and diagnosis:

- Refer to NICE clinical guideline CG116 'Food Allergy in Children and Young People' Feb 2011 for full details.¹
<http://guidance.nice.org.uk/CG116>
- Useful CMPA diagnosis and management flowcharts are available in 'Diagnosis and management of non-immunoglobulin-E (IgE) mediated cow's milk allergy in infancy.'² <http://www.ctajournal.com/content/3/1/23>
- Symptoms are usually severe and of acute onset if the allergy is IgE-mediated and have a delayed onset if the allergy is non-IgE mediated. Symptoms can include:^{3,4}
 - Skin symptoms (pruritis, erythema, urticaria, atopic dermatitis).
 - Acute angioedema of the lips and face, tongue and palate, and around the eyes.
 - GI symptoms (diarrhoea, bloody stools, nausea and vomiting, abdominal distension and /or colicky pain, constipation, GOR).
 - Recurrent wheeze or cough, nasal itching, sneezing, rhinorrhoea or congestion.
 - Anaphylaxis.
 - Faltering growth.

Timing of onset of symptoms:

NICE recommends further investigation with a skin prick test or specific IgE antibody blood test if IgE-mediated allergy is suspected.¹ When non-IgE mediated allergy is likely, trial elimination for two to six weeks of the suspected allergen is advised.¹ Most infants with CMPA develop symptoms within one week of introduction.⁵

Onward referral:

Most infants with CMPA can be managed in primary care until weaned.

Referral to a paediatric dietitian should be made prior to weaning for all infants who will require a cow's milk free diet. Breastfeeding mothers following a milk free diet should be referred to the paediatric dietitian who will advise on both the mother's and the child's diet.

Refer to secondary or specialist care if any of the following apply:¹

- Faltering growth with one or more gastrointestinal symptoms.
- Acute systemic reactions or severe delayed reactions.
- Significant atopic eczema where multiple or cross-reactive food allergies are suspected by the parent or carer.
- Possible multiple food allergies.
- Persisting parental suspicion of food allergy despite a lack of supporting history (especially where symptoms are difficult or perplexing).

Dietary management:^{1,6,7}

- If symptoms persist in the exclusively breast-fed infant, a maternal milk free diet is indicated for a minimum trial of two weeks.
- Breast milk is the best choice for most infants with CMPA. Breastfeeding mothers on a milk free diet may require supplementation with 1000mg calcium per day.
- If breastfeeding is not occurring, extensively hydrolysed formula (EHF) are the first choice, unless the infant has a history of anaphylaxis to cow's milk, Heiner Syndrome, eosinophilic oesophagitis and severe gastro-intestinal and/or skin presentations, particularly in association with faltering growth.²
- Amino acid formula (AAF) should normally be started in secondary or specialist care. They are suitable only when EHF does not resolve symptoms and/or there is evidence of severe (anaphylactic) allergy.
- If breastfeeding mothers do not wish to or are unable to follow a milk free diet, or are following a milk free diet and symptoms persist, an AAF will be needed if top-ups are required and can be prescribed in primary care.
- If a patient has a history of anaphylactic reaction to cow's milk, AAF may be started in primary care, with immediate onward referral to secondary or specialist care.

CMPA first line options for primary care:

First line treatment is with an EHF⁸. For mild to moderate non- IgE cow's milk protein allergy, an initial trial of EHF should be followed by reintroduction of cow's milk protein formula after two to four weeks to confirm the diagnosis.

EHF and AAF (see second line options) have an unpleasant taste and smell, which is better tolerated by younger patients. It is widely accepted that whey based EHF's are more palatable than casein based EHF's, which may have an impact on volume consumed. The presence of lactose in an EHF also aids the palatability of the formula. Unless there is anaphylaxis, advise parents to introduce the new formula gradually by mixing with the usual formula in increasing quantities until the transition is complete. Serving in a closed cup or bottle or with a straw (depending on age) may improve tolerance.

EHF formulations available for CMPA (including lactose free preparations) ⁹			
	Product	Presentation	Age Restrictions
Lactose free products	Similac Alimentum	400g tin	Birth to 12 months
	Nutramigen 1 with LGG [®]	400g tin	Birth to 6 months
	Nutramigen 2 with LGG [®]	400g tin	6 months to 2 years
Lactose containing products	Althera [®]	450g tin	Birth to 2 years
	Aptamil Pepti 1 [®]	400g / 800g tins	Birth to 6 months
	Aptamil Pepti 2 [®]	400g / 800g tins	6 months to 2 years

Secondary line options:

Prescribing of these second line options should be initiated by a specialist.

- **Extensively hydrolysed formula with medium chain triglycerides (MCT)** These formulas are used where CMPA is accompanied by malabsorption.
- **Amino acid formula (AAF)** The AAF products are listed below. They are suitable only when an EHF does not resolve symptoms and/or there is evidence of severe (anaphylactic) allergy or if formula top-ups are needed for a child who is otherwise breastfed (mother on a milk free diet). Consequently, they should not normally be started in primary care, except if the infant has a history of anaphylactic reaction to cow's milk and is immediately referred to secondary care.

For some formula, calcium supplementation may be needed for infants depending on volume and type of formula taken. Breastfeeding mothers on a milk free diet may also need a calcium supplement. The dietitian will advise.

EHF with MCT formulations available to treat CMPA with malabsorption⁹		
Product	Presentation	Age Restrictions
Pepti-Junior® (contains lactose)	450g tin	Birth to 2 years
Pregestimil Lipil® (lactose free)	400g tin	Birth to 2 years
AAF formulations available to treat CMPA⁹		
Product	Presentation	Age Restrictions
Alfamino	400g tin	Birth until infant grows out of allergy
Nutramigen Puramino®	400g tin	Birth until infant grows out of allergy
Neocate LCP®	400g tin	Birth until infant grows out of allergy
Neocate Active® *see also under high energy	15 x 63g sachets	Over 1 year
Neocate Advance® *see also under high energy	15 x 50g sachets 10 x 100g sachets	Over 1 year
Neocate Junior® *see also under high energy	400g	Over 1 Year

Neocate Junior will replace Neocate Active and Neocate Advance over a period of 12 months, from April 2017 to April 2018.

Review and discontinuation of dietary management and challenges with cow's milk:

- Review prescriptions regularly to check that the formula prescribed is appropriate for the child's age.
- Quantities of formula required will change with age – see guide to quantities required (page 1) and/ or refer to the most recent correspondence from the paediatric dietitian.
- Avoid adding to the repeat template for these reasons, unless a review process is established.
- Challenging with cow's milk - The child should be evaluated every six to 12 months to assess whether they have developed a tolerance to cow's milk protein. This can be done at home provided there are no indications for referral to secondary care, for example one or more acute systemic reactions.¹⁰
- Prescriptions should be stopped when the child has outgrown the allergy. According to the latest European data, 57 to 69% of CMPA infants are able to tolerate cow's milk 12 months after initial diagnosis.¹¹
- Review the need for the prescription if you can answer 'yes' to any of the following questions:
 - Is the patient over two years of age?
 - Has the formula been prescribed for more than one year?
 - Is the patient prescribed more than the suggested quantities of formula according to their age?
 - Is the patient prescribed a formula for CMPA but able to eat/drink any of the following foods – cow's milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee? (Cooked milk products are usually better tolerated.)¹²
- Children with multiple or severe allergies may require prescriptions beyond two years. This should always be at the suggestion of the paediatric dietitian.

Additional notes:

- Soya formula (Wysoy®) should not routinely be used for patients with CMPA. It should not be used at all for those under six months due to high phyto-oestrogen content.^{8,13} It should only be advised in patients over six months who do not tolerate first line EHF since there is a risk that infants with CMPA may also develop allergy to soya. It is more likely that children will tolerate soya formula from one year. Parents should be advised to purchase soya formula as it is a similar cost to cow's milk formula and readily available. From two years, supermarket calcium enriched soya or oat milk may be suitable as an alternative. Alpro® Junior 1-3 + soya milk may be suitable from one year if the child is growing and eating well. The paediatric dietitian will advise on suitable over-the-counter products for appropriate ages.
- Rice milk is not suitable for children under five years due to its arsenic content.¹⁴
- Lactose free formula (SMA LF®, Enfamil O-Lac with LIPIL®) are not suitable for those with CMPA.
- Goat's, sheep, and other mammalian milks are not suitable for those with CMPA.
- Lactose and glucose polymers should be the preferred carbohydrates in formula based on cow's milk protein and hydrolysed protein. Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formulas.¹⁵
- Parents and carers should follow the manufacturer's advice for the safe preparation and storage of feeds.
- Calcium supplementation may be needed for infants depending on volume and type of formula taken. Breast-feeding mothers on a milk free diet may also need a calcium supplement, the dietitian will advise.
- There is no evidence to suggest that changing the brand of infant formula causes any harm.¹⁶

Gastro-oesophageal reflux (GOR)¹⁸

Symptoms and diagnosis:

- GOR is the passage of gastric contents into the oesophagus causing troublesome symptoms and/or complications.
- Symptoms may include regurgitation of a significant volume of feed, reluctance to feed, distress/ crying at feed times, small volumes of feed being taken.
- Diagnosis is made from history that may include effortless vomiting (not projectile) after feeding (up to two hours), usually in the first six months of life, and usually resolves spontaneously by 12-15 months age.
- It should be noted that 50% of babies have some degree of reflux at some time.
- Specific infant formula is not always necessary and resolution of symptoms can occur through reducing the quantity of feed and suitable positioning post-feed.

Overfeeding needs to be ruled out by establishing the volume and frequency of feeds. Average requirements of formula are 150mls/kg/day for babies up to six months, and should be offered spread over six to seven feeds.

Onward referral:

Infants with faltering growth as a result of GOR should be referred to paediatric services without delay.

If symptoms do not improve one month after commencing treatment refer to a paediatrician for further investigations since CMPA can co-exist with GOR and treatment as for CMPA may be required.

Treatment :

- If the infant is thriving and not distressed reassure the parents and monitor.
- Provide advice on avoidance of overfeeding, positioning during and after feeding, and activity after feeding. If bottle-fed suggest over-the-counter (OTC) products listed below.
- If the bottle fed infant is not gaining weight and/or not settled trial with thickening formula or antacid, e.g. Infant Gaviscon®. Advice for those with faltering growth will be given by secondary/ specialist care.
- If breast-fed infant is not gaining weight and/or not settled trial with Infant Gaviscon® offered on a spoon before feeds. Advice for those with faltering growth will be given by secondary/specialist care.
- Pre-thickened formulas should not be used along with other thickening agents, e.g. Gaviscon®, Carobel® to avoid over thickening of the stomach contents. Over the counter pre-thickened formula contain carob gum. This produces a thickened formula and will require the use of a large hole (fast-flow) teat.
- Formulas that thicken in the stomach react with stomach acids to thicken and should not be used in conjunction with separate thickeners or with medication such as ranitidine, or proton pump inhibitors. As they thicken in the stomach rather than the bottle there is no need to use a large hole (fast flow) teat.
- Alert parents/carers to the need to make up formula that thicken in the stomach and pre-thickened formula with fridge cooled pre-boiled water (see tin for full instructions).
- Thickeners such as Infant Gaviscon® are preferred for babies who vomit immediately post-feed. Infant Gaviscon® contains sodium, and should not be given more than six times in 24 hours or where the infant has diarrhoea or a fever. N.B. Each half of the dual sachet of Infant Gaviscon® is identified as 'one dose'. To avoid errors, prescribe with directions in terms of 'dose'. Dispensing pharmacists should advise about appropriate doses of OTC products.

Over the counter Thickened formulas to be purchased – Not allowed on prescription	
<i>In the first instance, Carobel® can be used to thicken standard formula or one of the following can be tried</i>	
Aptamil® Anti-reflux (Milupa)	Birth to one year (pre-thickened)
Cow & Gate® Anti-reflux (Cow & Gate)	Birth to one year (pre-thickened)
SMA PRO Anti-Reflux (SMA)	Birth to one year (pre-thickened)
Note: Thickening Formulas – to be purchased but if necessary can be prescribed	
Enfamil AR® (Mead Johnson)	Birth to 18 months (thickens in the stomach - contains rice starch)

Review and discontinuation of treatment:

- Review after one month.
- Infants with GOR will need regular review to check growth and symptoms.
- Since GOR will usually resolve spontaneously between 12-15 months, cessation of treatment can be trialled from 12 months.

Lactose intolerance¹⁹

Symptoms and diagnosis:

- Primary lactase deficiency is less common than secondary lactose intolerance and does not usually present until after two years of age and may not fully manifest until adulthood.
- Secondary lactose intolerance usually occurs following an infectious gastrointestinal illness but may be present alongside newly or undiagnosed coeliac disease.
- Symptoms include abdominal bloating, increased (explosive) wind, loose green stools.
- Lactose intolerance should be suspected in infants who have had any of the above symptoms that persist for more than two weeks.
- Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis.

Onward referral:

- If symptoms do not resolve when standard formula and/or milk products are reintroduced to the diet, refer to secondary or specialist care.
- Refer to the paediatric dietitian if the child is weaned and a milk free diet is required.
- Congenital lactase deficiency requires specialist management.

Treatment:

Treat secondary lactose intolerance with low lactose/lactose free formula for six to eight weeks to allow symptoms to resolve. Rarely symptoms may last up to three months. Standard formula and/or milk products should then be slowly reintroduced to the diet.

Lactose free formula can be purchased at a similar price to standard formula and the GP should not routinely prescribe; advice to use lactose free formula with appropriate safety netting (advice on what to do if symptoms do not improve) may be all that is needed and parents should be asked to purchase the quantity required.

In infants who have been weaned, low lactose/lactose free formula should be used in conjunction with a milk free diet. In children over one year who previously tolerated cow's milk, do not prescribe low lactose/lactose free formula. Suggest use of lactose free full fat cow's milk, yoghurt and other dairy products which can be purchased from supermarkets (Lactofree® brand).

Soya formula (SMA Wysoy®) should not routinely be used for patients with secondary lactose intolerance. It should not be prescribed at all for those under six months due to high phyto-oestrogen content. It should only be advised in patients over six months who do not tolerate the first line formula suggested here. Parents should be advised to purchase it as it is a similar cost to cow's milk formula and readily available.

Over the counter Low lactose/lactose free formula <i>can be purchased but if necessary can be prescribed</i>	
SMA LF® (low lactose, whole protein cows milk formula)	Birth to two years but see treatment note above for those over one year.
Enfamil O-Lac with LIPL (lactose, sucrose and fructose free cow's milk formula)	Birth to one year

Review and discontinuation of treatment:

Low lactose/lactose free formula should not be used/prescribed for longer than eight weeks without review and trial of discontinuation of treatment.

Faltering growth

The NICE clinical guideline entitled 'Faltering Growth – recognition and management of faltering growth in children' is currently in development and is due to be published in October 2017.²⁰

Symptoms and diagnosis:

- Diagnosis is made when the growth of an infant falls below the 0.4th centile or crosses 2 centiles downwards on a growth chart or weight is 2 centiles below length centile.
- The height/length of an infant are measured to properly interpret changes in weight using appropriate growth charts to be able to diagnose.
- Individual growth pattern, feeding behaviours, parental factors and any indicators of underlying illness should be taken into account when assessing the need for high energy formula.
- It is essential to rule out possible disease related/medical causes for the faltering growth e.g. iron deficiency anaemia, constipation, GOR or a child protection issue. If identified appropriate action should be taken.

Onward referral:

- Infants with faltering growth should be referred to paediatric services without delay.
- Refer any infant who is weaned to a paediatric dietitian for advice on a high energy high protein diet.
- If the problem appears related to food refusal/fussy eating, consider referral for behavioural intervention.

Treatment:

- Prescribe an equivalent volume of high energy formula to the child's usual intake of regular formula until an assessment has been performed and recommendations made by a paediatrician or paediatric dietitian.
- For otherwise healthy term infants who are born with birthweight <10th centile (small for gestational age), current evidence suggests that it is not beneficial to promote catch-up growth in these infants as it may increase later risk of obesity and metabolic disease. If they are otherwise healthy, they should be breast-fed or fed with a standard term formula.
- Where all nutrition is provided via nasogastric (NG)/nasojejunal (NJ)/percutaneous endoscopic gastrostomy (PEG) tubes, the paediatric dietitian will advise on appropriate monthly amounts of formula required which may exceed the guideline amounts for other infants. These formulas are not suitable as a sole source of nutrition for infants over 8kg or 18 months of age.
- Do not add formula to repeat templates as ongoing need for formula and amount required will need to be checked with each prescription request.
- Manufacturer's instructions regarding safe storage once opened and expiry of ready to drink formula should be adhered to – this may differ from manufacturer to manufacturer.
- Neocate Junior will replace Neocate Active and Neocate Advance over a period of 12 months, from April 2017 to April 2018.

High energy formula for faltering growth ⁹		
Product	Presentation	Age / Weight Restrictions
SMA PRO High Energy®	200mls	Birth up to 18 months
Infatrini®	125mls/200mls/500ml	Birth up to 18 months or 8kg
Similac High Energy®	200mls/ 48 x 60ml	Birth up to 18 months
Neocate Active® *see also under high energy	15 x 63g sachets	Over 1 Year
Neocate Advance® *see also under high energy	15 x 50g sachets 10 x 100g sachets	Over 1 Year
Neocate Junior® *see also under high energy	400g	Over 1 Year
High energy formula to be started in secondary care only		
(N.B. This formula is suitable for infants with faltering growth and intolerance to whole protein feeds, e.g. short bowel syndrome, intractable malabsorption, inflammatory bowel disease, bowel fistulae.)		
Product	Presentation	Age / Weight Restrictions
Infatrini Peptisorb®	200mls	Birth up to 18 months or 8kg

Review and discontinuation of treatment:

- The team to whom the infant is referred should indicate who is responsible for review and discontinuation. If the team hand responsibility back to the GP this should be with an indication of what the goal is at which point discontinuation can occur.
- All infants on high energy formula will need growth (weight and height/length) monitored regularly to ensure catch up growth occurs.

Once this is achieved the formula should be discontinued to minimise excessive weight gain

Post discharge nutrition for pre-term infants²¹⁻²³

Indications: These infants will have had their prescribed formula commenced on discharge from the neonatal unit.

- It should not be started in primary care.
- It is started for babies born before 34 weeks gestation, weighing less than 2kg at birth.
- These formulas should not be used in primary care to promote weight gain in patients other than babies born prematurely.

Onward referral: These infants should already be under regular review by the paediatricians.

- If there are concerns regarding growth whilst the infant is on these formulas, refer to the paediatric dietitian.
- If there are concerns regarding growth at six months corrected age or at review one month after these formula are stopped, refer to the paediatric dietitian.

Pre-term infant formula to be initiated in secondary care ⁹		
Product	Presentation	
Nutriprem 2 [®]	900g	Birth up to a maximum of 6 months corrected age
SMA PRO Gold Prem 2 [®]	400g	Birth up to a maximum of 6 months corrected age
Pre-term infant formula which should not routinely be prescribed unless there is a clinical need, e.g. immunocompromised infant		
Nutriprem 2 liquid [®]	200mls	Birth up to a maximum of 6 months corrected age
SMA PRO Gold Prem 2 liquid [®]	90mls/200mls	Birth up to a maximum of 6 months corrected age

Review and discontinuation of treatment:

- The Health Visitor or other suitable healthcare professional should monitor growth (weight, length and head circumference) while the baby is on these formulas.
- These products should be discontinued by six months corrected age.
- Not all babies need these formulas for the full 26 weeks from expected date of delivery (EDD).
- If there is excessive weight gain at any stage up to six months corrected age, stop the formula.

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