NHS West Essex Clinical Commissioning Group

All conditions **How much powdered infant formula should I prescribe monthly?** Please note: Only prescribe 1 or 2 tins initially until compliance/ tolerance is established to avoid waste	Under 6 months	6-12 months	12 months- 2 years*
	13 x 400g, 12 x 450g or 6 x 900g tins	**7-13 x 400g/450g or 3-6 900g tins**	**7 x 400g, 6 x 450g or 3 x 900g tins**

Cow's milk protein allergy (CMPA)

- Symptoms differ if the allergy is IgE-mediated or non-IgE mediated and can include: timing of onset of symptoms skin symptoms, e.g. pruritis, erythema, urticaria, atopic dermatitis, acute angioedema. GI symptoms, e.g. diarrhoea, bloody stools, nausea and vomiting, abdominal distention, irritability, constipation, Gastro-Oesophageal Reflux Disease (GORD), respiratory symptoms, e.g. current wheeze or cough, nasal itching, sneezing, rhinorrhoe or congestion, anaphylaxis or faltering growth. An allergy focused clinical history (click here) and physical examination is required for accurate diagnosis. Refer to WECCG GOR/ CMPA guidance (click here). **Most infants with CMPA develop symptoms within one week of introduction.**

Refer infants with faltering growth or anaphylaxis to secondary care

- **Breast milk is the best choice for most infants with CMPA.** A maternal milk free diet is indicated for a minimum trial of two weeks. Breastfeeding mothers on a milk free diet require a suitable calcium fortified milk substitute click here for information leaflet. These mothers may also require supplementation with calcium +/- vitamin D- refer mother to a dietitian for individual assessment of requirements.

IgE mediated CMPA is suspected:

- NICE recommends referral to secondary/specialist care for further investigation with a serum specific IgE antibody blood test or a skin prick test.

Mild to moderate non-IgE mediated CMPA:

- can be managed in Primary Care following an allergy focused clinical history and will involve initial elimination of cow's milk protein followed by a **re-challenge, within 6 weeks, to confirm diagnosis.** Click here for WECCG GOR/CMPA management guidelines NOTE: CMPA can exist with GORD

EXTENSIVELY HYDROLYSED FORMULAE (lactose free) FIRST LINE	**Similac Alimentum®** 400g	• If formula top-ups are needed for breast fed infants • *Nutramigen 2 with LGG® may be a more appropriate first line for infants whom (following assessment by a dietitian) there are concerns about insufficient calcium intake.
EXTENSIVELY HYDROLYSED FORMULAE (containing lactose) SECOND LINE	**SMA Althéra®** 450g	• This formula can be tried if the infant/child is not tolerating the first-line product because of taste.
AMINO ACID FORMULAE & IMMEDIATE ONWARD REFERRAL TO SECONDARY CARE	**Nutramigen Puramino®** 400g	• If Extensively Hydrolysed Formula does not resolve symptoms • If there is evidence of severe (anaphylactic) allergy

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	• Challenging with cow's milk to confirm the clinical remission of mild to moderate non-IgE Cow's Milk Protein Allergy - usually at 9 to 12 months of age or after at least 6 completed months of exclusion. This can be done at home provided there are no indications for referral to secondary care (i.e. immediate symptoms). Click here for milk ladder. • **Prescriptions should be stopped** when the child has grown out of the allergy. *Children with multiple or severe allergies may require prescriptions beyond 2 years old. This should always be on the recommendation and supervision of a paediatric dietitian/specialist. • Refer to NICE clinical guideline CG116 'Food Allergy in Children and Young People', Feb 2011. (click here) • Refer to iMAP guideline (International Milk Allergy in Primary Care) for presentation of CMPA, Aug 2019. (click here)

DOS AND DON'TS OF PRESCRIBING SPECIALIST INFANT FORMULAE

DO	Promote and encourage breast-feeding where it is clinically safe and the mother is in agreement. For information on local services available to support this encourage the mother to liaise with her health visitor.
	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 2 years old, the formula has been prescribed for more than 1 year, or greater amounts of formula are being prescribed than would be expected.
	Review the prescription if the patient is prescribed a formula for Cow's Milk Protein Allergy but able to eat any of the following foods – cow's milk, cheese, yogurt, ice cream, custard, chocolate, cakes, cream, butter, margarine, ghee (list is non-exhaustive).
	Prescribe only 1 or 2 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.
	Refer where appropriate to secondary or specialist care - see advice for each condition.
	Refer where appropriate to the paediatric dietitians e.g. prior to weaning for infants who will require a cow's milk free diet.
	Seek prescribing advice if needed in primary care from the Medicines Optimisation Team, and in secondary care from the local Hospital Medicines Information Centre.

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DO NOT	Add infant formulae 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 lactose free formulae (SMA LF®, Enfamil-O-Lac with Lipil®) for infants with Cow's Milk Protein Allergy.
	Routinely prescribe soya formula (SMA Wysoy®) for those with Cow's Milk Protein Allergy or secondary lactose intolerance. It should not be prescribed at all in those under 6 months due to high phytoestrogen content. May be appropriate for a vegan diet – discuss benefits vs risks.
	Suggest milk/formulae made from goat, sheep or mammalian milks for those with Cow's Milk Protein Allergy or secondary lactose intolerance.
	Suggest rice milk for those under 5 years due to high arsenic content.
	Prescribe Nutriprem 2 Liquid® or SMA Gold Prem 2 Liquid® unless there is a clinical need.
	Formulae 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 formulae need stomach acids to thicken and reduce reflux.
	Pre-thickened formulae 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 6 times in 24 hours or where the infant has diarrhoea or a fever, due to its sodium content.
	Prescribe low lactose/lactose free formulae in children with secondary lactose intolerance over 1 year who previously tolerated cow's milk, since they can use lactose free products (e.g.Lactofree®) from supermarkets.

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Gastro-oesophageal reflux disease (GORD)

- **Symptoms** may include regurgitation of a significant volume of feed, reluctance to feed, distress / crying at feed times, small volumes of feed being taken.

Refer infants with faltering growth to secondary care without delay

- **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 to 15 months age.
- It should be noted that 50% of babies have some degree of reflux at some time.
- Specific infant formulae 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.
- Introduction of weaning early (4 to 6 months) may improve the reflux.
- Infants with Gastro-Oesophageal Reflux Disease will need regular review to check growth and symptoms.
- Once vomiting resolves return to standard formula.
- NOTE: Cow's Milk Protein Allergy can co-exist with Gastro-Oesophageal Reflux Disease. Click here for West Essex CCG'S GOR/CMA management guidelines.

Gaviscon

Gaviscon is no longer considered a useful part of reflux management; it can often cause more side effects than help. More appropriate treatment is either 'stay down / thickened / anti-reflux' formula or breast milk thickener i.e. carobel®.

If Infant Gaviscon® is prescribed, please note it contains sodium, and should not be given more than six times in 24 hours or where the infant has diarrhoea or a fever. Each half of the dual sachet of Infant Gaviscon® is identified as 'one dose'. To avoid errors, prescribe with directions in terms of

Recommend over the counter formula from community pharmacy (similar price to standard formula): Cow and Gate® or Aptamil® anti-reflux, Enfamil AR® or SMA Stay Down®. NOTE: can obtain using 'healthy start' vouchers if on low income*.

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Gastro-oesophageal reflux disease (GORD)

Ranitidine

Method of preparation & administration:

Please refer to the Medicines for Children Leaflet "Ranitidine for Acid Reflux"
https://www.medicinesforchildren.org.uk/ranitidine-acid-reflux

Doses of Ranitidine need to be increased as the child gains weight. If the dose is not increased enough the symptoms will return.

Age of Child	Dose of Ranitidine /kg required
1month to 6months	1mg/kg three times daily, increasing to 2mg/kg three times a day if necessary then increasing if necessary to a maximum of 3mg/kg three times daily
6 months to 2 years	2mg/kg twice daily, increasing if necessary to 3mg/kg twice a day, then if necessary increasing to a maximum of 4mg/kg twice daily.
3 years to 11 years	2–4 mg/kg twice daily (max. per dose 150 mg) increased to up to 5 mg/kg twice daily (max. per dose 300 mg), dose increase for severe gastro-oesophageal disease.

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Gastro-oesophageal reflux disease (GORD

Omeprazole

Prescribers should stick to multiples of half a tablet, so anyone less than 1 year old will get 5, 10, 15 or possibly 20mg per dose. Anything else is unmeasurable because the tablets do not disperse evenly. Warming the water slightly can help the dissolution process and slightly more volume can be used if the patient can tolerate it. The resulting liquid is a suspension rather than a clear solution. Some prescribers may choose to round up to the nearest easy tablet dose because halving a tablet cannot guarantee an exact dose – it's a time limited trial anyway.

The use of such liquids (unlicensed specials) should only be prescribed to those patients with feeding tubes because it is least problematic in blocking the tube. Everyone else should get the MUPS dissolved in water (unlicensed use in children).

In a child already weaned prescribe Omeprazole capsules. The capsules can be opened and the contents mixed with fruit juice or yoghurt.

Method of preparation & administration:

Please refer to the Medicines for Children Leaflet "Omeprazole for Gastro-Oesophageal Reflux Disease" https://www.medicinesforchildren.org.uk/sites/default/files/content-type/leaflet/pdf/MfC_Omeprazole_for_GORD_PV2_2015-03-20.pdf)

Doses Required:

Doses of Omeprazole need to be increased as the child gains weight. If the dose is not increased enough the symptoms will return.

Age of Child	Dose of Omeprazole/ kg required
1month to 2years	700mcg/kg once daily, increased if necessary to 1.4m/kg then if necessary to a maximum of 3mg/kg (max 20mg) once daily
2 years to 17 years Body weight 10 to 19kg	10mg once daily increased if necessary to 20mg once daily (if severe reflux, max. 12 weeks at higher dose)

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Lactose intolerance	• Primary lactase deficiency usually occurs after two years of age and may not fully manifest until adulthood. Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis. • Congenital lactase deficiency requires specialist management. • Secondary lactose intolerance usually occurs following an infectious GI illness (but can occur alongside new or undiagnosed coeliac disease). • Symptoms include abdominal bloating, increased explosive wind and loose green stools and persist for more than two weeks. • If symptoms return when standard formula and/or milk products are reintroduced to the diet, refer to secondary or specialist care.
	Recommend over the counter formula from community pharmacy (similar price to standard formula): Enfamil-O-Lac with Lipil® or SMA LF®. NOTE: can obtain using 'healthy start' vouchers if on low income*.
	DO NOT recommend for longer than eight weeks without review. Symptoms usually resolve within this time but can take up to three months. For children over one year – lactose-free supermarket products are suitable.

Faltering growth	• Diagnosis is made when the growth of an infant: ○ falls across 1 or more weight centile spaces, if birthweight was below the 9th centile ○ falls across 2 or more weight centile spaces, if birthweight was between the 9th and 91st centiles ○ falls across 3 or more weight centile spaces, if birthweight was above the 91st centile ○ when current weight is below the 2nd centile for age, whatever the birthweight. • Prescribe an equivalent volume of formula to the child's usual intake unless recommended otherwise. Review recent correspondence from the paediatrician or paediatric dietitian. • The team to whom the infant is referred should indicate who is responsible for review and discontinuation.	**Refer infants to secondary care without delay**
	Started in secondary care and continued in primary care	**Infatrini® / Similac High Energy® / SMA High Energy®**

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Pre-term formulae	• These infants will have had their pre-term formula commenced in hospital. • Any infant discharged on these formulae should have their growth (this includes weight, length and head circumference) monitored by the health visitor or other suitable healthcare professional. • These products should be discontinued by six months corrected age. • Not all babies need these formulae 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.	
	Started in secondary care and continued in primary care	**SMA Gold Prem 2® powder / Nutriprem 2® powder**
	DO NOT prescribe liquid formula unless clinically indicated by secondary care e.g. immunocompromised infant	

***Healthy Start vouchers** are available for parents and carers on **low incomes** and can be used towards the cost of formula milk labelled '*suitable from birth*' *if based on cow's milk* www.healthystart.nhs.uk/

NOTES

- Halal diet

"Islamic law allows the use of hydrolysed baby milk that involves the use of pork enzyme in its production process when it is necessary to do so and there is no viable Halal alternative".

Statement provided by Mufti Zubair Butt, Shariah Advisor at Muslim Council of Britain (MCB).

- Other milk alternatives for the older child – from 2 years. Click here For information leaflet to provide to parents.

Oat milk

- Supermarket calcium enriched oat milk may be suitable as an alternative.
- The protein content is low, at about a third of that of cow's milk, and hence may not be suitable for children with nutritional deficiencies or for those with failure to thrive.
- Lactose free.

Nut milks, most common almond or hazelnut

- Nut based so would be unsuitable for infants and older children with a history of nut allergy.
- Relatively low in protein and calories so may not be suitable.

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- Enriched with calcium and some vitamins.
- Lactose free.

The paediatric dietitian will advise on suitable over-the-counter products for appropriate ages.

REFERENCES

PrescQIPP Bulletin 146 – Nutrition – Infant feeds update

NICE Clinical Guideline 116 Food Allergy in Children and Young People. 2011

Omeprazole leaflet - London Medicines Information Service, Northwick Park Hospital

The iMAP guideline (Milk Allergy in Primary Care), August 2019.

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