

## APPROPRIATE PRESCRIBING OF SPECIALIST INFANT FORMULAE

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### Colour key used on the following pages:

**GREEN** Recommended for prescribing and treatment considered to be suitable for initiation in Primary or Secondary care and continuation in Primary Care.

**YELLOW** Recommended for prescribing but only considered suitable for initiation by specialists in Secondary and Tertiary care with prescribing (and monitoring, where applicable) continued by GPs and Primary Care Clinicians. Shared care is not required but the GP must be supplied with sufficient information on the prescribed medication.

**BLACK** To be purchased over the counter from supermarket or pharmacy.

<b>References</b>	Refer to end of document
<b>Acknowledgements</b>	Mid and South Essex CCGs Medicines Management Teams
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Whilst these guidelines advise on appropriate prescribing of specialist infant formulae, 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.

It is recommended that all breast fed babies are given vitamin D supplements containing 8.5-10 micrograms ( $\mu\text{g}$ ) from birth to 1 year. If formula fed babies are taking less than 500mls of formula daily, over the counter vitamin supplements containing vitamins A,C and D will be needed.

## PURPOSE OF THE GUIDELINES

These guidelines aim to assist GPs and other practice staff, Health Visitors, Dietitians and hospital medical staff with information on the use of prescribable infant formula for the specific conditions covered in the document. The guidelines are targeted at infants 0-12 months. However, some of the prescribable items mentioned here can be used beyond this age and advice on this is included in the guidelines. The guidelines advise on:

- over the counter products available where appropriate
- initiating prescribing
- quantities to prescribe
- which products to prescribe for the specific clinical conditions covered in the guideline
- triggers for reviewing and discontinuing prescriptions
- when onward referral for dietetic advice and/or secondary/specialist care should be considered

## QUANTITIES OF FORMULA TO PRESCRIBE

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

An initial prescription of a 1 week supply or 2 x 400g tins as a trial followed by the amounts below.

#### **For powdered formula:**

<b>Age of child</b>	<b>Number of tins for 28 days</b>
Under 6 months	13 x 400g tins or 6-7 x 800g tins
6-12 months	7-13 x 400g tins or 3-7 x 800g tins
Over 12 months	7 x 400g tins or 3-4 x 800g 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 600mls 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 eg. those with faltering growth.

N.B. Review recent correspondence from the paediatrician or paediatric dietitian.

**The dietitian may suggest a formula which is not the most cost effective** if this is felt to be more clinically appropriate for the infant. When requesting a prescription which is not for the most cost effective product, the clinical justification should be included with the prescription request.

## COW'S MILK ALLERGY (CMA)

The CMA template on SystmOne and Ardens guides users on the symptoms, diagnosis and locally agreed management pathway for CMA. The template includes a symptom score (CoMiSS shown below) to aid diagnosis and a locally agreed milk allergy pathway and management strategy (pages 4 and 5).

### CoMiSS: Cow's Milk-related Symptom Score

Last name:  First name:  Age:  Date:

#### PURPOSE

The CoMiSS is a simple, fast and easy-to-use awareness tool for cow's milk-related symptoms. It increases awareness of the most common symptoms of cow's milk protein allergy (CMPA) that in turn can aid an earlier diagnosis. CoMiSS can also be used to evaluate and quantify the evolution of symptoms during a therapeutic intervention.

#### INSTRUCTIONS

If there is a suspicion of cow's milk-related symptoms, rate the observed/reported symptoms by choosing the most appropriate score for each type of symptom. Once completed, add the scores together and put the total in the box at the bottom of the scoring form.

SYMPTOM	SCORE				
<b>Crying*</b>	0	≤ 1 hour/day	SCORE <input type="text"/>		
	1	1 to 1.5 hours/day			
	2	1.5 to 2 hours/day			
	3	2 to 3 hours/day			
	4	3 to 4 hours/day			
	5	4 to 5 hours/day			
	6	≥ 5 hours/day			
<b>Regurgitation</b>	0	0 to 2 episodes/day	SCORE <input type="text"/>		
	1	≥ 3 to ≤ 5 of small volume			
	2	> 5 episodes of > 1 coffee spoon			
	3	> 5 episodes of ± half of the feeds in < half of the feeds			
	4	Continuous regurgitations of small volumes > 30 min after each feed			
	5	Regurgitation of half to complete volume of a feed in at least half of the feeds			
	6	Regurgitation of the complete feed after each feeding			
<b>Stools</b> (Bristol scale)	4	Type 1 and 2 (hard stools)	SCORE <input type="text"/>		
	0	Type 3 and 4 (normal stools)			
	2	Type 5 (soft stool)			
	4	Type 6 (liquid stool, if unrelated to infection)			
	6	Type 7 (watery stools)			
<b>Skin symptoms</b>	0 to 6	Atopic eczema	HEAD-NECK-TRUNK	ARMS-HANDS-LEGS-FEET	SCORE <input type="text"/>
		Absent	0	0	
		Mild	1	1	
		Moderate	2	2	
		Severe	3	3	
	0 or 6	Urticaria	NO	YES	SCORE <input type="text"/>
			0	6	
<b>Respiratory symptoms</b>	0	No respiratory symptoms		SCORE <input type="text"/>	
	1	Slight symptoms			
	2	Mild symptoms			
	3	Severe symptoms			

\* Crying only considered if the child has been crying for 1 week or more, assessed by the parents, without any other obvious cause.

**TOTAL SCORE**

#### READING THE RESULT

The scoring ranges from 0 to 33. Each symptom has a maximal score of 6, except respiratory symptoms where the maximal score is 3.

If final score ≥ 12, the symptoms are likely cow's milk-related. This could potentially be CMPA.

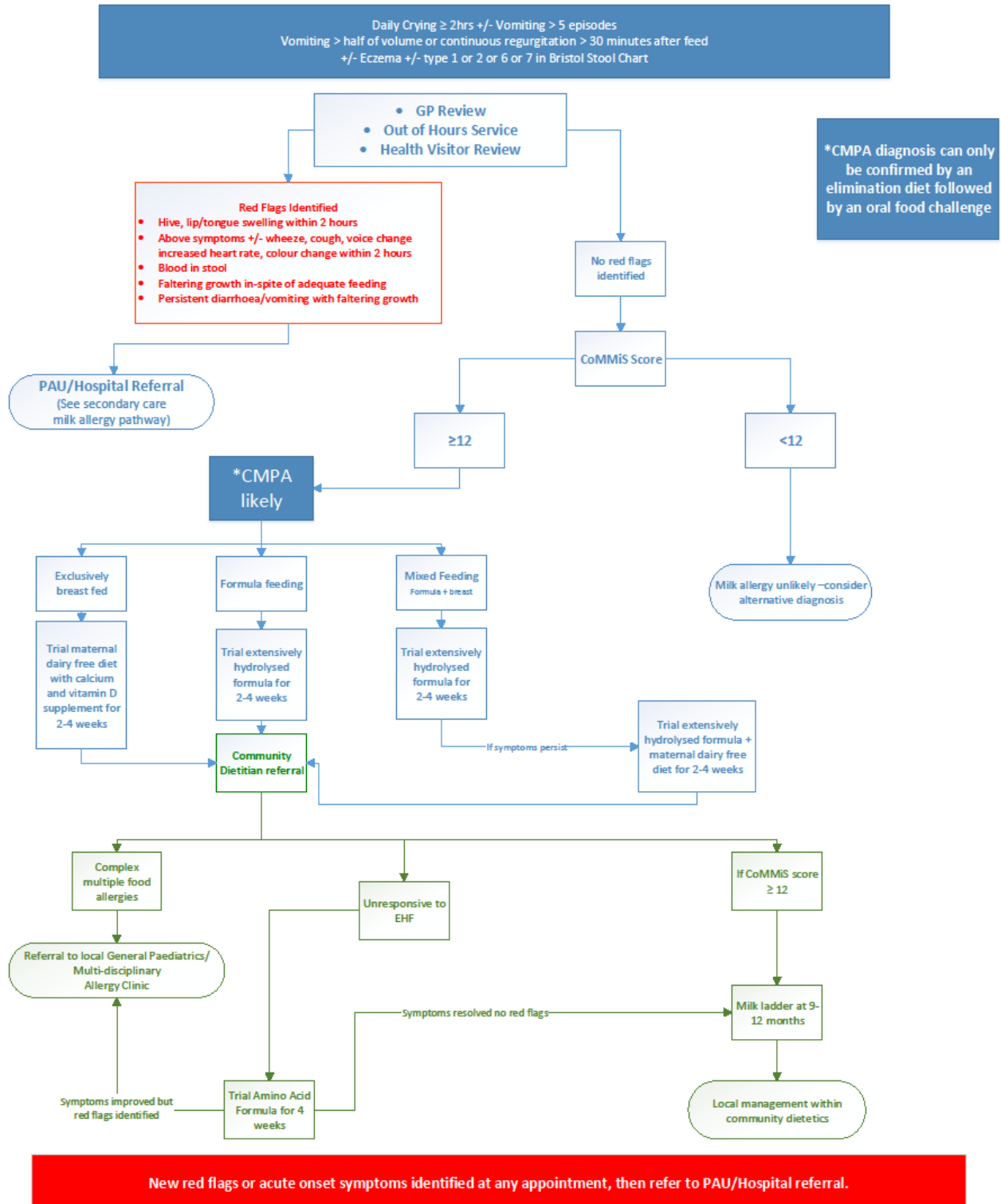
If final score < 12, the symptoms are less likely related to cow's milk. Look for other causes.

**CMPA diagnosis can only be confirmed by an elimination diet followed by an oral food challenge.**

Vandenplas, Y., Dupont, C., Eigenmann, P., Host, A., Kuitunen, M., Ribes-Koninck, C., Shah, N., Shamir, R., Staiano, A., Szajewska, H. and Von Berg, A. (2015), A workshop report on the development of the Cow's Milk-related Symptom Score awareness tool for young children. Acta Paediatrica. doi: 10.1111/apa.12902

# COW'S MILK ALLERGY (CMA) LOCAL PRIMARY CARE MANAGEMENT PATHWAY IN SOUTH WEST ESSEX

## Primary Care Milk Allergy Pathway in South West Essex



## COW'S MILK ALLERGY (CMA) LOCAL PRIMARY CARE MANAGEMENT PATHWAY IN MID ESSEX AND SOUTH EAST ESSEX



## COW'S MILK ALLERGY (CMA) continued

### SYMPTOMS, DIAGNOSIS AND INITIAL INFORMATION FOR FAMILIES

- **Infants with red flag symptoms should be referred immediately** to the paediatric assessment unit in secondary care.
- **RED FLAG** symptoms include
  1. hives or lip/tongue/eye or facial swelling within 2 hours of consumption
  2. Above symptoms +/- wheeze, cough, voice-change, increased heart rate, colour change within 2 hours
  3. Blood in stool
  4. Faltering growth with adequate feeding
  5. Persistent diarrhoea/vomiting
- **If there are no red flag symptoms** complete the CoMiSS questionnaire (page 3 or via the SystmOne/Ardens template) and generate a score. If the score is < 12 CMA is unlikely and an alternative diagnosis should be considered.
- Often several symptoms may be present and can include:
  - Skin symptoms (pruritis, erythema, urticaria, atopic dermatitis or eczema, non-specific rashes)
  - Gastrointestinal (GI) symptoms (loose, frequent or mucus containing stools, nausea and vomiting, abdominal distension and/or colicky pain, constipation sometimes soft stools with excessive straining, GORD)
  - Recurrent wheeze or cough (but see red flag symptoms above), nasal itching, sneezing, rhinorrhea or congestion
  - Food refusal or aversion
- **If the CoMiSS score is  $\geq 12$ , follow the management algorithm on the Primary Care Milk Allergy Pathway** on pages 4 or 5.

An information leaflet for families of infants suspected of having CMA is available on the SystmOne template and is also available on line, within the infant feeding folder at this address: <https://coronavirus.msehealthandcarepartnership.co.uk/nutrition-and-blood/>. Information is also provided to families of infants with suspected CMA who are under the care of Oviva, through their smartphone application.

**It is important that families are made aware that cow's milk allergy can only be confirmed by an elimination diet followed by an oral milk challenge.**

### ONWARD REFERRALS

- **Most infants with CMA can be managed in primary care.**
- **Referral to a paediatric dietitian is ESSENTIAL** and should be made as soon as possible for all infants who will require a cow's milk free diet (see page 4 or 5). Breastfeeding mothers following a milk free diet should also be referred to the paediatric dietitian who will advise them regarding their diet and that of their child.
- **Refer infant to secondary or specialist care if any of the following apply:**
  - **Red flag** symptoms
  - Severe delayed reactions
  - Possible multiple food allergies identified
  - Persisting parental suspicion of food allergy despite a lack of supporting history (especially where symptoms are difficult or perplexing)

## COW'S MILK ALLERGY (CMA) continued

### INITIAL MANAGEMENT FOR THE FIRST 4 WEEKS

- Refer to the locally agreed pathway on pages 4 or 5.

#### MANAGEMENT - breast fed infants

- **Mothers should be encouraged to continue breastfeeding** even when their infants have cow's milk allergy. Breast milk is the optimum choice for most infants with CMA.
- If symptoms persist in the exclusively breast fed infant, a maternal milk free diet is indicated for a trial period of 4 weeks (minimum 2 weeks). This requires dietary counselling from a suitably qualified dietitian to completely exclude all sources of cow's milk protein from the mothers' diet.
- Initial dietary advice (whilst awaiting an appointment with the dietitian) is available within the infant feeding folder at the link below and should be shared with the mother:  
<https://coronavirus.msehealthandcarepartnership.co.uk/nutrition-and-blood/>.
- It is recommended that breastfeeding mothers on a milk free diet should purchase supplementation with 700-1000mg calcium per day as advised by the dietitian following dietary assessment, as well as the recommended 10mcg (400 units) Vitamin D.
- If breastfeeding mothers do not wish to or are unable to follow a milk free diet, or are following a milk free diet and top-ups are required, an extensively hydrolysed (EHF) formula may well be tolerated and should be prescribed. Only if EHF is not tolerated **after a trial period of 4 weeks** (minimum 2 weeks) should amino acid formula (AAF) be prescribed. Refer to the locally agreed formulary on page 9.

#### MANAGEMENT- formula fed infants

- **If breastfeeding is not occurring, EHF are the first choice**, unless the infant has a history of anaphylactic symptoms. EHF should be prescribed for a trial period of 4 weeks (minimum 2 weeks).
- AAF should not routinely be started in primary care as the first formula prescribed. They are suitable only when EHF do not resolve symptoms and/or there is evidence of severe or anaphylactic allergy. Refer to the primary care pathway on pages 4 and 5.
- If a patient has a history of anaphylactic reaction to cow's milk, AAF may be started in primary care as the first formula prescribed, with immediate onward referral to secondary or specialist care.
- **Only 10% of infants with CMA should require management with AAF.**

### MANAGEMENT AFTER INITIAL 4 WEEKS

#### If symptoms resolve during the initial 4 weeks

- For the diagnosis to be confirmed it is important to know whether this has been due to exclusion of cow's milk or is coincidental. Therefore a milk challenge is required unless **red flag** symptoms were present.
- Breast feeding mothers should put milk back into their diets and formula fed babies should reintroduce the formula previously used. The dietitian will advise how to do this and an example is given within the infant feeding folder at this address: <https://coronavirus.msehealthandcarepartnership.co.uk/nutrition-and-blood/>. Information is also provided to families of infants with suspected CMA who are under the care of Oviva, through their smartphone application.
- If CMA is the cause of the symptoms they will reappear within a few days and cow's milk should be withdrawn again with EHF re-established or a milk free diet for breastfeeding mothers continuing until the infant is 9-12 months old.
- If the infant remains well there is no need to continue with cow's milk exclusion for breastfeeding mothers or with EHF for formula fed babies.

#### If symptoms do not resolve during the initial 4 weeks

- The dietitian will advise on next steps which will vary according to the clinical picture but may include exclusion of other foods such as eggs in breastfeeding mothers' diets, or a switch to an AAF for formula fed infants.
- If multiple food allergy is suspected or if there is faltering growth a referral to secondary care is recommended.

## COW'S MILK ALLERGY (CMA) continued

### SUBSEQUENT MANAGEMENT OF CMA

The dietitian will advise on reintroduction of cow's milk to the infant's diet stepwise using a 'milk ladder' from the age of 9 months to 1 year. The milk ladder is available within the infant feeding folder at this address: <https://coronavirus.msehealthandcarepartnership.co.uk/nutrition-and-blood/>. Information is also provided to families of infants with suspected CMA who are under the care of Oviva, through their smartphone application.

**Review the need for the prescription if you can answer 'yes' to any of the following questions:**

- Is the patient over 1 year of age? Or has the formula been prescribed for more than 1 year?
- Is the patient prescribed more than the suggested quantities of formula for their age?
- Is the patient prescribed a formula for CMA but able to eat any of the following foods – cow's milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee?

**Children with multiple or severe allergies may require prescriptions beyond 1 year.** This should always be at the suggestion of and with supervision from the paediatric dietitian.

### NOTES

1. **Soya formula (SMA Wysoy®) should not be used at all for those under 6 months** due to high phyto-oestrogen content and the risk that infants with CMA may also develop allergy to soya. It is more likely that children will tolerate soya formula from 1 year. If soya formula is used, parents should be advised to purchase this over the counter as it is a similar cost to cow's milk formula and readily available. Alpro® Soya Growing Up Drink may be suitable from 1 year. The paediatric dietitian will advise on this and on other alternative milks which may be suitable.
2. **EHF and AAF have an unpleasant taste and smell**, which is better tolerated by younger patients. 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.
3. **Prescribe a one week supply initially i.e. 2 x 400g tins** until compliance/tolerance is established to avoid waste.
4. **If AAF are not clinically indicated they should not be prescribed.** Although most EHF are not halal or kosher, if they are medically indicated a medical exemption should be sought from the local faith leader. Consider SMA® Althera which is halal and kosher.
5. **Rice milk** is not suitable for children under 5 years due to its arsenic content.
6. Due to their probiotic content, Nutramigen 1 & 2 with LGG® and Neocate Syneo® should be prepared with boiled water cooled down to room temperature (not 70°C). **Note: This is currently not in line with DOH guidance on safe preparation of infant formula and parents should be made aware of the risk of infection. These formulae should not be commenced in primary care.**
7. **Outgrowing CMA** – 60-75% of children outgrow CMPA by 2 years of age, rising to 85-90% of children at 3 years of age.
8. **Lactose free formulae, goat's, sheep's, and other mammalian** milks are not suitable for those with CMA.



## COW'S MILK ALLERGY (CMA) continued

### EXTENSIVELY HYDROLYSED FORMULAE

<ul style="list-style-type: none"> <li>▪ <b>Alimentum</b><sup>®</sup> (Abbott Nutrition)</li> </ul>	Birth to 1 year or able to tolerate over the counter products. Lactose free. Casein based.
<ul style="list-style-type: none"> <li>▪ <b>Aptamil Pepti</b><sup>®</sup> 1 (Nutricia)</li> </ul>	Birth to 6 months. Whey based. Contains prebiotic.
<ul style="list-style-type: none"> <li>▪ <b>Aptamil Pepti</b><sup>®</sup> 2 (Nutricia)</li> </ul>	6 months to 1 year or able to tolerate over the counter products. Whey based. Contains prebiotic.
<ul style="list-style-type: none"> <li>▪ <b>SMA Althera</b><sup>®</sup> (Nestle)</li> </ul>	Birth to 1 year or until able to tolerate over the counter products. Whey based. Halal and kosher.
<p><b><i>Prescribing these EHF will give a cost saving of up to £1500 in the first year of a child's life compared with amino acid formulae</i></b></p>	

### EXTENSIVELY HYDROLYSED FORMULAE TO BE STARTED IN SECONDARY CARE

<ul style="list-style-type: none"> <li>▪ Aptamil Pepti Syneo<sup>®</sup> (Nutricia)</li> </ul>	Birth to 1 year or able to tolerate over the counter products. Contains pre and probiotic. Whey based. Not suitable for premature or immunocompromised infants. Not suitable for those with a central venous catheter or short bowel syndrome without assessment of risks and benefits and careful monitoring by the healthcare team. Follow manufacturer's instructions on water temperature for preparation.
<ul style="list-style-type: none"> <li>▪ Nutramigen 1 with LGG<sup>®</sup> (Mead Johnson)</li> </ul>	Birth to 6 months. Contains probiotics. Lactose free. Casein based.. Not suitable for premature or immunocompromised infants unless directed and supervised by a healthcare professional. Follow manufacturer's instructions on water temperature for preparation.
<ul style="list-style-type: none"> <li>▪ Nutramigen 2 with LGG<sup>®</sup> (Mead Johnson)</li> </ul>	6 months to 1 year or until able to tolerate over the counter products. Lactose free. Casein based. Contains probiotic. Not suitable for premature or immunocompromised infants unless directed and supervised by a healthcare professional. Follow manufacturer's instructions on water temperature for preparation.
<ul style="list-style-type: none"> <li>▪ Pepti – Junior<sup>®</sup> (Nutricia)</li> </ul>	Birth to 1 year or until able to tolerate over the counter products. Higher medium chain triglyceride content.
<ul style="list-style-type: none"> <li>▪ Pregestimil Lipil<sup>®</sup> (Mead Johnson)</li> </ul>	Birth to 1 year or until able to tolerate over the counter products. Higher medium chain triglyceride content.
<p>These formulae can be considered where CMA is accompanied by malabsorption or gastro-intestinal symptoms.</p>	

### AMINO ACID FORMULAE - NOT TO BE ROUTINELY STARTED IN PRIMARY CARE

<ul style="list-style-type: none"> <li>▪ EleCare<sup>®</sup> (Abbott Nutrition)</li> </ul>	Birth until 1 year or when able to tolerate over the counter products. Contains prebiotic.
<ul style="list-style-type: none"> <li>▪ Neocate LCP<sup>®</sup> (Nutricia)</li> </ul>	Birth until 1 year or when able to tolerate over the counter products.
<ul style="list-style-type: none"> <li>▪ Nutramigen Puramino<sup>®</sup> (Mead Johnson)</li> </ul>	Birth until 1 year or able to tolerate over the counter products.
<ul style="list-style-type: none"> <li>▪ SMA Alfamino<sup>®</sup> (Nestle)</li> </ul>	Birth until 1 year or when able to tolerate over the counter products
<p><b>If a patient presents with clear anaphylactic reaction to cow's milk and requires formula these AAF should be commenced in primary care, with immediate onward referral to secondary or specialist care.</b></p>	

### OTHER AMINO ACID FORMULA TO BE STARTED IN SECONDARY CARE

<ul style="list-style-type: none"> <li>▪ Neocate Syneo<sup>®</sup> (Nutricia)</li> </ul>	Birth until 1 year or when able to tolerate over the counter products. Contains prebiotic. Not suitable for premature or immunocompromised infants. Not suitable for those with a central venous catheter or short bowel syndrome without assessment of risks and benefits and careful monitoring by the healthcare team Follow manufacturer's instructions on water temperature for preparation.
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## PRE-TERM INFANTS

### INDICATIONS

- These infants will have had their pre-term nutrient enriched post discharge formula (NEPDF) commenced on discharge from the neonatal unit (NICU). It is not needed for all pre-term babies and those who do require it will be identified by NICU.
- **Pre-term infants, who are formula fed, have shown adequate growth during their NICU stay and do not have increased energy requirements should be discharged home on standard term formula.**
- NEPDF is used for some babies born < 34 weeks gestation, weighing < 2kg at birth who are not breast fed and who have higher energy requirements (e.g. on home oxygen).
- It is also used for infants who have had poor growth e.g. have crossed down >2 centiles on growth charts during their neonatal stay.
- If, following discharge, breast feeding reduces or stops and a formula is required the NICU or dietitian should advise whether a NEPDF is required or standard formula can be used.
- NEPDF should not be used in primary care to promote weight gain in patients other than babies born prematurely and meeting criteria as above.
- **If SMA<sup>®</sup> Gold Prem 2 is prescribed iron supplementation is recommended as 1ml Sytron<sup>®</sup> daily (5.5mg elemental iron).**
- **If Nutriprem<sup>®</sup> 2 is prescribed iron supplementation is not needed.**

### ONWARD REFERRAL

- These infants should already be under regular review by the paediatricians and health visitors.
- If there are concerns regarding poor growth whilst the infant is on these formulae, or there are concerns regarding growth at review one month after these formulae are stopped, a referral to the paediatric dietitian is appropriate.

### REVIEW AND DISCONTINUATION OF FORMULA

- Monitoring of growth (weight, length and head circumference) should be carried out by the health visitor or paediatric team while the baby is on these formulae.
- **NEPDF is rarely needed beyond 3 months corrected age and should be stopped as soon as the baby is demonstrating good catch up growth. It is very important that these products should be discontinued at an appropriate age.**
- Any requirement for NEPDF beyond 3 months corrected age should be at the request of the neonatal paediatric dietitian who will review.

### MOST COST EFFECTIVE PRE-TERM FORMULAE TO BE STARTED IN SECONDARY CARE

▪ SMA <sup>®</sup> Gold Prem 2 powder (SMA)	Up to 3 months corrected age or catch up growth achieved
▪ Nutriprem <sup>®</sup> 2 powder (Cow and Gate)	Up 3 months corrected age or catch up growth achieved

### OTHER PRE-TERM FORMULAE WHICH SHOULD ONLY BE STARTED IN SECONDARY CARE WHEN THERE IS A CLINICAL NEED e.g. immunocompromised infant

▪ SMA <sup>®</sup> Gold Prem 2 liquid (SMA)	Up to 3 months corrected age or catch up growth achieved
▪ Nutriprem <sup>®</sup> 2 liquid (Cow and Gate)	Up to 3 months corrected age or catch up growth achieved

**Cost per 100kcal of liquids is 4-5 times cost of powders.**

## FALTERING GROWTH

### SYMPTOMS AND DIAGNOSIS

- Refer to NICE clinical guideline NG75 'Faltering Growth – recognition and management of faltering growth in children' Sept 2017. <https://www.nice.org.uk/guidance/ng75>
- UK WHO growth charts should be used to measure growth. It is not possible to detect faltering growth without using appropriate growth charts.

#### Early days of life

- Some weight loss in the first days after birth is normal with most infants returning to birth weight by 3 weeks of age.
- If infants in the early days of life lose more than 10% of their birth weight a clinical assessment is needed checking for signs of dehydration, illness or disorder that may account for this. Feeding history should be taken and direct observation of feeding may be required.

#### After the early days of life, diagnosis is made when:

- There is a fall of 1 or more weight centile spaces if birthweight was below the 9<sup>th</sup> centile.
- There is a fall of 2 or more weight centile spaces if birth weight was between the 9<sup>th</sup> and 91<sup>st</sup> centiles.
- There is a fall of 3 or more weight centile spaces if birthweight was above the 91<sup>st</sup> centile.
- Length/height as well as weight should be measured. If possible the biological parents' heights should be obtained and if the infant's length/height is below the range predicted from parental heights (more than 2 spaces below the mid-parental centile) this could suggest undernutrition or a primary growth disorder.
- Feeding behaviours, presence of pre-term birth, neurodevelopmental concerns, parental factors (e.g. maternal postnatal depression or anxiety) and any indicators of underlying illness (e.g. urinary tract infection, coeliac disease if taking solid foods) should be taken into account.
- It is essential to rule out possible causes for the faltering growth including safe guarding concerns and disease related/medical causes e.g. iron deficiency anaemia, constipation, GORD. If identified appropriate action should be taken.

### ONWARD REFERRAL

#### Early days of life

- Refer to paediatric services if there is marked weight loss of more than 10% of birth weight, illness or failure to respond to feeding support.

#### After the early days of life

- Additional support should be offered by the health visitor and a referral to the paediatric community dietitian made. Advice on a short-term high calorie/protein diet together with advice on encouraging a good meal time pattern and behaviours will be offered.

#### Refer to secondary care paediatric services if there are

- Signs or symptoms that may indicate an underlying disorder
- A failure to respond to interventions delivered in primary care by the health visitor and paediatric dietitian (see 'Treatment' below)
- Slow linear growth or unexplained short stature
- Rapid weight loss or severe undernutrition
- Features that cause safe guarding concerns

## FALTERING GROWTH continued

### TREATMENT

- Feeding support will be offered by the health visitor and paediatric dietitian.
- Breast feeding mothers should be encouraged to continue. Be aware that supplementary feeding with infant formula in a breastfed infant may help with weight gain, but often results in cessation of breastfeeding. Advise expressing breast milk to promote supply **and** feed the infant any available breast milk before giving any infant formula.
- If the infant is weaned, a short-term nutrient dense diet will be advised together with advice on encouraging a good meal time pattern and behaviours.
- If suggested by the paediatric dietitian consider a trial of a high energy formula.
- Enteral tube feeding should only be considered after assessment by a multidisciplinary team and after all other interventions have been tried with no improvement.

### REVIEW AND DISCONTINUATION OF TREATMENT

- All infants on high energy formula will need growth (weight and height/length) monitored to ensure catch up growth occurs.
- Once this is achieved the high energy formula should be discontinued to minimise excessive weight gain and to avoid reducing an infant's appetite for other foods.
- Withdrawal may need to be phased and the dietitian will advise.

### MOST COST EFFECTIVE HIGH ENERGY FORMULA

- |                                                                   |                              |
|-------------------------------------------------------------------|------------------------------|
| ▪ <b>SMA<sup>®</sup> High Energy 200ml bottle (SMA Nutrition)</b> | <b>Birth up to 18 months</b> |
|-------------------------------------------------------------------|------------------------------|

### OTHER HIGH ENERGY FORMULAE

- |                                                            |                                     |
|------------------------------------------------------------|-------------------------------------|
| ▪ <b>Similac<sup>®</sup> High Energy 200ml bottle</b>      | <b>Birth up to 18 months or 8kg</b> |
| ▪ <b>Infatrini<sup>®</sup> 125/200ml bottle (Nutricia)</b> | <b>Birth up to 18 months or 8kg</b> |

### HIGH ENERGY FORMULA TO BE STARTED IN SECONDARY CARE

- |                                                       |                                     |
|-------------------------------------------------------|-------------------------------------|
| ▪ <b>Infatrini<sup>®</sup> Peptisorb 200ml bottle</b> | <b>Birth up to 18 months or 8kg</b> |
|-------------------------------------------------------|-------------------------------------|

**NB This formula is suitable for infants with faltering growth *and* intolerance to whole protein feeds eg. short bowel syndrome, intractable malabsorption, inflammatory bowel disease, bowel fistulae**

### NOTES

1. For otherwise healthy term infants who are born with birthweight <10<sup>th</sup> 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.
2. Where all nutrition is provided via NG/NJ/PEG tubes, there should be no need for prescriptions to be written as tube feeds are supplied on contract and ordered (off FP10) by the dietitians.
3. The paediatric dietitian will advise on appropriate monthly amounts of formula required which may exceed the guideline amounts for other infants. These formulae are not suitable as a sole source of nutrition for infants over 8kg or 18 months of age.
4. Do not add formula to repeat templates as ongoing need for formula and amount needed will need to be checked with each prescription request.
5. Manufacturers instructions regarding safe storage once opened and expiry of ready to drink formulae should be adhered to – this may differ from manufacturer to manufacturer.

## GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

### SYMPTOMS AND DIAGNOSIS

- Please refer to NICE Guideline NG1 Jan 2015 Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people <https://www.nice.org.uk/guidance/ng1>
- GORD is the presence of troublesome symptoms (e.g. discomfort or pain) or complications (e.g. oesophagitis or aspiration) arising from gastro-oesophageal reflux.
- Over 50% of babies experience non-distressing regurgitation, and reassurance should be given that this will improve over time.
- Symptoms of GORD may include distressed behaviour (e.g. excessive crying, crying while feeding, adopting unusual neck postures), hoarseness and/or chronic cough, a single episode of pneumonia, unexplained feeding difficulties, faltering growth.
- Regurgitation and GORD usually begin before the age of 8 weeks and resolve in 90% of infants before they are 1 year old.
- **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 6 months, and should be offered spread over 6-7 feeds.

### ONWARD REFERRAL

- Same-day admission should be arranged if the child has haematemesis (not caused by swallowed blood from a nosebleed or cracked nipple), melaena or dysphagia.
- Infants with faltering growth as a result of GORD should be referred to paediatric services without delay.
- Uncertain diagnosis or red flag symptoms suggesting a more serious condition, recurrent aspiration pneumonia or unexplained apnoeas should also prompt urgent referral for specialist assessment.
- If symptoms do not improve 4 weeks after commencing treatment as below, refer to a paediatrician for further investigations. CMA can co-exist with GORD and treatment as for CMA may be required with a trial of EHF initiated.

### TREATMENT, REVIEW AND DISCONTINUATION OF TREATMENT

- **If infant is thriving and not distressed by regurgitation** reassure parents and monitor.
- Provide advice on avoidance of overfeeding, positioning during and after feeding, and activity after feeding.
- Where there is evidence of GORD, provide advice as above and if not helpful after 1-2 weeks treat as below (see overleaf for medication advice).

#### STEP 1 breast fed infants

- **Expressed breast milk can be mixed with Instant Carobel® to thicken it. Or**
- **1-2 week trial of Gaviscon Infant® may be considered.** Mix each dose with 5ml (1 teaspoon) of boiled cooled water to make a smooth paste. Add another 10ml (2 teaspoons) of boiled cooled water and mix. Part way through the feed use a spoon or feeding bottle to give the dose of Gaviscon® Infant.

#### STEP 1 formula fed infants

- **Sequential 1-2 week trial of each of the following options:**
  - 1. Thickened formula to purchase** - SMA® Anti-Reflux, Aptamil® Anti-Reflux or Cow & Gate® Anti-Reflux formula or Instant Carobel® added to regular formula. **Or thickening formula to purchase** - Enfamil AR® (see notes page 14) If these are ineffective trial Gaviscon Infant®. **This should not be used with other preparations containing thickening agents.**
  - 2. Gaviscon Infant®.** Mix the dose into 115ml of regular formula feed in the bottle, shake well and feed as normal.

Gaviscon Infant® can also be given (after mixing with boiled cooled water) at the end of each meal using a spoon or feeding bottle.

**If STEP 1 treatment is successful** continue, but stop every 2 weeks to see if symptoms improve and treatment can be stopped.

#### STEP 2 for breast and formula fed infants

- **If STEP 1 treatment is not successful** a 4 week trial of a proton pump inhibitor (PPI) may be considered.
  - **If symptoms persist despite medication, the child should be referred for specialist assessment.**
- Infants with GORD will need regular review to check symptoms and growth

## GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD) cont'd

### THICKENED FORMULAE TO PURCHASE FROM SUPERMARKETS

- SMA<sup>®</sup> Anti-Reflux From birth
- Aptamil<sup>®</sup> Anti-Reflux From birth
- Cow & Gate<sup>®</sup> Anti-Reflux From birth
- HiPP<sup>®</sup> Anti-Reflux From birth

### OR THICKENING FORMULA TO PURCHASE FROM PHARMACIES

- Enfamil AR<sup>®</sup> From birth

### OR THICKENER TO PURCHASE FROM PHARMACIES FOR ADDITION TO REGULAR FORMULA OR BREAST MILK

- Instant Carobel<sup>®</sup> (Cow and Gate) From birth

### NOTES ON THICKENED AND THICKENING FORMULAE AND THICKENER

1. SMA<sup>®</sup> Anti-Reflux formula is thickened with potato starch. Aptamil<sup>®</sup> Anti-Reflux, Cow & Gate<sup>®</sup> Anti-Reflux and HiPP Anti-Reflux formulae are pre-thickened with carob gum. A large hole (fast flow) teat will be needed. They are available over the counter in supermarkets at a similar cost to regular formulae and are not for prescription.
2. **Thickening formula (Enfamil AR<sup>®</sup>) is not recommended for prescription because of the ready availability of thickened formulae from supermarkets.** If parents choose to purchase thickening formula, this would need to be ordered from a pharmacy and they should be advised not to use in conjunction with separate thickeners or with medication such as Gaviscon Infant<sup>®</sup>, ranitidine, or omeprazole. This formula needs to be mixed with fridge cooled pre-boiled water (see tin for full instructions).
3. **Instant Carobel<sup>®</sup>** feed thickener contains carob gum, is mixed with regular formula or breast milk to produce a thickened drink and will require the use of a large hole (fast-flow) teat. It may also be suggested for addition to EHF or AAF where CMA co-exists with GORD. Parents should purchase the thickener at a pharmacy.
4. **Do not use Gaviscon Infant<sup>®</sup> with feed thickener, thickened feeds or thickening formulae**, as this could lead to over thickening of the stomach contents.

### NOTES ON MEDICATION

Please refer to Appendix 1 for prescribing guidance on PPI use in paediatric patients

## SECONDARY LACTOSE INTOLERANCE

### SYMPTOMS AND DIAGNOSIS

- Can occur 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 2 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.

### TREATMENT

- Treat with low lactose/lactose free formula for **4-8 weeks** to allow symptoms to resolve. Rarely symptoms may last up to 3 months.
- Lactose free formula can be purchased over the counter in supermarkets at a similar price to standard formula and the GP should not prescribe.
- In infants who have been weaned, low lactose/lactose free formula should be used in conjunction with a milk free diet.
- Standard formula and/or milk products should then be slowly reintroduced to the diet.
- In children over 1 year who previously tolerated cow's milk, suggest the use of lactose free full fat cow's milk which can be purchased from supermarkets (e.g. Lactofree® brand).

### REVIEW AND DISCONTINUATION OF TREATMENT

- Low lactose/lactose free formula should not be used for longer than 8 weeks without review and trial of discontinuation of treatment.

### LOW LACTOSE/LACTOSE FREE FORMULA TO PURCHASE FROM SUPERMARKETS

- |                         |                           |
|-------------------------|---------------------------|
| ▪ SMA® Lactose free     | From birth                |
| ▪ Aptamil® Lactose Free | From birth – lactose free |

### NOTES

1. Primary lactose intolerance is less common than secondary lactose intolerance and does not usually present until later childhood or adulthood.
2. All lactose reduced or lactose free formula are unsuitable for CMA as they are whole protein formula or only partially hydrolysed.
3. Soya formula (SMA® WySoy) should not routinely be used for patients with secondary lactose intolerance. **It should not be used at all for those under 6 months due to high phyto-oestrogen content.** It should only be advised in patients over 6 months who do not tolerate the formula suggested here. Parents should be advised to purchase this, if used, as it is a similar cost to cow's milk formula and is readily available.

**Comparative costs of infant formulae for prescription – Dec 2020 Drug Tariff prices**

<b>Cow's milk allergy</b>				
<b>Product</b>	<b>Presentation</b>	<b>Price</b>	<b>Cost per 100g</b>	<b>Cost per 100kcal</b>
<b>Extensively hydrolysed formulae</b>				
*Alimentum®	400g tin	£10.01	£2.50	£0.48
*Aptamil Pepti® 1	400g/800g tin	£9.87/£19.73	£2.47	£0.50
*Aptamil Pepti® 2	400g/800g tin	£9.41/£18.82	£2.35	£0.50
*SMA Althera®	400g tin	£9.86	£2.46	£0.44
Aptamil Pepti Syneo®	400g tin	£10.65	£2.66	£0.55
Nutramigen® 1 with LGG®	400g tin	£11.21	£2.80	£0.56
Nutramigen® 2 with LGG®	400g tin	£11.21	£2.80	£0.58
Pepti-Junior®	450g tin	£14.03	£3.12	£0.60
Pregestimil Lipil®	400g tin	£12.43	£3.11	£0.62
<b>Amino acid formulae</b>				
*Elecare®	400g tin	£22.98	£5.75	£1.11
*Neocate LCP®	400g tin	£22.98	£5.75	£1.19
*Nutramigen Puramino®	400g tin	£22.98	£5.75	£1.15
*SMA Alfamino®	400g tin	£22.98	£5.75	£1.14
Neocate Syneo®	400g tin	£29.56	£7.39	£1.59

<b>Pre-term infant formulae</b>				
<b>Product</b>	<b>Presentation</b>	<b>Price</b>	<b>Cost per 100g</b>	<b>Cost per 100kcal</b>
*SMA® Gold Prem 2 powder	400g tin	£5.06	£1.27	£0.25
*Nutriprem® 2 powder	800g tin	£10.64	£1.33	£0.27
SMA® Gold Prem 2 liquid	200mls	£1.68		£1.15
Nutriprem® 2 liquid	200mls	£1.78		£1.19

<b>High energy formulae</b>				
<b>Product</b>	<b>Presentation</b>	<b>Price</b>	<b>Cost per 100g</b>	<b>Cost per 100kcal</b>
*SMA® High Energy	200mls	£2.01		£1.00
Similac® High Energy	200mls	£2.50		£1.25
Infatrini®	200mls	£2.56		£1.28
Infatrini®	125mls	£1.60		£1.28
Infatrini® Peptisorb	200mls	£3.92		£1.96

**Examples of Oct 2020 retail costs of grey list products to purchase from supermarkets or pharmacies**

<b>Thickened formulae, thickening formulae and thickener</b>		
SMA® Anti-Reflux	800g	£13.00
Cow & Gate® Anti-Reflux	800g	£10.49
Aptamil® Anti-Reflux	900g	£14.00
HiPP Organic Combiotic Anti-Reflux	800g	£12.50
Enfamil AR®	400g	£5.89
Instant Carobel®	135g	£4.10

<b>Lactose free formulae</b>		
Aptamil® Lactose Free	400g	£7.50
SMA® Lactose free	400g	£6.00

<b>Soya formula</b>		
SMA® WySoy	800g	£13.00

\*Most cost effective products in each category



## 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.
- 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 (see page 2) and /or refer to the most recent correspondence from the paediatric dietitian.
- Review any prescription where the child is over 1 year 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 CMA but able to eat any of the following foods – cow's milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee.
- Prescribe only 1 or 2 tins/bottles initially until compliance/tolerance is established.
- Remind parents to follow the advice given by the formula manufacturer regarding mixing of the formula and 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.
- **Seek prescribing advice if needed in primary care from the local Medicines Optimisation Team**
- **Seek prescribing advice if needed in secondary care from the Hospital Medicines Information Centre, Pharmacy Department.**

### Don't:

- **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.
- **Do not** suggest lactose free or low lactose formulae for infants with CMA.
- **Do not** suggest soya formula (SMA WySoy®) for those with CMA or secondary lactose intolerance. It is not suitable at all in those under 6 months due to high phyto-oestrogen content.
- **Do not** suggest goat's milk and formulae made from it, sheep's milk or other mammalian milks for those with CMPA or secondary lactose intolerance or other conditions covered in this guideline.
- **Do not** suggest rice milk for those under 5 years old due to high arsenic content.
- **Do not** suggest thickened formulae (e.g. SMA® Anti-Reflux, Aptamil® Anti-Reflux or Cow & Gate® Anti-Reflux formulae) or thickening formula (Enfamil AR®) with separate thickener (Instant Carobel®) or Gaviscon Infant® as this could lead to over thickening of the stomach contents.
- **Do not** prescribe PPI medication in conjunction with thickening formula if parents choose to purchase this, since the formulae need stomach acids to thicken and reduce reflux.
- **Do not** prescribe Instant Carobel® where this is being added to regular formula as a choice rather than using a pre-thickened formula. Parents should be encouraged to purchase it.
- **Do not** suggest Gaviscon Infant® if intestinal obstruction is suspected, or in pre-term neonates, or more than 6 times in 24 hours or where the infant has diarrhoea, vomiting, renal impairment or a fever, due to its sodium content.(See page 14)
- **Do not** suggest low lactose/lactose free formulae in children with secondary lactose intolerance over 1 year who previously tolerated cow's milk, since they can use supermarket full fat lactose free milk e.g. Lactofree® brand.
- **Do not** prescribe formulae marked in this document as black list formulae to be purchased over the counter at a supermarket or pharmacy.

## REFERENCES AND FURTHER READING

### Cow's milk allergy:

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

<http://guidance.nice.org.uk/CG116/Guidance/pdf/English>

NICE Clinical Knowledge Summaries (CKS). Cow's milk protein allergy in children. Last revised July 2015. <http://cks.nice.org.uk/cows-milk-protein-allergy-in-children>

Venter C. et al *Clinical and Translational Allergy* 2017; 7:26 Better recognition, diagnosis and management of non-IgE mediated cow's milk allergy in infancy :iMAP an international interpretation of of the MAP (Milk Allergy in Primary Care) Guideline

iMAP guideline presentation algorithm:<https://www.allergyuk.org/health-professionals/mapguideline#anchor1>

iMAP management algorithm:<https://www.allergyuk.org/health-professionals/mapguideline#anchor1>

iMAP taking an allergy focused history document:

[https://www.allergyuk.org/assets/000/001/293/iMAP-Allergy-focused\\_History\\_original.pdf?1502804761](https://www.allergyuk.org/assets/000/001/293/iMAP-Allergy-focused_History_original.pdf?1502804761)

Royal College of Paediatrics and Child Health (RCPCH) Care pathway for food allergy

<http://www.rcpch.ac.uk/allergy/foodallergy>

Vandenplas et al A workshop report on the development of the Cow's Milk-related Symptom Score awareness tool for young children. *Acta Paediatrica* 2015 doi:10.1111/apa.12902

Vandenplas et al *SAGE Open Medicine* 2: 20503121452423 2014. A pilot study on the application of a symptom-based score for the diagnosis of cow's milk protein allergy

Food Hypersensitivity. Diagnosing and managing food allergy and intolerance. (2009). Edited by Isabel Skypala and Carina Venter. Published by Wiley- Blackwell.

World Allergy Organisation DRACMA guidelines 2010 (Diagnosis and Rationale Against Cow's Milk Allergy)

Dietary products used in infants for treatment and prevention of food allergy. Joint statement of the European Society for Paediatric Allergology and Clinical Immunology (ESPACI) Committee on Hypoallergenic Formulas and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Committee on Nutrition. *Arch Dis Child* 1990; 81:80-84.

Host A. Frequency of cow's milk allergy in childhood. 2002; *Ann Allergy Immunol*;89 (suppl): 33-37.

Schoemaker AA et al. Incidence and natural history of challenge-proven cow's milk allergy in European children-EuroPrevall birth cohort. *Allergy* 2015; 70(8):963-72.

Vandenplas Y, Koletzko S et al. Guidelines for the diagnosis and management of cow's milk protein allergy in infants. *Arch Dis Child* 2007;92:902-908

Dupont C. et al *British Journal of Nutrition* 2011:1-14

Taylor R. et al *Pediatric Allergy Immunol* 2012;23:240-249

Canani R. et al *Journal of Allergy and Clinical Immunology* 2012;129:580-582

Canani R. et al *J Pediatr* 2013;163(3):771-777

### **Soya formula:**

Department of Health: CMO's Update 37 (2004). *Advice issued on soya based infant formula.*

Paediatric group Position Statement on Use of Soya Protein for Infants. *British Dietetic Association: February 2004.*

Vandenplas, Y et al. Systematic review with Meta-analysis. Safety of soya-based infant formulas in children. *British Journal of Nutrition* 2014;111,1340-1360

### **Rice milk:**

Food Standard Agency statement on arsenic levels in rice milk, 2009.

### **Pre-term infants:**

East of England Neonatal Network March 2018. Enteral Feeding of Preterm Infants on the Neonatal Unit.

<https://www.networks.nhs.uk/nhs-networks/eoe-neonatal-odn/guidelines>

East of England Neonatal Network December 2018. Enteral feeding – Iron Supplementation.

<https://www.networks.nhs.uk/nhs-networks/eoe-neonatal-odn/guidelines/current-guidelines>

### **Faltering growth:**

National Institute for Health and Care Excellence. NICE Clinical Guideline Faltering growth – recognition and management of faltering growth in children. Sept 2017.

<https://www.nice.org.uk/guidance/ng75>

### **Gastro-oesophageal reflux Disease:**

NICE Guideline NG1 Jan 2015 Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people <https://www.nice.org.uk/guidance/ng1>

Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society of Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) and the European Society of Pediatric Gastroenterology, Hepatology and Nutrition. (ESPGHAN) *Journal of Ped Gastroenterology and Nutrition* 2009 49: 498-547.

Gaviscon Infant® Summary of Product Characteristics:

<http://www.medicines.org.uk/emc/medicine/21981>

Losec® MUPS® Tablets 10mg Summary of Product Characteristics:

<http://www.medicines.org.uk/emc/medicine/7249>

### **Secondary Lactose Intolerance:**

Buller HA, Rings EH, Montgomery RK, Grand RJ. Clinical aspects of lactose intolerance in children and adults. *Scand J Gastroenterology Suppl* 1991;188:73-80

### **General:**

Clinical Paediatric Dietetics 5<sup>th</sup> Edition (2020). Edited by Vanessa Shaw. Published by Wiley-Blackwell Publishing.

Department of Health (2009) *Birth to Five*. [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_107303](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_107303)

Department of Health report on Health and Social Subjects No 45. 1994. Weaning and the weaning diet. The Stationary Office.

Healthy lifestyle and breastfeeding. NHS Choices. Accessed online:  
<http://www.nhs.uk/conditions/pregnancy-and-baby/pages/lifestyle-breastfeeding.aspx#close>

BNF for Children 2019-2020

## APPENDIX 1

## PROTON PUMP INHIBITOR (PPI) USE IN PAEDIATRIC PATIENTS – PRESCRIBING GUIDANCE FOR PRIMARY, COMMUNITY AND SECONDARY CARE

### Lansoprazole - dosage and administration information

(Not licensed for use in children. Refer to BNF for Children for further information)

**Child (body-weight under 30kg):** 0.5mg - 1 mg/kg once daily (maximum 15mg once daily)

**Child (body-weight 30kg and above):** 15mg - 30 mg once daily

Doses to be taken in the morning

**Lansoprazole dose schedules for children who weigh  $\geq 3.5$ kg:** lansoprazole doses have been weight banded to enable the orodispersible tablet to be halved/quartered before use for accuracy of dosing.

Weight	Daily dose	Portion of lansoprazole orodispersible tablet
3.5kg - 7.5kg	3.75mg	Quarter of a 15mg orodispersible tablet
7.5kg - 15kg	7.5mg	Half of a 15mg orodispersible tablet
15kg - 30kg	15mg	One 15mg orodispersible tablet
> 30kg	15mg - 30mg	One 15mg or 30mg orodispersible tablet
Adjust dose as child's weight changes		

- 1) **For doses of 15mg or 30mg where the child is able to swallow capsules** - use the appropriate strength of lansoprazole capsule.
- 2) **For doses of 15mg or 30mg where the child is unable to swallow capsules** - use the appropriate strength of lansoprazole orodispersible tablet.
- 3) **For children who weigh  $\geq 3.5$ kg who require less than a 15mg dose** - use the appropriate strength of lansoprazole orodispersible tablet. Dose can be given as a proportion of an orodispersible tablet using a tablet cutter. Refer to section A for further information.
- 4) **For children who weigh less than 3.5kg** - use the appropriate strength of lansoprazole oral suspension (unlicensed liquid special). Once a baby weighs 3.5kg and if therapy is still required, lansoprazole oral suspension should be changed to lansoprazole orodispersible tablets. Refer to section B for further information.
- 5) **For children with an enteral feeding tube  $\geq 8$ Fr** - use the appropriate strength of lansoprazole orodispersible tablets. Refer to section C for further information.
- 6) **For children with an enteral feeding tube  $< 8$ Fr** - use the appropriate strength of lansoprazole capsules dissolved in 8.4% sodium bicarbonate. Refer to section D for further information.

### Section A: Oral administration - lansoprazole orodispersible tablets:

- Lansoprazole orodispersible tablets do not form an even suspension in water, therefore, cannot be part dosed by dissolving in water and giving an aliquot, as this will lead to inaccurate dosing.
- Lansoprazole orodispersible tablets can be halved or quartered to achieve part-doses. Where this is required, a tablet cutter should be supplied on dispensing of the medication.
- Lansoprazole orodispersible tablets can be placed on the tongue, allowed to disperse and swallowed, or may be swallowed whole with a glass of water.
- Lansoprazole orodispersible tablets can be dispersed in water and given orally.
- Do not chew or crush the microgranules in the dispersion.
- If only a portion of an orodispersible tablet is administered do not keep the remainder of the tablet to use for the next dose. A new orodispersible tablet should be used for each dose.

- Prescribe lansoprazole orodispersible tablets generically. Do not prescribe as the brand name Zoton FasTab.

**Section B: Oral administration - lansoprazole oral suspension (unlicensed liquid special):**

- Lansoprazole oral suspension should be restricted for use in children who weigh less than 3.5kg.
- Use the appropriate strength of lansoprazole oral suspension for the dose:
  - Lansoprazole 5mg/5ml oral suspension (alcohol free and sugar free)
- Review the appropriateness of lansoprazole oral suspension on a regular basis due to the higher cost and unlicensed formulation.
- Once a baby weighs 3.5kg and if therapy is still required, lansoprazole oral suspension should be changed to lansoprazole orodispersible tablets.

**Section C: Administration via enteral tubes ≥8Fr:**

- Lansoprazole orodispersible tablets are licensed for nasogastric tube administration and can be administered via an 8Fr tube without blockage.
- Lansoprazole orodispersible tablets can be dispersed in 10 ml of water and flushed down the feeding tube using a push-pull technique to keep the granules suspended.
- Stop the enteral feed 30 minutes before dose.
- Flush the enteral feeding tube with the recommended volume of water.
- Place the whole, halved or quartered orodispersible tablet in the barrel of an appropriate size and type of syringe.
- Draw 10 ml of water into the syringe and allow the tablet to disperse, shaking if necessary.
- Flush the medication dose down the feeding tube using a push-pull technique to keep the granules suspended.
- Draw another 10 ml of water into the syringe and also flush this via the feeding tube (this will rinse the syringe and ensure that the total dose is administered).
- Flush with the recommended volume of water.
- Restart the feed 30 minutes after dose.
- If only a portion of an orodispersible tablet is administered do not keep the remainder of the tablet to use for the next dose. A new orodispersible tablet should be used for each dose.

**Section D: Administration via enteral tubes <8Fr:**

- Some brands of lansoprazole capsules are licensed for administration via nasogastric feeding tubes.
- For fine-bore tubes smaller than 8Fr, dissolve the contents of the lansoprazole capsule in 8.4% sodium bicarbonate (licensed 420mg/5ml, 1mmol/ml oral solution sugar free) before administration.
- Stop the enteral feed 30 minutes before dose.
- Flush the enteral feeding tube with the recommended volume of water.
- Open the capsule and pour the contents into a medicine pot.
- Add 15 ml of sodium bicarbonate 8.4% (this creates a 15mg/15ml strength for a 15mg capsule and a 30mg/15ml strength for a 30mg capsules).
- Stir to dissolve the granules.
- Draw into the syringe and administer via the feeding tube (draw up the proportion of the volume needed if the dose is less than the capsule strength).
- If the dose is a whole capsule strength, add a further 15 ml of water to the medicine pot; stir to ensure that any drug remaining in the pot is mixed with water.
- Draw up this dispersion and flush down tube. This will ensure that the whole dose is given.
- Flush the tube with the recommended volume of water.
- Restart the feed 30 minutes after dose.
- If the tube becomes blocked, lock the tube using 8.4% sodium bicarbonate to dissolve any enteric-coated granules lodged in the tube.

- There is limited information to support administration of lansoprazole oral suspension via enteral feeding tubes, and it may be too viscous for administration via enteral feeding tubes, therefore, should not be used.

#### Section E: Additional information:

- **Review:** Review appropriateness of treatment and formulation choice at each review.
- **Interactions:** The intake of food with lansoprazole slows down the absorption and decreases the bioavailability by about 50%; it is, therefore recommended that lansoprazole is taken one hour before meals.
- **Discharge and hospital supply:** Where appropriate, tablet cutters will be provided by the hospital pharmacy and an appropriate treatment plan communicated to the GP including dose and formulation.

<b>References</b>	BNF for Children: <a href="https://bnfc.nice.org.uk/drug/lansoprazole.html">https://bnfc.nice.org.uk/drug/lansoprazole.html</a> (accessed 17.12.20) Handbook of Drug Administration via Enteral Feeding Tubes via Medicines Complete. Lansoprazole monograph: <a href="https://www.medicinescomplete.com/#/content/tubes/c211">https://www.medicinescomplete.com/#/content/tubes/c211</a> (accessed 18.12.20) The NEWT Guidelines. Lansoprazole monograph: <a href="https://access.newtguidelines.com/L/Lansoprazole.html">https://access.newtguidelines.com/L/Lansoprazole.html</a> (accessed 18.12.20) Drug Tariff online (December 2020): <a href="https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff">https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff</a> (accessed 18.12.20) The Leeds Children's Hospital Prescribing and Administration Guide: Lansoprazole and Omeprazole: <a href="http://www.leedsformulary.nhs.uk/docs/Paediatriclansoprazolemonograph.pdf">http://www.leedsformulary.nhs.uk/docs/Paediatriclansoprazolemonograph.pdf</a> West Essex CCG and the Princess Alexandra Hospital: <a href="https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/clinical-guidelines-and-prescribing-formularies/01-gastro-intestinal-system/3594-ppi-paediatric-guidance/file">https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/clinical-guidelines-and-prescribing-formularies/01-gastro-intestinal-system/3594-ppi-paediatric-guidance/file</a> West Hertfordshire Hospitals and Herts Valleys CCG: <a href="https://hertsvalleysccg.nhs.uk/application/files/5516/0803/4083/Proton_Pump_Inhibitor_PPI_use_in_paediatric_patients_-_joint_guidance_for_primary_and_secondary_care_v2.0_October_2020.pdf">https://hertsvalleysccg.nhs.uk/application/files/5516/0803/4083/Proton_Pump_Inhibitor_PPI_use_in_paediatric_patients_-_joint_guidance_for_primary_and_secondary_care_v2.0_October_2020.pdf</a>
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