

## APPROPRIATE PRESCRIBING OF SPECIALIST INFANT FORMULAE

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Colour key used on the following pages:

<b>Prescribe as first line</b>
<b>Prescribe as second line</b>
<b>Should not routinely be commenced in primary care</b>
<b>Should not routinely be prescribed – available over the counter from pharmacy</b>
<b>Purchase from supermarket</b>

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## INTRODUCTION

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.

## 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. The guidelines are targeted at infants 0-12 months. However, some of the prescribable items mentioned here can be used past 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 different clinical conditions
- triggers for reviewing and discontinuing prescriptions
- when onward referral for dietetic advice and/or secondary/specialist care should be considered

## QUANTITIES OF FORMULAE TO PRESCRIBE

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

**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 x 900g tins
6-12 months	7-13 x 400g tins	or 3-6 x 900g tins
Over 12 months	7 x 400g tins	or 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 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.

## COW'S MILK PROTEIN ALLERGY (CMPA)

### SYMPTOMS AND DIAGNOSIS

- Refer to NICE guideline CG116 'Food Allergy in Children and Young People' Feb 2011 for full details of symptoms, taking an allergy focused history, diagnosis and challenging with foods. <http://guidance.nice.org.uk/CG116/Guidance/pdf/English>
- Refer also to MAP guideline (Milk Allergy in Primary Care) - electronic interactive version here: <http://cowsmilkallergyguidelines.co.uk/interactive-algorithm/#div3>
- Symptoms can include:
  - Skin symptoms (pruritis, erythema, urticaria, atopic dermatitis or eczema)
  - Acute angioedema of the lips and face, tongue and palate and around the eyes
  - Gastrointestinal (GI) symptoms (loose, frequent, bloody or mucus containing stools, nausea and vomiting, abdominal distension and/or colicky pain, constipation, GORD)
  - Recurrent wheeze or cough, nasal itching, sneezing, rhinorrhea or congestion
  - Anaphylaxis
  - Faltering growth, food refusal or aversion
- **Most infants with non-IgE-mediated CMPA develop symptoms within 2-72 hours of exposure to cow's milk protein. Most infants with IgE-mediated CMPA develop symptoms within minutes of exposure to cow's milk protein.**

### ONWARD REFERRAL

- **Most infants with CMPA can be managed in primary care.**
- **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 them regarding their diet and that of their child.
- **Refer infant to secondary or specialist care if any of the following apply:**
  - Faltering growth with one or more GI 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)

### TREATMENT- Breast fed infants

- **Breast milk** is the optimum choice for most infants with CMPA.
- If symptoms persist in the exclusively breast fed infant, a maternal milk free diet is indicated for a minimum trial of 2 weeks. Dietary advice is available here: <https://www.bda.uk.com/foodfacts/milkallergy.pdf>
- It is recommended that breastfeeding mothers on a milk free diet should purchase supplementation with 1000mg calcium per day 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 amino acid formula (AAF) will be needed and can be prescribed in primary care.

### TREATMENT- Bottle fed infants

- **If breastfeeding is not occurring, extensively hydrolysed formulae (EHF) are the first choice**, unless the infant has a history of anaphylactic symptoms.
- AAF should normally be started in secondary or specialist care. They are suitable only when EHF do not resolve symptoms and/or there is evidence of severe (anaphylactic) allergy. See MAP guideline as above.
- 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.
- **Only 10% of infants with CMPA should require management with AAF.**

## COW'S MILK PROTEIN ALLERGY (CMPA) continued

### THE MOST COST EFFECTIVE EXTENSIVELY HYDROLYSED FORMULA IS

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>▪ <b>Similac Alimentum<sup>®</sup></b> (Abbott Nutrition)</li> </ul> | Birth to 2 years or able to tolerate over the counter products. Lactose free. Casein based. |
|---|---|

***Prescribing this EHF will give a cost saving of ~£200 in the first year of a child's life compared with other EHF listed below***

### OTHER EXTENSIVELY HYDROLYSED FORMULAE

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>▪ <b>Nutramigen<sup>®</sup> 1 with LGG<sup>®</sup></b> (Mead Johnson)</li> </ul> | Birth to 6 months. Contains probiotics. Lactose free. Casein based.   |
| <ul style="list-style-type: none"> <li>▪ <b>Nutramigen<sup>®</sup> 2 with LGG<sup>®</sup></b> (Mead Johnson)</li> </ul> | 6 months to 2 years or until able to tolerate over the counter products. Contains probiotics. Lactose free. Casein based. |
| <ul style="list-style-type: none"> <li>▪ <b>SMA Althera<sup>®</sup></b> (Nestle)</li> </ul>                             | Birth to 3 years or until able to tolerate over the counter products. Whey based.   |
| <ul style="list-style-type: none"> <li>▪ <b>Pepti<sup>®</sup> 1</b> (Milupa Aptamil)</li> </ul>                         | Birth to 6 months. Whey based.  |
| <ul style="list-style-type: none"> <li>▪ <b>Pepti<sup>®</sup> 2</b> (Milupa Aptamil)</li> </ul>                         | 6 months to 2 years or able to tolerate over the counter products. Whey based.  |

### EXTENSIVELY HYDROLYSED FORMULAE WITH MEDIUM CHAIN TRIGLYCERIDES TO BE STARTED IN SECONDARY CARE

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>▪ <b>Pregestimil Lipil<sup>®</sup></b> (Mead Johnson)</li> </ul> | Birth to 2 years or until able to tolerate over the counter products |
| <ul style="list-style-type: none"> <li>▪ <b>Pepti – Junior<sup>®</sup></b> (Cow &amp; Gate)</li> </ul>  | Birth to 2 years or until able to tolerate over the counter products |

**These formulae are used where CMPA is accompanied by malabsorption**

### AMINO ACID FORMULAE NORMALLY TO BE STARTED IN SECONDARY CARE

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>▪ <b>Nutramigen<sup>®</sup> Puramino<sup>®</sup></b> (Mead Johnson)</li> </ul>    | Birth until at least 1 year or when able to tolerate over the counter products |
| <ul style="list-style-type: none"> <li>▪ <b>Neocate LCP<sup>®</sup></b> (Nutricia)</li> </ul>                            | Birth until at least 1 year or when able to tolerate over the counter products |
| <ul style="list-style-type: none"> <li>▪ <b>Neocate<sup>®</sup> Active unflavoured</b> (Nutricia)</li> </ul>             | over 1 year  |
| <ul style="list-style-type: none"> <li>▪ <b>Neocate<sup>®</sup> Active blackcurrant flavour</b> (Nutricia)</li> </ul>    | over 1 year  |
| <ul style="list-style-type: none"> <li>▪ <b>Neocate<sup>®</sup> Advance unflavoured</b> (Nutricia)</li> </ul>            | over 1 year  |
| <ul style="list-style-type: none"> <li>▪ <b>Neocate<sup>®</sup> Advance banana/vanilla flavour</b> (Nutricia)</li> </ul> | over 1 year  |

1. If a patient presents with clear anaphylactic reaction to cow's milk these formula should be commenced in primary care, with immediate onward referral to secondary or specialist care.
2. If formula top-ups are needed for a child who is otherwise breastfed (mother on a milk free diet) AAF will be required.
3. Neocate Active<sup>®</sup> is a high calorie formula and will not be required automatically by all infants over 1 year. It is not suitable as a sole source of nutrition.
4. Neocate Advance<sup>®</sup> is a sole source of nutrition for patients with CMPA aged 1-10 years. It is a high calorie product and will not be required automatically by all patients over 1 year.

## COW'S MILK PROTEIN ALLERGY (CMPA) continued

### DIAGNOSTIC CHALLENGE WITH COW'S MILK IN MILD TO MODERATE NON-IgE- MEDIATED CMPA

- To confirm the initial diagnosis of CMPA, the MAP guideline recommends reintroduction of cow's milk after 4 weeks of exclusion in mild to moderate non-IgE-mediated CMPA. Therefore prescribe EHF for one month only initially.
- A leaflet explaining the diagnostic milk challenge for parents is available to download here: <http://cowsmilkallergyguidelines.co.uk/downloads-and-resources/downloadable-map-home-challenge/>.

### REVIEW AND DISCONTINUATION OF PRESCRIPTIONS

- **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 page 2, 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** – refer to MAP guideline or NICE guidelines on which children should be challenged with cow's milk in secondary care setting. The paediatric dietitian will advise and support on this. The MAP milk ladder for home challenges and reintroductions is downloadable here. <http://cowsmilkallergyguidelines.co.uk/downloads-and-resources/downloadable-map-milk-ladder/>.
- **Prescriptions should be stopped** when the child has outgrown the allergy (see notes 1 and 5 below).
- **Review the need for the prescription if you can answer 'yes' to any of the following questions:**
  - Is the patient over 2 years of age? Or has the formula been prescribed for more than 1 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 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 2 years.** This should always be at the suggestion of 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 CMPA 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 only 1 or 2 tins initially** until compliance/tolerance is established to avoid waste.
4. **Rice milk** is not suitable for children under 5 years due to its arsenic content.
5. **Outgrowing CMPA** – 60-75% of children outgrow CMPA by 2 years of age, rising to 85-90% of children at 3 years of age.
6. **Calcium and vitamin D supplementation** may be needed for infants depending on volume and type of formula taken – the dietitian will advise.
7. **Lactose free formulae**, goat's, sheep, and other mammalian milks are not suitable for those with CMPA.

## PRE-TERM INFANTS

### INDICATIONS

- These infants will have had their pre-term nutrient enriched post discharge formula commenced on discharge from the neonatal unit. It is not needed for all pre-term babies and those who do require it will be identified by the neonatal unit.
- When used it is for some babies born before 34 weeks gestation, weighing less than 2kg at birth who are not breast fed.
- If, following discharge, breast feeding reduces or stops and a formula is required the neonatal unit should advise whether a pre-term formula is required or regular formula can be used.
- **These formulae 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 and health visitors.
- If there are concerns regarding poor growth whilst the infant is on these formulae, or there are concerns regarding growth at 6 months corrected age or at review one month after these formulae are stopped, a referral to the paediatric dietitian is appropriate.

### REVIEW AND DISCONTINUATION OF TREATMENT

- Monitoring of growth (weight, length and head circumference) should be carried out by the Health Visitor while the baby is on these formulae. Once catch up growth is achieved they should be stopped.
- It is very important that these products should be discontinued by 6 months corrected age at the latest.
- 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 6 months corrected age, the formula should be stopped.

#### PRE-TERM INFANT FORMULAE USUALLY STARTED IN SECONDARY CARE

- |  |   |
|--|---|
| ▪ SMA <sup>®</sup> Pro Gold Prem 2 powder (SMA)  | Discharge up to a maximum of 6 months corrected age |
| ▪ Nutriprem <sup>®</sup> 2 powder (Cow and Gate) | Discharge up to a maximum of 6 months corrected age |

**6 months corrected age = EDD + 26 weeks**

#### PRE-TERM INFANT FORMULAE WHICH SHOULD NOT ROUTINELY BE PRESCRIBED unless there is a clinical need e.g. immunocompromised infant

- |  |   |
|--|---|
| ▪ SMA <sup>®</sup> Gold Prem 2 liquid (SMA)      | Discharge up to a maximum of 6 months corrected age |
| ▪ Nutriprem <sup>®</sup> 2 liquid (Cow and Gate) | Discharge up to a maximum of 6 months corrected age |

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

## FALTERING GROWTH

### SYMPTOMS AND DIAGNOSIS

- The NICE clinical guideline 'Faltering Growth – recognition and management of faltering growth in children' is currently in development and is due for publication in 2018.
- Diagnosis is made when the growth of an infant falls below the 0.4<sup>th</sup> centile *or* crosses 2 centiles downwards on a growth chart *or* weight is 2 centiles below length centile.
- It is not possible to detect faltering growth without using appropriate growth charts.
- Individual growth pattern (height/length as well as weight), feeding behaviours, parental factors and any indicators of underlying illness should be taken into account when assessing the need for high energy formulae.
- It is essential to rule out possible disease related/medical causes for the faltering growth eg. iron deficiency anaemia, constipation, GORD 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.

### 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 formula should be discontinued to minimise excessive weight gain.

### HIGH ENERGY FORMULA FIRST LINE

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

### HIGH ENERGY FORMULAE SECOND LINE

- |  |                                     |
|--|-------------------------------------|
| ▪ <b>SMA<sup>®</sup> High Energy 250ml bottle (SMA Nutrition)</b>            | <b>Birth up to 18 months or 8kg</b> |
| ▪ <b>Similac<sup>®</sup> High Energy 48 x 60ml bottle (Abbott Nutrition)</b> | <b>Birth up to 18 months or 8kg</b> |
| ▪ <b>Infatrini<sup>®</sup> 100/200ml bottle (Nutricia)</b>                   | <b>Birth up to 18 months or 8kg</b> |

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

- |   |                                     |
|---|-------------------------------------|
| ▪ <b>Infatrini Peptisorb<sup>®</sup> 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

## FALTERING GROWTH

### 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. CMPA can co-exist with GORD and treatment as for CMPA 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

- **1-2 week trial of Gaviscon Infant<sup>®</sup> 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<sup>®</sup> Infant.

#### STEP 1 bottle fed infants

- **Sequential 1-2 week trial of each of the following options:**
  - 1. Thickened feeds to purchase** - Aptamil<sup>®</sup> Anti-Reflux or Cow & Gate<sup>®</sup> Anti-Reflux formula or Instant Carobel<sup>®</sup> added to regular formula. **Or thickening formula to purchase** - SMA Staydown<sup>®</sup> or Enfamil AR<sup>®</sup> (see notes page 10)
  - If these are ineffective trial Gaviscon Infant<sup>®</sup>. This should not be used with other preparations containing thickening agents.
  - 2. Gaviscon Infant<sup>®</sup>.** Mix the dose into 115ml of regular formula feed in the bottle, shake well and feed as normal.

Gaviscon Infant<sup>®</sup> 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 bottle fed infants

- **If STEP 1 treatment is not successful** a 4 week trial of omeprazole or ranitidine may be considered.
  - **If symptoms still persist, 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)

### THICKENED FORMULAE TO PURCHASE FROM SUPERMARKETS

- |   |            |
|---|------------|
| <b>▪ Aptamil<sup>®</sup> Anti-Reflux</b>        | From birth |
| <b>▪ Cow &amp; Gate<sup>®</sup> Anti-Reflux</b> | From birth |

### THICKENING FORMULA TO PURCHASE FROM SUPERMARKETS OR PHARMACIES

- |                                   |   |
|-----------------------------------|---|
| <b>▪ SMA Staydown<sup>®</sup></b> | From birth (available in supermarket)         |
| <b>▪ Enfamil AR<sup>®</sup></b>   | From birth (available to order from pharmacy) |

### THICKENER TO PURCHASE FROM PHARMACIES FOR ADDITION TO REGULAR FORMULA

- |   |   |
|---|---|
| <b>▪ Instant Carobel<sup>®</sup> (Cow and Gate)</b> | From birth (available to order from pharmacy) |
|---|---|

### NOTES ON THICKENED AND THICKENING FORMULAE AND THICKENER

- Aptamil<sup>®</sup> Anti-Reflux and Cow & Gate<sup>®</sup> 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.
- Thickening formulae (SMA Staydown<sup>®</sup> and Enfamil AR<sup>®</sup>) are no longer recommended for prescription because of the ready availability of thickened formulae.** If parents choose to purchase thickening formulae (SMA Staydown<sup>®</sup> is readily available to purchase in supermarkets, Enfamil AR<sup>®</sup> would need to be ordered from a pharmacy) they should be advised not to use them in conjunction with separate thickeners or with medication such as Gaviscon Infant<sup>®</sup>, ranitidine, or omeprazole. These formulae need to be mixed with fridge cooled pre-boiled water (see tin for full instructions).
- Instant Carobel<sup>®</sup> feed thickener** contains carob gum, is mixed with regular formula to produce a thickened formula and will require the use of a large hole (fast-flow) teat. It may be suggested for addition to CMPA formulae where CMPA co-exists with GORD. Parents should purchase the product at a pharmacy.
- 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 (BNF for children 2016-2017, SPC for products)

- Gaviscon Infant<sup>®</sup>** contains sodium, and should not be given more than 6 times in 24 hours or where the infant has diarrhoea, vomiting, renal impairment or a fever. It should not be given if intestinal obstruction is suspected or in pre-term neonates.

Each half of the dual sachet of Gaviscon Infant<sup>®</sup> is identified as 'one dose'. To avoid errors, prescribe with directions in terms of 'dose'. Dispensing pharmacists should advise about appropriate doses of over the counter products.

Gaviscon Infant<sup>®</sup> is suitable from 1 month to 2 years old.

**Weight less than 4.5kg:** prescribe 1 dose, mixed with feeds when required, up to 6 times in 24hours (maximum 6 doses in 24 hours).

**Weight 4.5kg and above:** prescribe 2 doses, mixed with feeds when required, up to a maximum of 6 times in 24 hours (maximum 12 doses in 24 hours).

- Ranitidine** – the recommended dose of ranitidine is:
  - Aged 1-5 months: 1mg/kg 3 times daily (maximum 3mg/kg 3 times daily)**
  - Aged 6 months to 2 years: 2 - 4mg/kg twice daily**
  - Ranitidine is available as 5mg/5ml oral suspension (unlicensed liquid special)
- Omeprazole** – the recommended dose of omeprazole is:
  - Aged 1 month to 1 year: 700micrograms/kg once daily. Increase if necessary to 3mg/kg once daily (max of 20mg)**
  - Omeprazole is available as Losec<sup>®</sup> MUPS<sup>®</sup> tablets (10mg and 20mg) and an oral suspension. Tablets are a licensed product (but not licensed for use in children except for severe ulcerating reflux oesophagitis in children over 1 year). Oral suspension (5mg/5ml, 10mg/5ml or 20mg/5ml) is an unlicensed liquid special. Dependent on dose required and age of infant, please consider use of Losec<sup>®</sup> MUPS<sup>®</sup> tablets in the first instance. Disperse tablets in water, and if needed mix with some fruit juice.

## SECONDARY LACTOSE INTOLERANCE

### SYMPTOMS AND DIAGNOSIS

- 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 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<sup>®</sup> 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

- |                                     |                           |
|-------------------------------------|---------------------------|
| ▪ Aptamil <sup>®</sup> Lactose Free | From birth – lactose free |
| ▪ Cow & Gate <sup>®</sup> Comfort   | From birth – low lactose  |

### 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 CMPA as they are whole protein formula (with the exception of Cow & Gate<sup>®</sup> Comfort, which is only partially hydrolysed and still unsuitable).
3. Soya formula (SMA Wysoy<sup>®</sup>) 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 – Jan 2017 MIMS prices**

<b>Cow's milk protein allergy – for prescription</b>				
<b>Product</b>	<b>Presentation</b>	<b>Price</b>	<b>Cost per 100g</b>	<b>Cost per 100kcal</b>
Similac Alimentum®	400g tin	£9.10	£2.28	£0.43
Nutramigen® 1 with LGG®	400g tin	£10.99	£2.75	£0.55
Nutramigen® 2 with LGG®	400g tin	£10.99	£2.75	£0.57
SMA Althera®	450g tin	£10.68	£2.37	£0.47
Pepti® 1	400g tin	£9.87	£2.47	£0.50
Pepti® 1	800g tin	£19.73	£2.47	£0.50
Pepti® 2	400g tin	£9.41	£2.35	£0.50
Pepti® 2	800g tin	£18.82	£2.35	£0.50
Pregestimil Lipil®	400g tin	£12.19	£3.05	£0.61
Pepti-Junior®	450g tin	£13.06	£2.90	£0.55
Nutramigen Puramino®	400g tin	£27.09	£6.77	£1.35
Neocate LCP®	400g tin	£28.70	£7.18	£1.51
Neocate® Active unflavoured or blackcurrant flavour	15 x 63g sachets	£67.50	£7.14	£1.50
Neocate® Advance unflavoured	10 x 100g sachets	£59.40	£5.94	£1.49
Neocate® Advance Banana/vanilla flavour	15 x 50g sachets	£46.95	£6.26	£1.57

<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® Pro Gold Prem 2	400g tin	£4.92	£1.23	£0.24
Nutriprem® 2	900g tin	£11.67	£1.30	£0.26
SMA® Pro Gold Prem 2 liquid	200mls	£1.64		£1.12
Nutriprem® 2 liquid	200mls	£1.74		£1.16

<b>High energy formulae – for prescription</b>				
<b>Product</b>	<b>Presentation</b>	<b>Price</b>	<b>Cost per 100g</b>	<b>Cost per 100kcal</b>
Similac® High Energy	200mls	£2.13		£1.05
SMA® High Energy	250mls	£2.46		£1.08
Similac® High Energy	48 x 60mls	£31.68		£1.10
Infatrini®	200mls	£2.31		£1.16
Infatrini®	125mls	£1.43		£1.14
Infatrini Peptisorb®	200mls	£3.54		£1.77

**Examples of retail costs of products to purchase from supermarkets or pharmacies – Jan 2017**

<b>Thickened formulae, thickening formulae and thickener</b>		
<b>Product</b>	<b>Presentation</b>	<b>Price</b>
Cow & Gate® Anti-Reflux	900g	£11.50
Aptamil® Anti-Reflux	900g	£13.00
SMA Staydown®	900g	£10.00
Enfamil AR®	400g	£6.71
Instant Carobel®	135g	£5.11

<b>Lactose free and low lactose formulae</b>		
<b>Product</b>	<b>Presentation</b>	<b>Price</b>
Aptamil® Lactose Free	400g	£6.90
Cow & Gate® Comfort	900g	£11.50

## 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 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 CMPA 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 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 (Tel: 0300 300 1503).
- **Seek prescribing advice if needed in primary care from the Medicines Optimisation Team (Tel: 01375 365811).**
- **Seek prescribing advice if needed in secondary care from the Basildon Hospital Medicines Information Centre, Pharmacy Department (Tel: 01268 593788).**

### 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 CMPA.
- **Do not** routinely prescribe soya formula (SMA Wysoy<sup>®</sup>) for those with CMPA or secondary lactose intolerance. It should not be prescribed at all in those under 6 months due to high phyto-oestrogen content.
- **Do not prescribe formulae for GORD or lactose intolerance since suitable over the counter formulae can be purchased at a similar price to regular formula.**
- **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 (Aptamil<sup>®</sup> Anti-Reflux or Cow & Gate<sup>®</sup> Anti-Reflux formulae) or thickening formulae (SMA Staydown<sup>®</sup>, Enfamil AR<sup>®</sup>) with separate thickener (Instant Carobel<sup>®</sup>) or Gaviscon Infant<sup>®</sup> as this could lead to over thickening of the stomach contents.
- **Do not** prescribe medication such as ranitidine or omeprazole in conjunction with thickening formulae (SMA Staydown<sup>®</sup>, Enfamil AR<sup>®</sup>) if parents choose to purchase this, since the formulae need stomach acids to thicken and reduce reflux.
- **Do not prescribe Instant Carobel<sup>®</sup> 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<sup>®</sup> 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 10)

## REFERENCES AND FURTHER READING

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

Losec® MUPS® Tablets 10mg Summary of Product Characteristics:  
<http://www.medicines.org.uk/emc/medicine/7249>

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