Infant Feeding Guidelines

(A) PRIMARY CARE MANAGEMENT OF INFANTILE COLIC

HSC Health and Social Care Board

Definition and Facts

•Infantile Colic has had an internationally agreed but not well known clinical definition for many years

'Inconsolable crying with limb flexure in an otherwise healthy, thriving infant, which lasts for more than 3 hours per day, occurs on 3 or more days per week, has persisted for more than 3 weeks starting in the first weeks of life and ceasing around 3 to 4 months of age'[1]

•Understandably many parents will seek medical help for their unsettled infants - whose crying falls short of these defined clinical criteria

•It occurs in both formula fed and breast fed infants

•It is common – affecting up to 20% of infants[2]

•The cause or causes of colic are very poorly understood

• **Be aware of the following "WARNING SIGNALS"- pointing to alternative more serious possible diagnoses:** Bile-stained vomiting, forceful vomiting, vomiting onset after 6 months of age, faltering growth, abdominal tenderness/distension, fever, lethargy, enlarged spleen and/or liver, bulging anterior fontanelle, small or enlarged head circumference, seizures, significantly disturbed stool pattern, sudden onset inconsolable crying, documented or suspected genetic/metabolic syndrome.

Non Pharmacological Management

•Exclude common causes of excessive crying e.g. hunger, thirst, dirty nappy, extremes of temperature

•Try holding infant, burping post-feeds, gentle motion (pushing pram or ride in the car), "white noise" (vacuum cleaner, hairdryer etc.), bathing in warm bath, parental support (getting parents to "take a break", if relatives or friends can look after infant), CRY-SIS support group can offer support for families with excessively crying, sleepless and demanding babies. Website address: www.cry-sis.org.uk

•Reassure parents re: that their infant is well, they are not doing something wrong, their infant is not rejecting them, and the natural history is usually towards a relatively early remission

•Maternal smoking has been shown to be associated with infantile colic[3]

•Consider other causes e.g. Gastro-oesophageal Reflux Disease (GORD). See algorithm for Reflux

•Consider referral if parents are finding it difficult to cope or if there is diagnostic doubt

Possible Causes/ Pharmacological Treatments and Their Evidence

Transient Lactase Deficiency :

•There is no good evidence that it either occurs or if it does, that it could cause infantile colic

•Therefore there is **no support** for prescribing either Colief®, a partially hydrolysed, low-lactose formula e.g. Comfort ® **(**Aptamil, Cow &Gate or SMA) or a lactose-free formula e.g. SMA® LF or Enfamil® O-Lac

Intestinal Gas

•There is no good evidence that excess intestinal gas causes infantile colic

•Therefore there is **no support** for prescribing Infacol® or Dentinox Colic Drops® (Simeticone) or supporting the use of Gripe water or Herbal teas

Cow's Milk Allergy- CMA (see CMA Guideline)

There is evidence that a small subset - perhaps 10% - of infants with infantile colic have Cow's Milk Allergy[4]. Consider particularly when:

There is a positive history of atopic eczema, allergic rhinitis, asthma or food allergy in a 1st degree relative (mother, father or siblings)

+ or - other upper or lower gut dysmotility signs e.g. vomiting, regurgitation, food refusal, loose stools - which may be offensive and/or mucousy, perianal excoriation

+ or - skin signs e.g. apparent itching, flushing, urticaria, angioedema, eczema flares - especially with or following feeding.

Therefore a diagnostic dietary elimination trial of cow's milk protein could be considered...

Formula Fed Infant: For colic only: 2 week trial of an Extensively Hydrolysed Formula (eHF) e.g. Casein based Nutramigen® Lipil 1 or Whey based Milupa Aptamil Pepti® 1 with a then planned reintroduction. See CMA Algorithm. Do Not Prescribe: Soya, goats, other mammalian milks or lactose free milks e.g. SMA® LF or Enfamil ® O-Lac. There is also no place for using a partially hydrolysed, low lactose formula such as Comfort® (Aptamil, Cow & Gate or SMA) to carry out such an initial diagnostic dietary elimination trial. (See CMA Guideline)

Breast Fed Infant: A carefully supervised and strict maternal cow's milk protein free diet for 2 to 4 weeks with a then planned reintroduction. The mother will need 1,250mg of calcium and 10 mcg of vitamin D daily during the elimination trial. Early dietetic referral advised. (See CMA Guideline)

[1]*Wessel M A et al Pediatrics 1954; 14 : 421-424 Garrison M M et al Pediatrics 2000; 106 1Pt2 184-190*

[2]*Lucassen P L et al Arch Dis Child 2001; 4: 398-403*

[3]*Reijneveld S A et al Arch Dis Child 2000; 83(4): 302-3*

[4]*Jakobsson I et al Acta Paediatrica 2000 89(4); 18-21*

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(B) PRIMARY CARE MANAGEMENT OF LACTOSE INTOLERANCE (LI) IN CHILDREN (THE CLINICAL EXPRESSIONS– resulting from the different causes of Lactase Enzyme Deficiency)

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CONGENITAL LACTASE DEFICIENCY

- A very rare genetic illness - where the affected new born is unable to produce any lactase enzyme at all
- Presents from birth onwards and life threatening in practice.
- Mostly seen in infants from a Northern Scandinavian, Latvian or Russian ethnic background

EXTREMELY RARE IN THE UK INFANT POPULATION

PRIMARY LACTASE DEFICIENCY

- Lactase enzyme levels slowly decline in all mammals after the usual age of weaning from the mother's milk
- An inherited recessive genetic trait then causes the level to fall more commonly to symptomatic levels in some particular ethnic groups,

Up to 100% Asians and Native Americans

50-80% Hispanic and Black races

5-17% Europeans, especially Eastern Europeans

Only 2% Northern Europeans

No matter what the ethnic background– symptoms and signs rarely present before the age of 2 to 3 years

- Onset of symptoms is typically subtle and progressive over months or years

Rarely presents with an acute onset

- A clinical syndrome of 1 or more of the following GIT symptoms and signs: Loose stools, abdominal pain, flatulence, bloating, nausea, following the ingestion of lactose or lactose-containing food substances, the onset usually within 30 minutes to 2 hours following ingestion.
- The amount or source of lactose that will cause symptoms will vary from one child to another
- Most of the children will be from one of the above higher risk ethnic groups
- There is usually no need to test the stools for pH and/or reducing substances

(It can give both false positive and negative results)

- **Trial of a lactose-free diet** - should soon confirm the diagnosis, symptoms usually settling within a few days. A minority of children may take up to 3 to 4 weeks. Withdrawing all lactose containing food initially from the child's diet using a lactose free formula (e.g. SMA® LF, Enfamil® O-Lac or Aptamil® Lactose free) in children under 1 year of age and a supermarket purchased lactose free milk replacement in children over 1 year, who have previously tolerated cow's milk – Dietetic referral preferable

Positive Response - to remain on lactose-free diet until seen by a dietitian who will direct graded re-introduction of lactose containing foods to determine individual tolerance level

No Response– will need to consider other causes and specialist assessment

SECONDARY LACTASE DEFICIENCY

Due to transient injury of the lactase enzyme-containing brush border lining of the small intestine – the injury mostly due to 1 of 2 main causes **in infancy...**

Post-gastroenteritis LI

- WHO recommends that this form of lactose intolerance need only be considered when acute infectious diarrhoea persists for **> 14 days**
- In practice this has therefore become an uncommon condition in the UK; probably due to the better overall personal health and environment of our children, now leading to fewer significant GIT infections.

CMA (Cow's Milk Allergy) is a more common cause of protracted diarrhoea in infancy in the UK

On suspecting this form of LI

- There is no need to test stools for pH and/or reducing substances
- Usually a transient clinical deficiency
- **Trial of a lactose-free diet–** Withdrawing all lactose containing food. Using a lactose free formula (e.g. SMA® LF, Enfamil® O-Lac or Aptamil® Lactose free) in children under 1 year of age and a supermarket purchased lactose free milk replacement in children over 1 year, who have previously tolerated cow's milk.
- A positive response usually occurs within **48 hours** but the diet should then be maintained for about **6 weeks** to allow healing of the brush border with resulting recovery of the lactase enzyme levels
- Then reintroduce lactose containing foods into the diet– Dietetic referral preferable
- Should that not be tolerated– then early specialist referral is indicated

LI Secondary to Cow's Milk Allergy (CMA)

- Can occur when there are on-going GIT effects of undiagnosed Non-IgE CMA effecting the brush border of the small intestine - leading to a secondary and relative deficiency of lactase enzyme and then the typical symptoms of lactose intolerance.
- The key to making this diagnosis is the awareness of this possible presentation of CMA and then taking a detailed allergy focused clinical history.

See CMA Guideline

- Lactose-free formula (SMA® LF or Enfamil® O-Lac, Aptamil® Lactose free) or Colief® drops **must NOT be prescribed** - as in providing some partial relief to the lactase deficient - related signs, they will likely obscure the correct diagnosis of CMA
- There is **no place** for using a partially hydrolysed, low lactose formula such as Comfort® (Aptamil, Cow&Gate or SMA)

See CMA Guideline

Adapted from: The American Academy of Pediatrics Committee on Nutrition– Report on Lactose Intolerance - Heyman M B et al Pediatrics 2006 118: 1279-86 (*January 2017 Version 0.6 Final Draft*)

(C) PRIMARY CARE MANAGEMENT OF 'REFLUX' IN INFANCY - Are we using the correct terms?.....

Gastro - Oesophageal Reflux – GOR

is the passage of gastric contents into the oesophagus. It is a common physiological event which can happen at all ages from infancy to old age, and it is often asymptomatic. It occurs more frequently after feeds/meals. In many infants, GOR is associated with a tendency to 'overt regurgitation' - the visible regurgitation of feeds.

Parents/carers should be advised that:

- it is very common (at least 40% of Infants)
- usually begins before the infant is 8 weeks old
- may be frequent (5% of infants affected have 6 or more episodes a day)
- does not usually need further investigation or treatment
- usually becomes less frequent with time (resolves in 90% of infants before they are one year old)

Look out for 'red flags' which may suggest disorders other than GOR or GORD (see box below). Investigate or refer using clinical judgement

When reassuring parents about regurgitation, advise them that they should return for review if any of the following occur:

- Regurgitation becomes persistently projectile
- There is bile stained (green or yellow) vomiting or haematemesis (blood in vomit)
- There are new concerns, such as signs of marked distress, feeding difficulties or faltering growth

Do not routinely investigate or treat GOR if an infant or child without overt regurgitation presents with only 1 of the following:

- Unexplained feeding difficulties
- Distressed behaviour
- Faltering growth
- Chronic cough or hoarseness
- A single episode of pneumonia

See 'Reflux' Management Algorithm (Page 3.2)

Gastro - Oesophageal Reflux DISEASE - GORD

refers to gastro-oesophageal reflux that causes symptoms (e.g. discomfort or pain) severe enough to warrant medical treatment, or to gastro-oesophageal reflux-associated complications (such as oesophagitis or pulmonary aspiration).

See 'Reflux' Management Algorithm (Page 3.2)

Red Flag Symptoms

'Warning Signals' present ?…

Presence of bile i.e. dark green or yellow colour vomit, frequent forceful (projectile) vomiting, haematemesis (blood in vomit), persistent retching, vomiting onset after 6 months of age or persisting after 1 year, blood in stool, chronic diarrhoea, faltering growth, fever, lethargy, hepatosplenomegaly, bulging fontanelle, macro/ microcephaly, seizures, abdominal distension, tenderness or palpable mass, appearing unwell, fever, dysuria, altered responsiveness e.g. lethargy or irritability, documented or suspected genetic/ metabolic syndrome, infants with high risk of atopy - may suggest cows' milk protein allergy **(see CMA guideline page 4.1)**

(C) PRIMARY CARE MANAGEMENT OF 'REFLUX' IN INFANCY

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Initial Management of GOR and GORD

History and Examination
+/- Observe Feeding

- Reassure, educate and support family **(see page 3.1)**
- Monitor satisfactory weight progress
- Do not use positional management to treat GOR in sleeping infants. Infants should remain on their back whilst sleeping.

BREAST FED INFANTS

- Breast fed infants with frequent regurgitation associated with marked distress, ensure person with appropriate expertise carries out a breastfeeding assessment
- In breast fed infants with frequent regurgitation, associated with marked distress that continues despite a breastfeeding assessment and advice, consider alginate therapy (e.g. Gaviscon® Infant sachets) for a trial period of 1-2 weeks. If the alginate therapy is successful, continue with it, but try stopping at intervals to see if the infant has recovered.

FORMULA FED OR MIXED FEEDING INFANTS

In formula fed infants with frequent regurgitation associated with marked distress, use the following stepped-care approach:

- Review the feeding history, then
- Reduce the feed volumes only if excessive for the infant's weight, then
- Offer a trial of smaller, more frequent feeds (while maintaining an appropriate total daily amount of milk) unless feeds are already small and frequent, then
- Offer a trial of thickened formula. **In the first instance standard formula can be thickened with Carobel®** (a faster flow teat will be required) OR use one of the formulas suggested in tables below:

THICKENED FORMULAE These formulas are already thickened when made up and will require a faster flow teat	***Aptamil® Anti-reflux (Milupa)** (Birth to 1 year)	***Cow& Gate® Anti-reflux** (Birth to 1 year)
THICKENING FORMULAE These formulas thicken on contact with acid in the stomach and so should NOT be prescribed with antacid medications such as PPIs or H_2RAs	***SMA Stay Down®** (Birth to 18 months)	***Enfamil AR®** (Birth to 18 months)

***THESE FORMULAS CAN BE PURCHASED AT A SIMILAR PRICE TO STANDARD FORMULAS**

- In formula fed infants, if the stepped care approach is unsuccessful **STOP** the thickened formula and offer alginate therapy (Gaviscon® Infant sachets) for a trial period of 1-2 weeks. If the alginate therapy is successful, continue with it, but try stopping at intervals to see if the infant has recovered.

Pharmacological Treatment of GORD

- Do not offer acid-suppressing drugs such as proton pump inhibitors or H_2 receptor antagonists (H_2RAs) to treat overt regurgitation in infants and children occurring as an isolated symptom.
- Consider a 4-week trial of a PPI or H_2RA (e.g. ranitidine) in infants who have overt regurgitation with 1 or more of the following:
  - Unexplained feeding difficulties (e.g. refusing feeds, gagging or choking)
  - Distressed behaviour
  - Faltering growth
- Suitable PPIs are: Omeprazole Mups or, if Infant ≥ **2.5kg weight,** Lansoprazole Orodispersible. **See Appendix A** for article on 'Omeprazole / Lansoprazole / Ranitidine in Infants' for dosing and administration advice.
- When choosing between a PPI and H_2RA take into account the availability of age appropriate preparations, the preference of the parent (or carer) and cost.
- Assess the response to the 4 week trial of the PPI or the H_2RA and consider referral to a specialist for possible endoscopy if the symptoms:
  - Do not resolve or
  - Recur after stopping the treatment
- Do not offer metoclopramide, domperidone or erythromycin to treat GOR or GORD without seeking specialist advice and taking into account their potential to cause adverse effects
- **Look out for 'red flags' which may suggest disorders other than GOR or GORD** **(see page 3.1)**

Cows' Milk Protein Allergy

Be aware that some symptoms of non-IgE mediated Cows' Milk protein allergy can be similar to the symptoms of GORD, especially in infants with atopic symptoms and/or a family history . If a non-IgE medicated cows' milk protein allergy is suspected **(see CMA Algorithm)**

Prescribing Notes:

- Anti-regurgitation infant formulas such as Aptamil Anti Reflux®, Cow and Gate Anti Reflux®, Enfamil AR® or SMA Staydown® should **NOT** be prescribed along with other thickening agents such as Carobel® or Gaviscon® Infant sachets as this could lead to over-thickening of the stomach contents.
- Similarly Gaviscon® Infant Sachets should not be prescribed with Carobel®
- **Thickening** infant formulas such as Enfamil AR® or SMA Staydown® require an acid environment in order to thicken and therefore will not work properly when prescribed along with antacid medications such as PPIs or H_2RAs.

Adapted from NICE Guideline (CG116): Gastro-oesophageal reflux disease: recognition, diagnosis, and management in children and young people. January 2015. (*January 2017 Version 0.6 Final Draft)*

(D) Suspected Cow's Milk Allergy (CMA) in the 1st Year of Life

Contents

Dietitian Referral Guidance
Please forward all Dietetic Referrals to the designated Dietetic Department for your Trust– and the child and family will then be referred to an appropriately trained dietitian

Have you asked all the relevant questions ?

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BOX 2 Allergy-focused clinical history NICE Food Allergy Guideline 116 February 2011

Adapted from the NICE Guideline which is for all expressions of Food Allergy
- to better reflect Cow's Milk Allergy presenting in Infancy

Ask about:

- Any Family History of atopic disease (asthma, atopic eczema, allergic rhinitis or food allergy) in parents or siblings

- Any Personal History of early atopic disease - atopic eczema and less commonly in the 1st year of life - upper and lower airway signs
  - any obvious allergic reactions to other foods

- The infant's feeding history - whether breast fed or formula fed

  If breast fed - exclusively or whether early CMP post-natal top-up formulas were briefly given
  timing of introduction of later CMP top-up formulas and/or CMP in weaning food
  i.e. **'Mixed feeding'** - as referenced in the Algorithms
  - details of the maternal diet, especially dairy but also egg, soya, wheat, nuts, and fish

  If formula fed - details of which formulas

  If weaning commenced - age of starting and details of foods to date – especially what other forms of dairy have been introduced and whether any possible allergic symptoms and signs might have coincided with this
  - any suspected reactions to other weaning foods

- Presenting signs and symptoms that may be indicating possible CMA – see **BOX 1**

  Including :
  - age of onset
  - speed of onset of symptoms and signs
  - duration, severity and frequency
  - reproducibility of signs on repeated exposure
  - what form of cow's milk protein ingested and quantity that caused an apparent reaction/s

- Details of previous management, including any medication and the perceived response to any management

- Has anyone raised concern about possible food allergy, who that is and why do they think it may be food allergy

- Any attempts to change the diet, details and perceived response

Take account of cultural and religious factors that might influence the infant's or mother's diet

Suspected Cow's Milk Allergy (CMA) in the First Year of Life

- Cow's Milk Allergy currently affects 2-4% of all infants in the UK
  – the large majority of CMA first presents in infancy and in the primary care setting

- **Most of these infants will clinically present early - within days or within a few weeks of first ingesting Cow's Milk Protein (CMP).**

- Infants are exposed to CMP in normal infant formula, via breast milk if the mother is consuming cow's milk or cow's milk-containing foods in her own diet or when solids are introduced during the weaning period

- Consider the diagnosis in any infant showing any of the signs and symptoms in Box 1 from the NICE Food Allergy Guideline (No. 116 Feb 2011) - See BOX 1 opposite
  - especially if there is any family history of atopic eczema, allergic rhinitis, asthma or food allergy in a 1st degree relative (i.e. mother, father or sibling)

- **Pay particular attention to persistent signs or symptoms that involve different organ systems in the same infant – see BOX 1 opposite**

- Distinguish between signs or symptoms that present acutely following ingestion and those that have run a more chronic course.
  Acute signs or symptoms mostly occur within minutes of ingestion of CMP and certainly within 2 hours – they are usually '**IgE-antibody-mediated'.**
  Delayed signs or symptoms mostly occur 2 or more hours following ingestion and may be delayed for up to 48 hours or more – they are usually due to a '**Non-IgE-mediated'** pathway of the Immune System
  (the former term often used here was Cow's Milk Protein Intolerance)
  A minority of infants with CMA may either present with or evolve to a '**Mixed IgE and Non- IgE** clinical pattern of both acute and delayed onset signs and symptoms – in which case the IgE pathway needs to be primarily followed

- Particularly consider CMA in any infant who has been treated for such clinical presentations as moderate to severe atopic eczema, GORD or other persisting gastrointestinal symptoms (including 'colic', loose stools, constipation) but they have not responded to the usual initial therapeutic interventions.
  - especially if there is any family history of atopic eczema, allergic rhinitis, asthma or food allergy in a 1st degree relative
  In these infants faltering growth is not a consistent feature and good growth does not in any way exclude the possibility of the diagnosis of CMA

BOX 1 Signs and Symptoms of possible Food Allergy
NICE Food Allergy Guideline 116 Feb 2011

IgE-mediated	Non-IgE-mediated
The Skin	
Pruritus **Erythema** **Acute urticaria** localised or generalised **Acute angioedema** most commonly of the lips, face and around the eyes	**Pruritus** **Erythema** **Atopic Eczema**
The Gastrointestinal System	
Angioedema of the lips, tongue and palate **Oral pruritus** **Nausea** **Colicky abdominal pain** **Vomiting** **Diarrhoea**	**Gastroesophageal Reflux Disease** **Loose or frequent stools** **Blood and/or mucus in stools** **Abdominal pain** **Infantile colic** **Food refusal or aversion** **Constipation** **Perianal redness** **Pallor and tiredness** **Faltering growth - plus** **one or more GIT symptoms above** (with or without significant eczema)
The Respiratory System - usually in combination with one or more of the above signs and symptoms	
Upper Respiratory Tract Nasal itching, sneezing, rhinorrhoea or congestion (+/- conjunctivitis)	Isolated respiratory symptoms are usually not indicative of IgE or Non-IgE-mediated food allergy
Lower Respiratory Tract - Cough, chest tightness, wheezing or shortness of breath	
Anaphylaxis **or other systemic allergic reactions**	

The MAP guideline

Suspected Cow's Milk Allergy (CMA) in the First Year of Life

- having taken an Allergy-focused Clinical History

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Mild to Moderate Non-IgE-mediated CMA 'Delayed' Onset Symptoms

Mostly 2-72 hrs after ingestion of Cow's Milk Protein

Formula fed, exclusively breast fed or at onset of mixed feeding

One, or often more than one of these symptoms:

Gastrointestinal
'colic'
vomiting - 'reflux' - GORD
food refusal or aversion
loose or frequent stools
perianal redness
constipation—especially soft stools, with excessive straining
abdominal discomfort, painful flatus
blood and/or mucus in stools in an otherwise well infant

Skin
pruritus, erythema
significant atopic eczema

Respiratory
'catarrhal' airway symptoms
(usually in combination with one or more of the above symptoms)

Can be managed in Primary Care
See (Page 4.5)
Management Algorithm

*See Page 4.6 for examples of Specific Formulas

Severe Non-IgE-mediated CMA 'Delayed' Onset Symptoms

Mostly 2-72 hrs after ingestion of Cow's Milk Protein

Formula fed, exclusively breast fed or at onset of mixed feeding

One or more of these **severe** and **persisting** signs or symptoms:
Gastrointestinal
diarrhoea, vomiting, abdominal pain, food refusal or food aversion, significant blood and/or mucus in stools, irregular or uncomfortable stools.
+/- faltering growth

Skin
severe atopic eczema +/- faltering growth

Cow's Milk Protein free diet
Amino Acid Formula
AAF*
Alternatively, advise exclusively breast feeding mother to exclude all CMP from her own diet and to take daily Calcium (1250mg) and Vitamin D (10mcg) supplements
(see specific product examples on Page 4.8)

Ensure:
Urgent referral to a paediatrician with an interest in allergy
Urgent dietetic referral

Severe IgE CMA ANAPHYLAXIS

Immediate reaction with severe respiratory and/or CVS signs and symptoms.
(Rarely a severe gastrointestinal presentation)

Emergency treatment and admission

Mild to Moderate IgE-mediated CMA 'Immediate' Onset Symptoms

Mostly within minutes of ingestion of Cow's Milk Protein
Mostly formula fed or at onset of mixed feeding

One or more of these signs or symptoms:

Skin
acute pruritus, erythema, urticaria, angioedema
acute 'flaring' of atopic eczema

Gastrointestinal
Vomiting, diarrhoea, abdominal pain/colic

Respiratory
Acute rhinitis and/or conjunctivitis

Cow's Milk Protein free diet
Extensively Hydrolysed Formula - eHF*
(Initial choice, but some infants may then need an **Amino Acid Formula - AAF*** trial if not settling)
Alternatively, advise exclusively breast feeding mother to exclude all CMP from her own diet and to take daily Calcium (1250mg) and Vit D (10mcg) supplements
(see specific product examples on Page 4.8)

IgE testing needed.
If diagnosis confirmed (which may require a Supervised Challenge) – Follow-up with serial IgE testing and later planned and supervised challenge to test for acquired tolerance
Dietetic referral required
If competencies to arrange and interpret testing are not in place - early referral to a paediatrician with an interest in allergy is advised

The MAP guideline: Management of Mild to Moderate Non-IgE CMA

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(No initial IgE Skin Prick Tests or Serum Specific IgE Assays necessary)

Exclusively Breast-fed

Strict Exclusion of cow's milk protein (CMP) from Maternal Diet
Maternal supplements of calcium (1250mg) and vitamin D (10mcg) daily (see specific product examples on Page 4.8)
Refer to dietitian - a maternal milk substitute should be advised (not soya or rice based)
In cases with severe eczema or more severe gut symptoms also consider egg avoidance
If CMA - most symptoms will settle well within the agreed 2-4 week elimination diet
No Improvement **Improvement (need to confirm the diagnosis)**

CMA still suspected:
Need to consider other maternal foods e.g. egg
Refer to a paediatrician with an interest in allergy

CMA no longer suspected:
Return to usual maternal diet
Consider referral to general paediatricians if symptoms persist

Home Challenge: Mother to revert to normal diet including foods containing CMP over a period of one week (See Page 4.10) (to be done between 2-4 weeks of starting Elimination Diet)

No return of Symptoms: NOT CMA

Symptoms return

Exclude foods containing CMP from maternal diet again.
If symptoms settle: CMA NOW CONFIRMED
If top-up formula feeds needed: Use an AAF*

Symptoms do not settle

Formula-Fed or 'Mixed Feeding' (breast and formula)

Strict cow's milk protein (CMP) free Diet
Formula-fed - trial of an **Extensively Hydrolysed Formula (eHF)*** in infant
Mixed feeding - if symptoms occur only with introduction of top-up feeds, replace with eHF* top-ups. Mother can continue to consume foods containing CMP
Refer to dietitian
If CMA - most symptoms will settle well within the agreed 2-4 week EliminationDiet
Improvement (need to confirm diagnosis) **No Improvement**

Perform Home Challenge using cow's milk formula (See Page 4.9)

(to be done between 2-4 weeks of starting Elimination Diet)

Symptoms return

Return to the eHF* again

If symptoms settle: CMA NOW CONFIRMED

Symptoms do not settle

No return of Symptoms: NOT CMA

CMA still suspected:

Refer to a paediatrician with an interest in allergy
Consider a trial of AAF*

CMA no longer suspected:

Unrestricted diet again
Consider referral to general paediatricians if symptoms persist

*See Page 4.6 for examples of specific formulas

CMP-free diet until 9-12 months of age and for at least 6 months – with support of dietitian
A planned reintroduction or supervised challenge is then needed to determine if tolerance has been achieved
Performing a Reintroduction versus a supervised challenge is dependent on the answer to the question:
Does the child have **current eczema** or **ANY history at ANY time of acute onset symptoms?**

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No current eczema And no history at any stage of immediate onset symptoms
(No need to check serum specific IgE or perform skin prick test)
Reintroduction at home to test for tolerance using a **MILK LADDER** (see pages 4.11/12)

And still no history at any stage of acute onset symptoms
Reintroduction at home to test for tolerance using a **MILK LADDER** (see pages 4.11/12)

Current Eczema

Check serum specific IgE
or
skin prick test to cow's milk

Negative **Positive**

History of immediate onset symptoms at any time
Serum specific IgE or skin prick test needed

Negative
Liaise with local Allergy Service regarding next step

Positive
(or tests not available)

Refer to a paediatrician with an interest in allergy
(A **supervised challenge** may be needed)

The Hypoallergenic Formulas

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The constituents vary between the different individual Extensively Hydrolysed Formulas (eHFs) available and also between the different individual Amino Acid Formulas (AAFs) available. This then can sometimes influence both an infant's tolerance and even their perceived apparent palatability of that formula.

The Hypoallergenic Formulas currently most commonly used in the infant age group in the UK for term infants are:

Extensively Hydrolysed Formulas - eHFs

Casein-based constituents

Nutramigen 1 with LCG	Birth onwards	Mead Johnson	400g tin
Nutramigen 2 with LCG	> 6 months of age	Mead Johnson	400g tin
Similac Alimentum	Birth onwards	Abbott Nutrition	400g tin

Whey-based constituents

Milupa Aptamil Pepti 1	Birth onwards	Milupa	400g or 900g tin
Milupa Aptamil Pepti 2	> 6 months of age	Milupa	400g or 900g tin
SMA Althéra	Birth onwards	Nestle	450g tin

All of the above whey based extensively hydrolysed formulas contain Lactose

Amino Acid-based Formulas - AAFs

Neocate LCP	Birth onwards	Nutricia SHS	400g tin
Nutramigen PURAMINO	Birth onwards	Mead Johnson	400g tin
SMA Alfamino	Birth onwards	Nestle	400g tin

The Amino Acid-based Formulas are significantly more expensive than the Extensively Hydrolysed Formulas
Please ensure that an AAF is only prescribed if the CMA Algorithm recommends its use

Examples of recommended Initial Trial Elimination Periods – there is no good evidence base, but most recent guidelines support

Simple GOR or Simple Colic in Formula Fed Infants	**- 2 weeks**	- See also ' Reflux' and Colic Regional Algorithms
GORD or more complex GIT symptoms	**- 4 weeks**	- See also 'Reflux' Regional Algorithm
Severe GIT symptoms or Significant Atopic Eczema	**- Up to 6 weeks**	- See also NICE Guideline on Atopic Eczema

The Initial Introduction of a Hypoallergenic Formula to a Suspected CMA Infant

- In all suspected **IgE-mediated and in severe Non-IgE-mediated CMA** for clinical reasons the Hypoallergenic Formula may need to be introduced directly and without delay.
  - Refer the infant promptly to a Paediatric Dietitian.

See Algorithm Page 4.4

- In suspected **Mild to Moderate Non-IgE CMA** a gradual transitioning onto the Extensively Hydrolysed Formula may be needed over several days. This is because such formulas have a very different flavour and smell compared to either breast milk or cow's milk based formula.

See Algorithm Page 4.5

Transitioning Example:

Day	Volume of Boiled Water (mls)	Hypoallergenic Formula No. of Scoops	Cow's Milk Formula No. of Scoops
Day 1	180	1	5
Day 2	180	2	4
Day 3	180	3	3
Day 4	180	4	2
Day 5	180	5	1
Day 6	180	6	0

*Make up each bottle of the day in exactly the same way

*Do not interchange scoops

*The full schedule needs to be completed- continuing to give any mixture of both Hypoallergenic Formula and Cow's Milk Formula is not acceptable

Practical tips for all infants

- Be patient and persistent - it may take at least 10 days to establish the infant on a reasonable volume of the new Hypoallergenic Formula
- You may need to encourage "dream feeds" if volumes are poor
- During the introduction period encourage the new formula as the main drink and avoid 'baby juices'
- If the infant is of weaning age– use the formula to make baby rice or cow's milk free breakfast cereal and add fruit puree.
  -also try offering the formula in a closed beaker alone or mixed with a little fruit puree

If the infant is not achieving adequate volumes of the Hypoallergenic Formula – Refer promptly to a Paediatric Dietitian

Recommended Daily Supplements

The dietary exclusion of cow's milk and cow's milk products by a breastfeeding mother will have nutritional implications
- especially in achieving calcium and vitamin D daily requirements.

Breastfeeding Mother on a Cow's Milk Free Diet

RNI for lactation in mothers aged 19 years and over: 1250mg of calcium,10µg (400 IU) of Vitamin D daily.
Dose depends on mum's intake of calcium fortified foods.

Recommended Product
NATECAL D3® (Chiesi)
1 tablet contains: 600mg Calcium, 10µg Vitamin D
Dose: Usually 2 tablets daily

Paediatric Dietitian or Community Pharmacist can also provide advice on many other suitable non-proprietary calcium and vitamin D products

DOH Advice - On Vitamin D Supplements for 'At Risk Groups'

The DoH and Chief Medical Officers in the UK (2012), have advised prophylactic Vitamin D supplementation for ALL mothers during pregnancy and for certain infants.

See link: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132508.pdf

Home Challenge to Confirm the Diagnosis of Mild to Moderate Suspected Non-IgE CMA

The Formula Fed Infant - Fully formula fed or taking formula to complement breast feeds

Checklist

1. DO NOT challenge if the infant is unwell; if airways are compromised or if eczema is flared up.
2. DO NOT challenge if the infant is receiving medication that may adversely affect the gut e.g. a course of antibiotics.
3. DO NOT introduce any other new foods during the milk challenge.
4. It may be helpful to ask the parents to keep a record of the infant's oral intake, stool pattern and signs during the challenge.

IF SIGNS RETURN

STOP THE CHALLENGE - RETURN TO THE FULL EXCLUSION REGIME

The infant who shows signs again on the Home Challenge – the mother and infant should be promptly seen by a Dietitian for on-going support

IF NO SIGNS RETURN - THE INFANT DOES NOT HAVE COW'S MILK ALLERGY

- and may continue to consume cow's milk-based formula and milk containing products

Cow's milk itself is NOT A SUITABLE DRINK FOR INFANTS under 12 months of age

EXAMPLE

DAY 1 Into ONE morning bottle only, put 180mls (6oz) of previously boiled water, add 1 scoop of cow's milk based formula and 5 scoops of hypoallergenic formula

Following Days	Volume of Boiled Water (mls)	Hypoallergenic Formula No. of Scoops	Cow's Milk Formula No. of Scoops
Day 2	180	5	1
Day 3	180	4	2
Day 4	180	3	3
Day 5	180	2	4
Day 6	180	1	5
Day 7	180	0	6

*Make up each bottle of the day in exactly the same way
*Do not interchange scoops
*The full schedule needs to be completed (providing no symptoms return). Continuing to give any mixture of hypoallergenic formula and cow's milk formula is unacceptable

4.10 Home Challenge to Confirm the Diagnosis of Mild to Moderate Suspected Non-IgE CMA

The Exclusively Breast Fed Infant

Checklist

1. DO NOT challenge if the infant is unwell; if airways are compromised or if eczema is flared up
2. DO NOT challenge if the infant is receiving medication that may adversely affect the gut e.g. a course of antibiotics
3. It may be helpful to ask the parents to keep a record of the infant's stool pattern and symptoms during the challenge

Simply advise the mother to reintroduce cow's milk and milk containing foods gradually back into her own diet over a 1 week period

IF SIGNS RETURN

STOP THE CHALLENGE - RETURN TO THE FULL EXCLUSION REGIME

The infant who shows signs again on the Home Challenge - the mother and infant should continue to receive on-going support from the Dietitian

IF NO SIGNS – THE INFANT DOES NOT HAVE COW'S MILK ALLERGY

The mother may continue to consume cow's milk and milk containing products

The infant then on weaning, can be introduced to both dairy products and cow's milk in their solids

Home Challenge to Confirm the Clinical Remission of Mild to Moderate Non-IgE CMA

After a Period of Planned Avoidance

- **Usually at 9-12 months of age - or after at least 6 completed months of exclusion**

Checklist

If the child now has additional confirmed or suspected food allergies. DO NOT carry out a Home Challenge without Dietetic advice

1. DO NOT challenge if the child is unwell; if airways are compromised or if eczema is flared up
2. DO NOT challenge if the child is receiving medication that may adversely affect the gut e.g. a course of antibiotics
3. DO NOT introduce any other new foods during the milk challenge
4. It may be helpful to ask the parents to keep a record of the infant's oral intake, stool pattern and signs during the challenge
5. DO introduce the new food early in the day to allow the parents to observe any signs during daytime

The Dietitian can give individualised directions for moving through the stages of the home challenge - if necessary

IF NO SIGNS RETURN

– and the Challenge has been completed,
the child no longer has Cow's Milk Allergy

IF SIGNS RETURN-

DO NOT PROCEED FURTHER WITH THE CHALLENGE

However - the child can be allowed milk proteins at the Stage (if any) that was tolerated

The Challenge will need to be repeated at 4-6 monthly intervals - provided there was no escalation in reaction

Children who do develop signs on the Home Challenge - should be reviewed early by the Dietitian

Home Challenge to Confirm the Clinical Remission of Mild to Moderate Non-IgE CMA – usually at 9-12 months of age – or after at least 6 completed months of exclusion

Stage	Directions	Suitable Foods
Stage 1 **Usually 1 week** **Baked Foods containing Cow's Milk**	**Choose a food item containing milk as a minor ingredient.** Use the same type of food initially, then try other suitable foods **The mother or Dietitian can adjust portions with age** **Day 1** Eat ½ a portion **Day 2** Eat 1 portion **Day 3** Eat 1-2 portions **Day 4** Continue to eat foods containing milk as a minor ingredient more freely; at least for a few more days	**Examples of Baked Foods -** containing milk as a minor ingredient: **Plain Biscuits** e.g. Malted Milk, Digestive, Custard Cream, Certain Crackers **Breads** e.g. breads such as Wheaten or Soda Bread, Pancake (if tolerant of egg)
Stage 2 **Usually 1 week** **Milk Puddings and Continue to eat Baked Foods containing Cow's Milk**	Choose one type of milk pudding initially. Increase amount daily or on alternate days– as felt indicated **Day 1** Offer 1 teaspoon of milk pudding **Day 2** Offer ½ a portion e.g. 60g of custard **Day 3** Offer 1 portion e.g. 120g (individual pots may vary) **Day 4** If no symptoms, continue introducing milk puddings Allow 1 portion daily for a further 3 days If wished– butter can also be introduced now	Some may prefer to initially challenge with "Cooked" milk puddings first e.g. custard, semolina, creamed rice. Then move on to use "Uncooked" milk puddings e.g. yoghurt (natural or with fruit), fromage frais If child refuses or dislikes milk pudding, try gradually introducing cheese over a few days - before moving onto fresh milk
Stage 3 **Usually 1-2 weeks** **Fresh Cow's Milk and Continue to eat Baked Foods and Cow's Milk Products**	Gradual introduction helps the child adjust to the new taste of cow's milk - Introduce 30mls cow's milk early in the day e.g. in cereal - Gradually increase over 2-3 days until the whole serving is made with cow's milk - Continue using cow's milk in cereal and also in cooking - Then begin to gradually replace drinks of the milk substitute with age appropriate formula or cow's milk **You have now successfully reintroduced both milk products and cow's milk into the child's diet**	Under 12 months - use infant formula as milk drink (if not breast fed) Over 12 months, encourage cup for all drinks 12-24 months - Use full cream milk Over 24 months - Can use semi-skimmed milk If milk products are poorly accepted look for calcium fortified breads or cereals– Further Dietetic support may then be needed

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Any practical NI regional feed-back which might further improve the primary care clinical applicability of these guidelines would be welcomed by Dr Brown. Please email any comments to: trevorbrown65@hotmail.co.uk

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APPENDIX A

NORTHERN IRELAND MEDICINES MANAGEMENT

Updated February 2017

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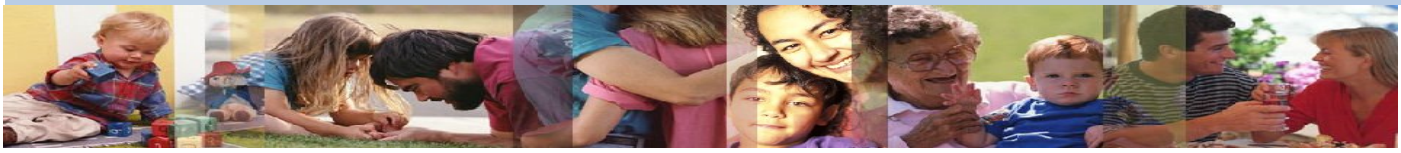
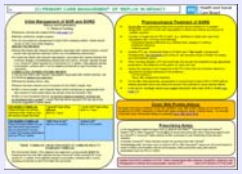


Supplement: Omeprazole / Lansoprazole / Ranitidine in Infants

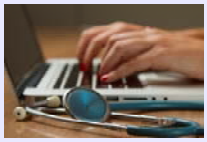
Choosing a suitable formulation of omeprazole / lansoprazole / ranitidine for infants can be problematic. Clinical practice does not always reflect the licensed products available.
The purpose of this newsletter supplement is to assist clinicians and pharmacists in selection and administration of suitable products.
Last year, unlicensed 'specials' of omeprazole, lansoprazole and ranitidine cost the NHS in Northern Ireland over £1,000,000.
While a suspension may be needed in some patients, it is often not the best option

Guidance on managing reflux in infants



If clinically indicated, a 4 week time-limited trial of a H_2-receptor antagonist or a proton pump inhibitor (PPI) may be considered.[1] Please refer to Northern Ireland Infant feeding guideline on the NI Formulary website for full details on managing reflux.

Choice of PPI — lansoprazole or omeprazole?



Royal Belfast Hospital for Sick Children (RBHSC) and the Royal Jubilee Maternity Service (RJMS) neonatal unit are moving to use lansoprazole orodispersible tablets as their preferred option. This is preferred over omeprazole suspension for a number of reasons, including bioavailability issues with omeprazole suspension, problems with enteral feeding tube blockage with omeprazole, and cost.[2]

'Off-label' use or unlicensed 'special'?

The General Medical Council advises that licensed medicines and indications should be used where possible. If this is not an option, consider using a licensed medicine in an unlicensed manner ('off-label' use). 'Specials' are unlicensed medicines and are not required to meet the same standards as licensed preparations. Prescribers assume greater liability when using them and they are considerably more expensive than licensed medicines.[3] Practice-generated scripts for omeprazole or lansoprazole suspension will result in an unlicensed product being dispensed to the patient. Refer to 'specials' supplement on NI Formulary website for further information on 'specials'.

The role of the community pharmacist

If omeprazole or lansoprazole suspension is prescribed, it has to be ordered as an unlicensed 'special', and costs can vary greatly. Community pharmacists are asked to inform the prescriber of the cost of omeprazole or lansoprazole suspension compared to orodispersible tablets before placing an order with a special order company. If the suspension continues to be prescribed, please consider checking alternative suppliers for cost-effective prices.

A need for review

As with any medicine, it is important to review the continued need for H_2-receptor antagonist or PPI use. Risks associated with long-term use of PPIs have been reported. See Medicines Management Newsletter article August 2015 on NI Formulary website.
If there is need for continued use, i.e. the child continues to be symptomatic, ensure that the dose is still suitable for the child's weight, i.e. dose escalation of the H_2-receptor antagonist or PPI may be required as the child gains weight.

Healthcare professionals should explore all alternatives before deciding to prescribe a 'special'

OMEPRAZOLE

Paediatric license: omeprazole is licensed for use in children from 1 year and > 10kg for the treatment of reflux oesophagitis, symptomatic treatment of heartburn and acid regurgitation in gastroesophageal reflux disease.[4,5] In clinical practice, omeprazole is also used off license in children under 1 year.[2]

Preparations: 10mg and 20mg tablets (MUPS®), 10mg and 20mg capsules, 10mg/5mL suspension (manufactured extemporaneously or ordered as a 'special').

Omeprazole Dosage [6]

Age/weight	Dose
Neonate	700 micrograms/kg once daily (max. 2.8mg/kg)
1mth to 2yr	700 micrograms/kg once daily (up to 3mg/kg; max.20mg)
10 to 20kg	10mg once daily (max.20mg)
Child >20kg	20mg once daily (max.40mg)

It is important that calculated doses are then considered in **practical** terms, in relation to available products, i.e. round to the nearest 5mg. In practice, children with a weight of ≥ 3.4kg may be given a dose of 10mg daily.[2] A 5mg dose is usually only prescribed in the hospital setting for babies of low weight.[3]

Omeprazole Unlicensed Specials

- There is only limited evidence of efficacy for the omeprazole suspension. Orodispersible tablets should be used where possible.[7]
- The sodium bicarbonate in the suspension gives it an unpleasant taste and a high sodium content.
- The suspension is usually reserved for children with feeding tubes under 12Fr in size.
- Omeprazole suspension can be ordered as an unlicensed preparation from special order companies. They are often formulated in the same way as the extemporaneous formulation, i.e. using omeprazole capsules in sodium bicarbonate.
- The price of omeprazole suspension can vary greatly between special order companies: invoices to BSO range from £23 to £1664 for omeprazole 10mg/5ml oral suspension).
- **Please ensure a cost-effective product is ordered.**

An extemporaneous formulation can be made up in pharmacies. However, if a suspension is required, it is preferred that this is ordered from a company with a specials manufacturing licence.

Omeprazole 10mg/5mL suspension Extemporaneous Formulation [8]

Ingredients:

Omeprazole capsules 20mg x 28
Sodium bicarbonate 8.4% x 280mL

Method: Open the omeprazole capsules and place contents in a mortar. Crush the granules and mix with a little sodium bicarbonate 8.4%. Make up to volume with the remainder of the sodium bicarbonate solution. Transfer to an amber bottle with an adaptor, label appropriately, and supply with an oral syringe.

COSHH requirements: wear gloves

Expiry: 28 days in fridge (2 to 8°C)

Oral administration of Losec MUPS® tablets

Children <1year who are not spoon fed:

- Use an oral syringe to administer the tablet.
- If a dose of 5mg is required, halve the tablet (using a tablet cutter) before dispersing.
- Place the tablet (or half of a tablet) in the barrel of an oral syringe.
- Replace the plunger and draw up 10mL of water. The resulting dispersion will contain enteric coated pellets.
- Give the 10mL dispersion to the infant.

If a 10mL oral syringe is not available, a medicine cup or 5mL oral syringe may be used to disperse the tablet in water. However, it is important to ensure that ALL of the pellets are drawn up into the oral syringe and administered.

Note: pellets tend to settle to the bottom in oral syringes / medicine cups and there is a risk that the child may not receive the full dose: ensure that all of the pellets are drawn up and administered

Aliquots are not suitable for administering doses under 10mg, i.e. do not try to dissolve a 10mg tablet in 10mL of water and assume 5mL will equal 5mg, as the pellets do not dissolve.[7]

Children who are spoon fed:

Disperse the tablet (or half tablet, depending on dose) in a spoonful of non-carbonated water. If so wished, the dispersion may then be mixed with fruit juice or apple sauce. Always stir just before drinking and rinse down with half a glass of water. Do not use milk or carbonated water. Do not chew the enteric-coated pellets.[5]

Enteral Feeding administration

Omeprazole capsules and MUPS® tablets are unlicensed via enteral feeding tubes but, in practice, MUPS® tablets will flush though tubes ≥ 12Fr. Omeprazole suspension or lansoprazole orodispersible tablets may be considered in finer bore tubes.[7,9,10]

LANSOPRAZOLE

Paediatric license: Lansoprazole is not licensed in children due to limited clinical data.[11] However there is increasing clinical experience and the Children's BNF provides information on use of lansoprazole in infants.

Preparations: 15mg and 30mg Fastabs®, 15mg and 30mg capsules, oral suspension of various strengths (manufactured extemporaneously or ordered as a 'special').

Lansoprazole Dosage [7]

Body weight	Dose	Preparation
For infants under 2.5kg, there is less clinical experience with lansoprazole, therefore use omeprazole		
2.5kg to 5kg	3.75mg once daily	Quarter a 15mg tablet
5kg to10kg	7.5mg once daily	Half a 15mg tablet
10 to 30kg	15mg once daily	One 15mg tablet
> 30kg	30mg once daily	One 30mg tablet

Lansoprazole Unlicensed Specials

- There is limited evidence of efficacy for the lansoprazole suspension. Therefore, orodispersible tablets should be used where possible.[7]
- The sodium bicarbonate in the suspension gives it an unpleasant taste and a high sodium content.
- The suspension is usually reserved for children with feeding tubes under 12Fr in size.
- The price of lansoprazole suspension can vary greatly between special order companies. **Please ensure a cost-effective product is ordered.**

Lansoprazole oral suspension Extemporaneous Formulation

An oral suspension has been made with sodium bicarbonate, but is not as stable as omeprazole in sodium bicarbonate.

Oral administration of orodispersible tablets®

Children <1year who are not spoon fed:

- Use an oral syringe to administer the tablet.
- If a dose of 7.5mg is required, halve the tablet; if a 3.75mg dose if required, quarter the tablet (using a tablet cutter) before dispersing.
- Place the tablet (or half of a tablet) in the barrel of an oral syringe.
- Replace the plunger and draw up10mL water. The dispersion will contain enteric coated pellets.
- Give the 10mL dispersion to the infant.

If a 10mL oral syringe is not available, a medicine cup or 5mL oral syringe may be used to disperse the tablet in water. However, it is important to ensure that ALL of the pellets are drawn up into the oral syringe and administered.

Note: pellets tend to settle to the bottom in oral syringes / medicine cups and there is a risk that the child may not receive the full dose: ensure that all of the pellets are drawn up and administered

Aliquots are not suitable for administering doses under 10mg.[7]

Children who are spoon fed:

Disperse the tablet (or fraction of) in a spoonful of non-carbonated water. FasTabs® may also be given with apple juice or orange juice.[10] Always stir just before drinking and rinse down with half a glass of water.

Enteral Feeding administration

FasTabs® are licensed for administration via nasogastric tube and will fit through feeding tubes of size ≥8Fr.[9,11]

RANITIDINE

Paediatric license: Ranitidine is not licensed in children below 3 years of age. However there is experience with the use of ranitidine in infants, and the Children's BNF provides information on doses of ranitidine in infants. [6]

Preparations: 150mg/10mL oral solution, 75mg, 150mg and 300mg tablets, 150mg and 300mg effervescent tablets, oral suspension of various strengths (manufactured extemporaneously or ordered as a 'special').

Ranitidine Dosage [6]

Age	Dose
Neonate	2mg/kg three times daily
1 to 6mths	1mg/kg three times daily
6mths to 3yrs	2 to 4mg/kg twice daily

Oral administration

The **licensed** 150mg/10mL liquid should be prescribed with a 1mL syringe to administer small doses to children, e.g. a dose of 4.3mg equates to 0.29mL.[2] See page 4.

Enteral Feeding administration

Although not licensed for enteral administration, the liquid preparation can be used for gastric administration (but note sorbitol content).[9]

Ranitidine Unlicensed Specials

- The licensed 75mg/5mL liquid should be used instead of diluting the licensed product or ordering unlicensed specials.
- A 1mL oral syringe should be dispensed with the licensed liquid.
- Rosemont and Zantac® liquids are sucrose-free but contain 8%w/v alcohol.[6,7] However, this generally is considered insignificant when given in such small quantities to infants.
- The licensed 75mg/5mL liquid costs £6.45 for 300mL; the cost of an unlicensed liquid can be up to £474.

Oral syringes

- Community pharmacies can order 1mL, 3mL and 5mL oral syringes from local pharmaceutical wholesalers.
- 1mL and 3mL syringes are available in small packs or single packs to avoid bulk buying and cost less than £1 each.
- Only the 5mL size oral syringe is currently on NI Drug Tariff.[13]
- 10mL oral syringes are available from local medical suppliers.

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