

# Guidelines for Prescribing Specialist Infant Formula in Primary Care

## November 2018

---

- **Whilst these guidelines are for specialist formula, breast milk is the optimal milk for infants.**
- **Breastfeeding should be promoted and encouraged where possible. This guideline aims to provide clinicians with guidance on prescribing specialist infant formula in primary care.**

*The information contained in this document is based on evidence available at the time of writing. It is intended for use within the NHS and may not be used outside the NHS without written permission. It is issued for guidance & advice only, and prescribers remain responsible for their patients' care and prescriptions signed.*

#### **With thanks to**

- **Carolyn Patchell - Head of Nutrition and Dietetics & CF Specialist Dietitian, Birmingham Womens and Children's NHS Foundation Trust.**
- **Lorna Hull, Paediatric Dietitian team leader, Heart of England Foundation Trust**  
**and**
- **Susan Meredith Clinical Lead Paediatric Dietetics/Deputy Head of Service for their assistance in adapting these guidelines for local use.**

<b>Contents</b>		<b>Page</b>
1	Buying/prescribing feeds for infants	3
2	Guidance on prescribing, reviewing and stopping formulae	
	• Secondary Lactose Intolerance	4
	• Cow's Milk Protein Allergy (CMPA)	5-6
	• Gastro-oesophageal Reflux (GOR)	7
	• Pre-Term Infants	8
	• Faltering Growth	8
3	Summary of Volumes of Feeds to Prescribe for Infants	9
4	Referrals to local Nutrition and Dietetics Service	10
5	References	11
6	Appendix 1 : Review and discontinuation of dietary management and challenges with cow's milk	12

## **Buying/prescribing feeds for infants**

### Buying infant formulas

Lactose free infant formulas (e.g. SMA LF) and thickening formulas (e.g. SMA Staydown) can be bought at a similar cost to standard infant formula and prescriptions of these feeds is at the clinical discretion of the GP.

As they are less commonly used they may have to be ordered, however most pharmacies and many supermarkets can obtain stock in a few days.

Infant formula milk that is based on cow's milk and says on the packaging that it can be used from birth can be bought with Healthy Start vouchers.

More information is available via: <http://www.healthystart.nhs.uk/healthy-start-vouchers/what-to-buy-with-the-vouchers/>

### Prescribing infant formulas

- Liquid formulation should **NOT** be prescribed where a powder formulation is available.
- It is advisable to prescribe only 1-2 tins initially for all formulas to assess tolerance and palatability. Once established:

For **infants under 6 months** of age (unless advised otherwise by a dietitian)

- the volume prescribed should be roughly the same as the volume of milk they are currently taking (NOTE: most commonly used shop bought formulas are in 900g tins).
- a 400g tin should last 3.5 days (therefore 8 x 400g tins a month or 4 x 900g tins a month would seem reasonable).

For **infants over 6 months** of age (unless advised otherwise by a dietitian)

- 7 x 400g tins a month
- 3 x 900g tins a month

## Guidance on Prescribing, Reviewing and Stopping Formulae

Condition/ Indication	Diagnosis	Treatment/Review Criteria	Name of Formula	Age restrictions	Information & criteria for stopping formula
<p><b>Secondary Lactose intolerance</b></p> <p>NOTE: Primary lactose intolerance is less common than secondary intolerance and does not usually present until later childhood or adulthood</p>	<p>Usually occurs following an infectious gastrointestinal illness. Symptoms include: abdominal bloating, wind, increased (explosive) and loose, green stools.</p> <p>Lactose intolerance should be suspected in infants who have had symptoms that persist for more than 2 weeks.</p> <p>Diagnosis is the resolution of symptoms, usually within 48 hours, once lactose is removed from the diet.</p>	<p>Treatment with lactose free formula for <b>2-8 weeks</b> to allow symptoms to resolve, then reintroduction to standard formula/milk products slowly into the diet.</p> <p>If symptoms do not resolve on commencing standard infant formula then <b>refer to a dietitian</b>.</p> <p>For treating lactose intolerance in infants who have been weaned, these formulas should be used in conjunction with a milk free diet.</p> <p>If an infant presents with suspected lactose intolerance at one year or older and is on cow's milk, then a lactose free full fat cow's milk can be used for the treatment period. This is available in supermarkets.</p> <p>Note: the use of lactase drops is not common practice.</p>	<p><b>1st line</b></p> <p><b>SMA LF</b> <b>(SMA Nutrition)</b></p>	<p>Birth to 2 years</p>	<p>Can be used for a maximum of 8 weeks without review.</p> <p>Can be purchased over the counter.</p> <p>Only prescribable for patients who currently do not pay for formula feeds (eg healthy start scheme)</p> <p>Note: Lactose free infant formulas can be bought at a similar cost to standard infant formula and prescribers should consider the need to prescribe.</p>

Condition/ Indication	Diagnosis	Treatment/Review Criteria	Name of Formula	Age restrictions	Information & criteria for stopping formula	
<b>Cow's Milk Protein Allergy (CMPA)</b>  <b>Extensively hydrolysed formulas (EHF).</b>	Suspect CMPA after careful history taking.  Refer to NICE guidelines (Food Allergy in Children and Young People, Feb 2011) - <a href="http://guidance.nice.org.uk/CG116">http://guidance.nice.org.uk/CG116</a> for history taking and symptoms and <b>when to refer to secondary care.</b>	For infants managed in <b>primary care</b> use extensively hydrolysed formulas (EHF), as first line treatment.	<b>1st line</b> (under 6 months)	Birth to 6 months	Continue formula until infant has grown out of allergy or they are 2 years old.  At 6 months change prescription to Nutramigen 2 unless a dietitian has advised otherwise. The same for Pepti 1 and 2.	
			<b>Nutramigen 1 with LGG</b> <b>(Mead Johnson)</b>	Trial of extensively hydrolysed formulas (EHF) for 2 weeks for tolerance.		<b>1st line</b> (over 6 months)
		<b>Nutramigen 2 with LGG</b> <b>(Mead Johnson)</b>	The taste of hydrolysed formulas is unpleasant, and it has a bitter smell therefore compliance can be improved by using a bottle, closed cup or a straw.		<b>Pepti 1</b> <b>(Aptamil)</b>	Birth to 6 months
		Can be used if infant not tolerating/taking Nutramigen with LGG. Does contain some lactose.				
		<b>Pepti 2</b> <b>(Aptamil)</b>		6 months to 2 years	If answer is <b>yes</b> to any of the following questions, review prescribing : <ul style="list-style-type: none"> <li>• Can the patient tolerate cow's milk, cheese?</li> <li>• Is the patient over 2 years of age?</li> <li>• Has the formula been prescribed for more than one year?</li> <li>• Is the quantity prescribed Please see appendix 1</li> </ul>	
		Can be used if infant not tolerating/taking Nutramigen . Does contain some lactose.				
		<b>Similac Alimentum</b> (Abbott Nutrition)	Birth until 2 years	Similar in composition and indication for use to Nutramigen with LGG	<b>Pepti Junior</b> <b>(Aptamil)</b>	Birth until 2 years
Can be used if above formulas are not tolerated/taken.						
		Younger infants take hydrolysed formulas more readily than older infants.  It may take up to 4-6 weeks for symptoms to resolve.			<b>ONLY ON DIETETIC ADVICE</b>	
		If <b>not</b> tolerated see over leaf.  <b>These infants should be reviewed by/referred to a dietitian.</b>  NOTE: Lactose free formulas are not suitable for treating CMPA.				

Condition/ Indication	Diagnosis	Treatment/Review Criteria	Name of Formula	Age restrictions	Information & criteria for stopping formula
<p><b>Cow's Milk Protein Allergy (CMPA)</b></p> <p><b>Amino acid formula</b></p>	<p>Suspect CMPA after careful history taking.</p> <p>Refer to NICE guidelines (Food Allergy in Children and Young People, Feb 2011) - <a href="http://guidance.nice.org.uk/CG116">http://guidance.nice.org.uk/CG116</a> for history taking and symptoms.</p>	<p>The taste of amino acid formulas is unpleasant and it has a bitter smell therefore compliance can be improved by using a bottle, closed cup or a straw.</p> <p>Younger infants take amino acid formulas more readily than older infants.</p> <p>Infants who do not tolerate one formula may tolerate another. Therefore it is worth prescribing only 1 or 2 tins initially and if not tolerated or taken after perseverance try another comparable formula.</p>	<p><b>Neocate Syneo (Nutricia)</b></p> <p>Contains Bifidobacterium breve M-16V to combat gut flora dysbiosis, shown by infants with allergies.</p> <p>Not suitable for premature infants or infants who maybe immunocompromised. Not for use in postpyloric tube feeding.</p> <p>Not recommended for infants with central venous catheter or <b>SHORT BOWEL SYNDROME</b> without full consideration of risks/benefits and monitoring by/on advice of a specialist.</p>	<p>Birth until infant grows out of allergy and suitable as a sole source of nutrition for infants under one year of age</p>	<p>These formulas are stopped when the infant has grown out of the allergy. They will require secondary/tertiary care input to establish this.</p> <p>Neocate Junior is a highly specialised product and therefore should only be used by secondary/tertiary care and not prescribed in infants under age of one year.</p> <p>For information only - Neocate spoon (non formula) is a weaning solid and should only be prescribed under advice of dietitian</p> <p>Continue formula until child has grown out of allergy or they are 12 months.</p> <p>Do not advise sheep or goats milk due to cross reactivity. Rice milk should not be advised in children under 4.5 years due to concerns with arsenic levels.</p> <p>Refer to NICE guidelines (2011) for which children should be challenged with cow's milk in secondary care setting.</p>

Condition/ Indication	Diagnosis	Treatment/Review Criteria	Name of Formula	Age restrictions	Information & criteria for stopping formula
<b>Cow's Milk Protein Allergy (CMPA)</b>  <b>Amino acid formula continued</b>	Suspect CMPA after careful history taking.  Refer to NICE guidelines (Food Allergy in Children and Young People, Feb 2011) - <a href="http://guidance.nice.org.uk/CG116">http://guidance.nice.org.uk/CG116</a> for history taking and symptoms.	The taste of amino acid formulas is unpleasant and it has a bitter smell therefore compliance can be improved by using a bottle, closed cup or a straw.  Younger infants take amino acid formulas more readily than older infants.	<b>Neocate LCP (Nutricia)</b> Indicated when hydrolysed formulas do not resolve symptoms or when there is evidence of severe/multiple allergy.  Do not use as a diagnostic tool  <b>Note: children over 9 months may need 750ml/day to meet their calcium requirements (9 tins/month)</b>	Birth until infant grows out of allergy	For information and criteria for stopping - please see page 6
		Infants who do not tolerate one formula may tolerate another. Therefore it is worth prescribing only 1 or 2 tins initially and if not tolerated or taken after perseverance try another comparable formula.	<b>Nutramigen Puramino (Mead Johnson)</b> Indicated when hydrolysed formulas do not resolve symptoms or when there is evidence of severe or multiple allergies.  Do not use as a diagnostic tool  <b>NOTE: children over 9 months may need 800ml/day to meet calcium requirements (10 tins/month).</b>	Birth until infant grows out of allergy	
<b>Cow's Milk Protein Allergy (CMPA)</b>  <b>Soya formula</b>		Soya formula can be considered in Infants over 6 months. The chief medical officer advises that soya formula should not be used as the first line treatment for CPMA under 6 months. Soya formula should be considered in infants who will not take a hypoallergenic formula (over 6 months).	<b>Wysoy (SMA Nutrition)</b>	6 months to 2 years	Alternatively, Alpro Junior 1+ milk can be used from one year of age onwards in place of formula (monitor intake). However, it is not widely available. Beyond 2 years calcium enriched soya milk can be used as an alternative source of milk.

Condition/ Indication	Diagnosis	Treatment/Review Criteria	Name of Formula	Age restrictions	Information & criteria for stopping formula
<p><b>Gastro-oesophageal Reflux (GOR)</b></p>	<p>A diagnosis of GOR is made clinically from a history of effortless vomiting occurring after meals. Rule out overfeeding by establishing volume of feed as initial treatment</p> <p>Symptoms of GOR may include:</p> <ul style="list-style-type: none"> <li>• Regurgitation of a significant volume of feed</li> <li>• Reluctance to feed</li> <li>• Distress / crying at feed times</li> <li>• Small volumes of feed being taken</li> </ul>	<p>Infants with faltering growth should be referred to paediatric services. For other infants the following can be tried:</p> <p><b>STEP ONE:</b> 50% of babies have some degree of reflux If baby is vomiting persistently (not projectile) but the baby is thriving and not distressed, reassure parents and monitor. Provide advice on feeding positioning, avoidance of over feeding and activity following a feed.</p> <p><b>STEP TWO:</b> If the bottle fed infant is not settled and not gaining weight – trial with thickening formula or thickening agent such as infant Gaviscon. These formulae should not be used in conjunction with antacid medication or thickeners.</p> <p>Review after one month. If no improvement in symptoms, may need further investigation by a paediatrician. These infants require regular review.</p>	<p><b>Instant Carobel (Cow &amp; Gate)</b></p> <p>Instant Carobel is a instant thickening agent added to formula feeds to prevent vomiting.</p> <p>Instant Carobel should be used added to formula for full term infants.</p>		<p>Infants are likely to have grown out of the reflux by 18 months.</p> <p>Introduction of weaning early (4-6 months) may also improve the reflux.</p> <p>Once vomiting resolves stop adding Instant Carobel to feeds.</p>

Condition/ Indication	Diagnosis	Treatment/Review Criteria	Name of Formula	Age restrictions	Information & criteria for stopping formula
<b>Pre-term Infants</b>	<p>These children will have had their formula commenced in hospital. It is started for babies born before 34 weeks gestation</p> <p><b>NOTE:</b> These formulas should not be used in primary care to promote weight gain in term infants</p>	<p>Any infant discharged on these formulas should have their growth (this includes weight, length and head circumference) monitored by the health visitor.</p> <p>Any concerns regarding the baby should be referred to the dietitian.</p> <p><b>This is in line with the Southern West Midlands Newborn network enteral feeding policy.</b></p>	<p><b>Nutriprem 2 Powder (Cow and Gate)</b>            Note: Nutriprem 2 Liquid (Cow &amp; Gate) should not be routinely prescribed unless there is a clinical need e.g. immunocompromised infant.</p>	<p>Use up to 6 month corrected age (i.e. six months plus the number of weeks premature added on).</p>	<p>Up to 6 months corrected age. These formulas should be stopped if there is excessive weight gain. If there is concerns regarding growth refer to the dietitian. Standard formula or follow on formula would be the appropriate next step.</p>
			<p><b>SMA PRO Gold Prem 2 Powder (SMA Nutrition)</b></p>		
<b>Faltering growth</b>	<p>Faltering growth is indicated when the weight of an infant falls below the bottom centile (0.4<sup>th</sup>) or crosses 2 centiles downwards on a growth chart.</p> <p>The height, as well as weight, of a child needs to be measured in order to properly interpret changes in the latter. It is not possible to detect growth faltering without using appropriate growth charts.</p> <p>If is important to rule out possible disease-related/medical causes for the faltering growth.</p>	<p>It is important to consider the reason for faltering growth e.g. iron deficiency anaemia, constipation, GOR or a child protection issue and treat accordingly.</p> <p>Consider behavioral involvement for children that are weaned.</p> <p>Before commencing a high energy formula ensure parents/carers are offered food first advice on suitable high calorie foods if the infant is weaned.</p> <p><b>Refer any infant being commenced on a high calorie formula to a dietitian.</b></p> <p>Note: All infants on a high energy formula will need growth (weight and length/height) monitoring to ensure catch up growth and appropriate discontinuation of formula to minimise excessive weight gain.</p>	<p><b>Infatrini (Nutricia)</b></p>	<p>From birth to 18 months or 8 kg</p>	<p>These formulas should be used until 18 months or 8kgs.</p> <p>Although the appropriateness of the supplements need to be assessed by growth monitoring / assessment.</p> <p>Requirement will end when the infant achieves and maintains a healthy nutritional status, or when they reach a suitable age or weight to change to an appropriate feed that meets their ongoing nutritional needs. If in any doubt refer back to a paediatric dietitian.</p>
			<p><b>SMA Pro High Energy (SMA Nutrition)</b></p>	<p>From birth to 18 months</p>	
			<p><b>Infatrini Peptisorb (Nutricia)</b></p> <p>A high calorie peptide feed for infants who also have faltering growth.</p>	<p>From birth to 18 months or 9 kg</p>	

## Summary of Volumes of Feeds to Prescribe for Infants

	Use as first line	Use if treatment unsuccessful with first line or should only be started in patients under secondary care or if started in primary care immediately referred for further support			
Formula	Size of Tin (g)	UNDER 6 MONTHS OLD	OVER 6 MONTHS OLD	Buy rather than prescribe	Dietician referral necessary
		Maximum Tins per 28 days	Maximum Tins per 28 days		
<b>Lactose free</b>					
SMA LF	430	7	6	✓	X
<b>Hydrolysed</b>					
Nutramigen 1 with LGG	400	8	X	X	✓
Nutramigen 2 with LGG	400	X	7	X	✓
Pepti 1 ( Aptamil)	400	8	X	X	✓
	800	4	X	X	✓
Pepti 2 ( Aptamil)	400	X	3	X	✓
	800	X	2	X	✓
Pepti Junior	450	7	6	X	✓
Similac Alimentum	400	8	7	X	✓
<b>Amino acid based</b>					
Neocate Syneo	400	8	7	X	✓
Neocate LCP	400	8	7	X	✓
Nutramigen Puramino	400	8	7	X	✓
<b>Soya-based</b>					
Wysoy	860	X	3	X	✓
<b>Thickener</b>					
Instant Carobel	135	8	8	X	X
<b>Pre-term formula</b>					
Nutriprem 2	900	4	3	X	✓
SMA PRO Gold Prem 2	400	8	7	X	✓
Formula	Size of bottle (ml)	UNDER 6 MONTHS OLD	OVER 6 MONTHS OLD	Buy rather than prescribe	Dietician referral necessary
		Maximum bottles per 28 days	Maximum bottles per 28 days		
<b>High Energy</b>					
Infatrini	125	180	135	X	✓
	200	112	86	X	✓
SMA Pro High Energy	200	112	86	X	✓
Infatrini Peptisorb	200	112	86	X	✓

**Specific exception:** If all nutrition is received by a tube (e.g. PEG) for clinical reasons, such as an unsafe swallow, then a dietitian should be involved in the care and will recommend a prescription for the appropriate monthly volume

### **3. Referrals to Nutrition and Dietetic Service in Primary Care:**

#### **Birmingham**

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

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

Birmingham Community Healthcare NHS Trust Paediatric Nutrition department will manage all Primary Care referrals across Birmingham.

**The referral form can be accessed using the link below:**

<http://www.bhamcommunity.nhs.uk/patients-public/adults/nutrition/referral-information-and-forms/>

#### **Solihull**

For Solihull to access a dietitian a referral has to be sent by the GP to Dept of Nutrition and Dietetics, Birmingham Heartlands Hospital, Bordesley Green East. Birmingham B9 5SS. Tel 0121 424 2673 and Fax 0121 424 1675.

Please note: New products may be launched into this market. For further advice on the indications and usage of these products, contact the dietetic service

#### **4. References**

1. Clinical Paediatric Dietetics, 3<sup>rd</sup> Edition, Blackwell Publishing, 2007
2. Department of Health Report on Health and Social Subjects No 45. Weaning and the weaning diet. London, The Stationary Office 1994.
3. Guarino A et al. European Society for Paediatrics Gastroenterology, Hepatology and Nutrition / European Society for Paediatric Infectious Diseases Evidence-based Guidelines for the Management of Acute Gastroenteritis in Children in Europe. *Journal of Paediatric Gastroenterology and Nutrition* 2008; 46: S81 – S184.
4. Martin J, editor. BNF for Children 2010-11. London: British Medical Association, the Royal Pharmaceutical Society of Great Britain, the Royal College of Paediatrics and Child Health, and the Neonatal and Paediatric Pharmacists Group.
5. Khin MU, Nyunt Nyunt W, Myo K, et al. Effect on clinical outcome of breast feeding during acute diarrhoea. *Br Med J (Clin Res Ed)* 1985; 290: 587-9.
6. 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.
7. Committee on Toxicity Report: Phytoestrogens and health. 2003. <http://cot.food.gov.uk/pdfs/phytoreport0503>
8. Buller HA, Rings EH, Montgomery RK, et al. Clinical aspects of lactose intolerance in children and adults. *Scand J Gastroenterology* 1991; 188 (Suppl):73 – 80.
9. Skypala I and Venter C. Food Hypersensitivity. Diagnosing and managing food allergy and intolerance. Wiley-Blackwell 2009.
10. De Boissieu D, Matarazzo P, Dupont C. Allergy to extensively hydrolysed cow milk proteins in infants: identification and treatment with amino acid-based formula. *J Pediatr* 1997; 131: 744 – 47.
11. Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society of Pediatric Gastroenterology, Hepatology, and Nutrition. *Journal of Pediatric Gastroenterology and Nutrition* 2009; 49: 498–547.
12. Enteral Feeding on the Neonatal Unit. Southern West Midlands Newborn Network. Johnson L, Gosling C, Simmons P, SWNNN nutrition interest group. January 2012.

**Guidelines adapted from Prescribing Specialist Infant Formula in Primary Care, PrescQIPP, NHS Midlands and East, March 2012 and November 2016**

**<https://www.prescqipp.info/infant-feeds/send/93-infant-feeds/3141-bulletin-146-infant-feeds>**

*The information contained in this document is based on evidence available at the time of writing. It is intended for use within the NHS and may not be used outside the NHS without written permission. It is issued for guidance & advice only, and prescribers remain responsible for their patients' care and prescriptions signed.*

## Appendix 1 : Review and discontinuation of dietary management and challenges with cow's milk

- Review prescriptions regularly to check that the formula prescribed is appropriate for the child's age.
- Quantities of formula required will change with age – see guide to quantities required (page 8) and/ or refer to the most recent correspondence from the paediatric dietitian.
- Avoid adding to the repeat template for these reasons, unless a review process is established.
- Challenging with cow's milk - The child should be evaluated every six to 12 months to assess whether they have developed a tolerance to cow's milk protein. This can be done at home provided there are no indications for referral to secondary care, for example one or more acute systemic reactions.
- Prescriptions should be stopped when the child has outgrown the allergy. According to the latest European data, 57 to 69% of CMPA infants are able to tolerate cow's milk 12 months after initial diagnosis
- Review the need for the prescription if you can answer 'yes' to any of the following questions:
  - Is the patient over two years of age?
  - Has the formula been prescribed for more than one year?
  - Is the patient prescribed more than the suggested quantities of formula according to their age?
  - Is the patient prescribed a formula for CMPA but able to eat/drink any of the following foods – cow's milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee? (Cooked milk products are usually better tolerated.)
  - Children with multiple or severe allergies may require prescriptions beyond two years. This should always be at the suggestion of the paediatric dietitian