

Formulas and milks for infants and children

Despite the fact that breastfeeding is the best way to feed an infant, each year there is an influx of more infant formulas onto the market. Are there real nutritional differences between various formulas? What is the best choice?



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With rare exceptions, human milk is the most appropriate form of feeding for all infants, including premature and sick newborns. Breastfeeding is recommended for at least the first year of life, and in the breastfed infant, water, juice, food and vitamin supplements are usually not necessary in the first six months. However, for infants who are not breastfed or who are weaned before 12 months, the use of an infant formula is recommended.¹

Currently there are more than 40 formulas for healthy term infants being sold by seven companies (Tables 1 to 4). Each company describes each of its products as having a particularly unique and desirable feature for optimal infant development. There has been an increase particularly in the number of formulas developed for the toddler age group (12 months and older). These toddler formulas are exempt from the advertising restrictions imposed on infant formulas to promote breastfeeding and ensure the proper use of breast milk substitutes.

It is not surprising then that parents are confused

about which is the best formula to use. Family doctors, therefore, should know the differences between formulas and which can be recommended. GPs should also take the opportunity when discussing formulas with parents to critically evaluate the requirement for such products.

Formulas for healthy infants

All formulas for infants up to 1 year of age have to comply with the Australia New Zealand Food Standards Code specific to infant formulas (Code 2.9.1).² This Standard regulates the quality, composition and labelling of infant formulas sold in Australia, and uses the composition of human mammalian milk as its reference.

The manufacturers of infant formulas try to make their formulas imitate human milk as closely as possible. However, the following differences always remain:

- the composition of an individual mother's milk is continually changing to meet the changing needs of her infant
- human milk contains live cells (macrophages,

IN SUMMARY

- Mothers should be encouraged to breastfeed their infants for at least the first 12 months.
- Healthy term infants who are not breastfed should be given cow's milk-based formulas. The choice of formula can be based on cost and availability.
- There are no nutritional advantages for healthy term infants in using 'follow-on' formulas, soy-based formulas or formulas with added nucleotides, long chain polyunsaturated fatty acids and/or thickening agents.
- Formulas or supplements are not necessary for healthy young children.
- Children can be given full cream cow's milk from the age of 12 months, preferably by cup rather than in a bottle. In general, reduced fat milks can be used from the age of 2 years. However, the use of skim milk is not recommended until after the age of 5 years.

continued

Table 1. Formulas for healthy infants, 0 to 12 months ('starter')

Formula	Manufacturer	Contains added long chain PUFAs	Contains added nucleotides	Contains added thickeners
Cow's milk-based products				
Baby Infant Formula – From Birth	Amcal	✗	✗	✗
Heinz Nurture Starter	Heinz	✗	✓	✗
Heinz Nurture Gold Starter	Heinz	✓	✓	✗
Karicare Starter	Nutricia	✗	✗	✗
Karicare Gold Starter	Nutricia	✓	✗	✗
Karicare Gold Plus Infant	Nutricia	✓	✓	✗
Lactogen	Nestle	✗	✗	✗
NAN 1 Gold Protect Start with Bifidus BL	Nestle	✓	✗	✗
Novalac 1	Bayer	✗	✗	✗
S-26	Wyeth	✗	✓	✗
S-26 Gold Alpha Pro	Wyeth	✓	✓	✗
SMA	Wyeth	✗	✓	✗
Soy or goat's milk-based products				
Isomil	Abbott	✗	✗	✗
Karicare Goat Starter	Nutricia	✗	✗	✗
Karicare Soya All-Ages	Nutricia	✗	✗	✗
S-26 Soy	Wyeth	✗	✓	✗

ABBREVIATION: PUFAs = polyunsaturated fatty acids.

lymphocytes and neutrophils)

- human milk contains antibodies (secretory IgA, IgG and IgM) and numerous bioactive substances
- human milk contains human protein
- human milk contains more than 120 oligosaccharides.

The Food Standard divides the standard formulas for healthy term infants into two categories:

- 'starter' formulas, which are suitable for infants from birth and for the whole of the first year (Table 1)
- 'follow-on' formulas, which are suitable for infants from 6 months until 1 year of age (Table 2).

Starter versus follow-on formulas

Both starter and follow-on formulas have an energy content of about 20 kcal/30 mL (approximately 280 kJ/100 mL). Follow-on formulas have been developed for infants aged 6 to 12 months, and have a slightly higher protein content and higher levels of some minerals (such as iron and calcium) and electrolytes, compared with starter formulas (see the box on page 41).

The term 'follow-on' formula could be considered misleading because it implies that these formulas automatically follow the 'starter' formulas. As the introduction of solids is recommended at 6 months of age there is no need to change from a

starter formula for additional nutrients. The family doctor can thus encourage parents to choose a standard starter infant formula and use it until the child is aged 12 months.

A 900 g can of standard infant formula retails for about \$14 to \$20.

Modified 'standard' infant formulas

Infant formulas for healthy infants can be further categorised by changes in the forms and sources of protein, fat and carbohydrate. These variations in formulas may also contribute to confusion about the appropriate choice of an infant formula. The available specialty formulas

for healthy infants are listed in Table 3.

Formulas may be based on cow's milk, soy or goat's milk. Cow's milk-based infant formulas for healthy infants may have the following modifications:

- be casein- or whey-dominant
- contain partially hydrolysed protein
- contain added nucleotides
- contain added long chain polyunsaturated fatty acids (PUFAs)
- contain added thickening agents
- be lactose-free
- contain added probiotics.

Table 5 summarises the available modifications of infant formulas for both healthy term infants and infants with medical conditions that require dietary changes.³ The more specialised formulas required by some infants are discussed later.

Modified formulas for healthy infants retail for about \$5 more per 900 g can

What's the difference between 'starter' and 'follow-on' formulas?

- 'Follow-on' formulas are marketed for use for healthy infants over the age of 6 months whereas starter formulas are marketed for healthy term infants from birth.
- 'Follow-on' formulas have a slightly higher protein content than starter formulas.
- 'Follow-on' formulas have slightly higher levels of calcium and iron than starter formulas.
- There is no nutritional reason to change to a 'follow-on' formula after 6 months as extra nutrients should be provided through the introduction of solids.

than the standard formula, although some retail for as much as \$35 per can.

Soy-based and goat milk-based formulas

Generally, healthy infants who are not breastfed should be given cow's milk-based formulas. There are, however, several soy-based formulas that are suitable and safe for healthy infants. Soy-based formula has no specific advantage over

cow's milk-based formula as a supplement for the breastfed infant, nor does the evidence suggest that using a soy formula instead of a cow's milk formula reduces allergies or food intolerance in infants and children.⁴

Soy formulas have higher amounts of aluminium and phytoestrogens than cow's milk-based formula. However, there does not appear to be any substantial risk of aluminium toxicity in healthy term infants

Table 2. Formulas for healthy infants, 6 to 12 months ('follow-on')

Formula	Manufacturer	Contains added long chain PUFAs	Contains added nucleotides	Contains added thickeners
Cow's milk-based products				
Baby Infant Formula – Follow-on	Amcal	×	×	×
Heinz Nurture Follow-on	Heinz	×	✓	×
Heinz Nurture Gold Follow-on	Heinz	✓	✓	×
Karicare Follow-on	Nutricia	×	×	×
Karicare Gold Follow-on	Nutricia	✓	×	×
Karicare Gold Plus Follow-on	Nutricia	✓	✓	×
NAN 2 Gold Protect Plus with Bifidus BL	Nestle	✓	×	×
Novalac 2 Follow-on	Bayer	×	×	×
S-26 Progress	Wyeth	×	✓	×
S-26 Gold Progress	Wyeth	✓	✓	×
Soy or goat's milk-based products				
Karicare Goat Follow-on	Nutricia	×	×	×
Karicare Soya All-Ages	Nutricia	×	×	×
S-26 Soy	Wyeth	×	✓	×

ABBREVIATION: PUFAs = polyunsaturated fatty acids.

continued

fed soy formulas. Nevertheless, these formulas are not designed or recommended for preterm infants.

Soy-based formulas should not be used for infants with cow's milk protein enteropathy or enterocolitis, because these infants are often also sensitive to soy protein. However, because soy formulas are lactose-free, they are suitable for infants with the rare inherited disease galactosaemia, although family doctors would not usually manage this condition. One is free of both lactose and sucrose (Karicare Soya All-Ages) and can be used in infants with primary or secondary lactose and/or sucrose intolerance.

There are no nutritional or medical indications to select a goat's milk-based infant formula. However, such a formula is safe for feeding infants – unlike pasteurised fresh goat's milk, which is not recommended because it is low in vitamins A, D, C, B₂, B₆, B₁₂ and folic acid.

Casein-dominant and whey-dominant formulas

Infant formulas and human milk contain protein in the form of both casein and whey. Initially, human milk is whey-dominant, but the proportions of whey to casein change with the stage of lactation. In immature human milk (colostrum, day 1), the whey to casein ratio is 90:10; in mature milk (from day 2), the ratio is 50:50.⁵ Cow's milk is casein-dominant. The types of whey proteins in human milk and cow's milk also differ.

Whey-dominant formulas are not nutritionally superior to those that are casein-dominant. The profile of amino acids is the same for both. It used to be thought that casein-dominant formulas were more satisfying to the infant but this has not been confirmed by randomised controlled trials. Therefore, there is no nutritional reason to select a formula for healthy term infants based

on the ratio of whey to casein. For preterm infants, however, a whey-dominant formula has been shown to produce less metabolic stress; whey-dominant formulas are, therefore, recommended for low birthweight infants (see later).

Partially hydrolysed formulas

In partially hydrolysed formulas, the protein has been broken down into smaller proteins that are alleged to be potentially less allergenic.⁶ These whey formulas, which are often labelled 'HA' (hypoallergenic), are relatively new on the market and cost significantly more than standard infant formulas.

Evidence suggests that prolonged supplementation with hydrolysed formula as opposed to cow's milk formula or exclusive breastfeeding does not reduce the risk of allergy.⁶ In addition, evidence indicated there was no significant difference in rates of asthma, eczema or

Table 3. Specialty formulas for healthy infants

Formula	Manufacturer	Contains added long chain PUFAs	Contains added nucleotides	Contains added thickeners
Lactose-free products				
Karicare De-Lact	Nutricia	✗	✗	✗
S-26 LF	Wyeth	✗	✓	✗
Partially hydrolysed protein products				
Karicare SensiKare HA	Nutricia	✗	✗	✗
Karicare SensiKare HA-AR	Nutricia	✗	✗	✓
Nan HA 1 Gold Protect Start with Bifidus BL	Nestle	✓	✗	✗
Nan HA 2 Gold Protect Plus with Bifidus BL	Nestle	✓	✗	✗
Formulas containing thickening agents				
Karicare AR Thickened Starter Formula	Nutricia	✗	✗	✓
Karicare SensiKare HA-AR	Nutricia	✗	✗	✓
Novalac AR	Bayer	✗	✗	✓
S-26 AR	Wyeth	✗	✓	✓

ABBREVIATIONS: PUFAs = polyunsaturated fatty acids; HA = hypoallergenic; AR = antiregurgitation.

rhinitis with the use of partially hydrolysed formulas.

Formulas with added nucleotides

The rationale for adding nucleotides to infant formulas is that human milk has nucleotides and that formula with added nucleotides may benefit gastrointestinal development, the immune system, intestinal microflora and iron absorption. The evidence for these perceived benefits is not conclusive. Further research is needed to determine optimal and safe levels of nucleotide supplementation and the functional effects in infants. Currently, there is no conclusive advantage in selecting these products.

Formulas with added long chain PUFAs

Some infant formulas have added long chain PUFAs such as docosahexaenoic and arachidonic acids (omega-3 and omega-6 fatty acids, respectively). These formulas are only recommended for infants from birth to a few months of age. The rationale for the addition of long chain PUFAs is firstly, that human milk contains these fatty acids but cow's milk-based infant formulas do not, and secondly, that infants may not be able to synthesise sufficient amounts of PUFAs from the precursors alpha-linolenic acid and linoleic acid.

Evidence for the perceived benefit of having long chain PUFAs in infant formulas for term infants is equivocal. Some

studies have shown an increase in the visual acuity of infants, while others have demonstrated this effect at an early age but not at a later age. It is thought that infants fed formulas containing long chain PUFAs would have a developmental benefit from the increased amount of long chain PUFAs in brain tissue. Again, the evidence in healthy term infants is equivocal, but there does appear to be a health benefit for premature and low birthweight infants from having these fatty acids in the specialised formulas.

Lactose-free formulas

Cow's milk-based formulas that have been modified to be lactose-free (Karicare De-Lact, S-26 LF) are suitable for infants with secondary lactose intolerance (the transitory lactose intolerance that occurs infrequently after gastroenteritis) or primary lactose intolerance (which is very rare in infancy).

The soy-based formulas (Isomil, Karicare Soya All-Ages, S-26 Soy) are lactose-free, and one (Karicare Soya All-Ages) is also sucrose-free.

Formulas with added thickening agents

Some formulas, usually labelled 'AR' (for antiregurgitation), have a small amount of thickening agent (rice starch, carob bean flour or pre-gelatinised cornstarch) substituted for some of the lactose. These

formulas are thought to stop regurgitation in infants but the clinical evidence supporting their use is limited.⁵

There are limitations with these anti-regurgitation formulas, including:

- only one degree of thickness can be made
- it is possible that they may contribute to the development of allergies
- they may have an effect on the time of gastric emptying and oesophageal clearance that could further exacerbate the symptoms of reflux.

The treatment of reflux requires proper medical assessment. To avoid overuse, it would probably be better if these antiregurgitation formulas were available only on prescription.

Formulas containing probiotics

The probiotic Bifidus (also known as *Bifidobacterium lactis* or BL) is added to some infant formulas and other milk drinks in an attempt to provide some protection against gastroenteritis (especially rotavirus gastroenteritis). The inclusion of probiotics is also promoted by manufacturers as decreasing the gastrointestinal related side effects (specifically diarrhoea) of antibiotics.⁷

B. lactis is found naturally in the gut of breastfed infants but not generally in that of formula-fed infants. Evidence is inconclusive to support probiotics changing the infant's bowel flora to be closer to that

Table 4. Toddler formulas

Formula	Manufacturer	Contains added long chain PUFAs	Contains added nucleotides	Contains added thickeners
Heinz Nurture Toddler Milk Drink	Heinz	×	×	×
Heinz Nurture Gold Toddler Milk Drink	Heinz	✓	×	×
Karicare Gold Toddler Milk	Nutricia	✓	×	×
Karicare Gold Plus Toddler Milk	Nutricia	✓	×	×
Nestle Neslac Toddler Gold	Nestle	✓	×	×
S-26 Toddler Gold	Wyeth	✓	×	×

ABBREVIATION: PUFAs = polyunsaturated fatty acids.

continued

Table 5. Modifications of cow's milk-based infant formulas³**Protein component**

- Instead of cow protein
 - soy protein
 - goat protein
- Instead of being casein-dominant, being whey-dominant
- Containing hydrolysates of whey, casein or amino acids

Fat component

- Instead of predominantly long chain triglycerides, predominantly medium chain triglycerides (some specialised formulas, not modified standard formulas)
- Addition of long chain omega 3 and 6 polyunsaturated fatty acids

Carbohydrate component

- Instead of lactose:
 - lactose-free
 - lactose-free and sucrose-free
 - lactose-free, sucrose-free and fructose-free
- Addition of thickening agents

Others

- Addition of nucleotides
- Addition of probiotics

of a breastfed baby and provide some protection against gastroenteritis.

Further research is needed to determine whether probiotics may help prevent allergies, in particular infantile eczema.⁸

Other formulas

A relatively new range of infant formulas is available labelled with the claims 'anti-diarrhoea', 'increased transit', 'anti-colic' and 'sweet dreams'. Caution should be taken in recommending these products as there is a lack of evidence supporting these claims and a risk of increased consumer confusion with these products.

These products contravene the Australia New Zealand Food Standards Code

Food Standard A1 (3) (a), which states 'any label on or attached to a package containing or any advertisement for food shall not include a claim for therapeutic or prophylactic action or a claim described by words of similar import.'

Specialised infant formulas

Specialised formulas are available for particular medical conditions where there is a need to alter the protein, fat and/or carbohydrate content of the cow's milk-based formulas (Tables 5 and 6).³ Most of these products are prescribed in a specialist/hospital setting.

Allergy or intolerance to cow, goat or soy protein

Extensively hydrolysed whey formulas (Alfaré, Pepti-Junior) and amino acid-based formulas (EleCare, Neocate) are suitable for infants with an allergy or intolerance to cow, goat or soy protein. A hydrolysed formula is the first choice; if this is not tolerated, an amino acid formula will be required.

Amino acid formulas are over-prescribed in Australia, with the yearly cost to the PBS nearly 10 times that of extensively hydrolysed formulas. The use of amino acid formulas should be limited to infants with well-defined clinical indications such as multiple food protein intolerance and other conditions where an elemental diet is indicated (e.g. intractable malabsorption or bowel fistulae).⁹

The PBS costs of EleCare and Neocate are, at about \$360 per script, about three times those of Alfaré and Pepti-Junior, which are about \$97 and \$108 per script, respectively.

Fat malabsorption

In clinical conditions where fat is poorly tolerated, a formula in which the fat is predominantly medium chain triglycerides (Monogen) can be used. Relevant indications, such as abetalipoproteinaemia, intestinal lymphangiectasia and cholestasis, are rare in infancy.

Lactose intolerance

For infants with secondary lactose intolerance (the transitory lactose intolerance that occurs infrequently after gastroenteritis), the preferred formulas are lactose-free and cow's milk-based (Karicare De-Lact, S-26 LF).

Primary lactose intolerance is very rare in infancy, although it may develop in later childhood, especially in people of Asian ethnic origin. The management of primary lactose intolerance is the same as for secondary lactose intolerance.

As mentioned previously, soy-based formulas are lactose-free and therefore suitable for infants with galactosaemia.

Lactose and sucrose intolerance

The soy formula Karicare Soya All-Ages is free of both lactose and sucrose and can be used in infants with primary or secondary lactose and/or sucrose intolerance.

Lactose, sucrose and fructose intolerance

The carbohydrate-modified formulas EleCare, Kindergen, Neocate and Pepti-Junior are lactose-free, sucrose-free and fructose-free and can all be used in infants with primary or secondary combined lactose, sucrose and fructose intolerance.

Severe enteropathy, maldigestion and malabsorptive disorders

Formulas that are lactose-free and fructose-free and which contain protein hydrolysate and medium chain triglycerides (Alfaré, Pepti-Junior) are suitable for infants who have cow's milk or soy protein intolerance, severe enteropathy with disaccharidase deficiency, maldigestion and malabsorptive disorders.

Failure to thrive and/or fluid restriction

An energy dense formula is appropriate for infants who are failing to thrive and/or who require fluid restriction. All powdered infant formulas can be concentrated to provide extra energy and nutrients to

children who are failing to thrive. The osmolarity of the formula increases with concentration increments. Alternatively, carbohydrate supplements (Poly-Joule, Polycose) or fat supplements (Calogen, Liquigen) can be added to standard infant formula to provide additional energy. Addition of carbohydrate also increases the osmolarity of formula to which it has been added. A paediatric dietitian can provide appropriate advice regarding this process.

Infatrini, a ready-to-use liquid, has an energy content of 30 kcal/30 mL or approximately 420 kJ/10 mL (most infant formulas have an energy content of about 20 kcal/30 mL and are in powder form). This formula is useful in clinical settings as it does not require manipulation to change its composition and it has a low osmolarity. Its cost, at about \$1.10 per 100 mL, can be a limitation for its use in a home setting.

Premature/low birthweight infants

Low birthweight infants have special nutritional requirements related to the immaturity of their gastrointestinal function. While all such infants should be under specialist care, family doctors may also be involved in their care. Although human milk is the preferred source of nutrition for premature infants, some may need extra energy, protein and minerals that can be provided by supplements designed to fortify human milk (S-26 Human Milk Fortifier, FM 85, Nutricia Breast Milk Fortifier).

The formulas designed for premature infants (Karicare Nutriprem Low Birthweight, S-26 LBW, S-26 LBW Gold, Pre-NAN) differ to standard formulas for full-term infants in various ways. Compared to standard formulas, the low birthweight/premature formulas:

- have increased energy or come with instructions to increase energy (24 kcal/30 mL [about 335 kJ/100 mL] instead of 20 kcal/30 mL)
- are whey-dominant
- contain extra protein

- contain glucose polymers
- contain medium chain triglycerides
- contain PUFAs (except S-26 LBW)
- have higher concentrations of minerals, particularly iron.

Formulas for young children (1 to 5 years)

Well children

Healthy young children do not require formulas or supplements because they will be having a varied diet by the age of 1 year. At this age, cow's milk is recommended as the main beverage instead of infant formula. To ensure that young children obtain enough energy, full cream milk should be used until they are 2 years of age, after which reduced fat milks can be introduced. Skim milk, however, should not be used for children under 5 years of age.

If soy drinks are used instead of cow's milk, it is important to select a soy beverage with added calcium. This fortification can be identified on the product's ingredients list.

Appetites can fluctuate widely in young children and parents can be worried about the fussy eating of their toddler. However, the use of a supplement will not rectify poor eating habits, and family doctors may need to make parents aware of the inability of supplements such as toddler formulas to correct a poor diet. Toddler formulas are not covered by the agreement relating to the marketing of infant formulas so they can be advertised directly to parents.

By the age of 12 months, children should be able to use a cup for drinking, rather than a bottle. Consuming liquids from a bottle after this age increases the risk of overconsumption of these products, which may lead to overweight/obesity, iron deficiency and/or a decrease the child's appetite for solid foods.

Unwell children

For chronically unwell young children, a paediatric dietitian should be consulted. From 1 to 2 years of age, specialised

Table 6. Specialised formulas for infants with medical conditions or low birthweight*

Cow, goat or soy protein allergy or intolerance

Alfaré
Pepti-Junior
EleCare
Neocate

Fat malabsorption

Monogen

Lactose intolerance

Karicare De-Lact
S-26 LF

Lactose and sucrose intolerance

Karicare Soya All-Ages

Lactose, sucrose and fructose intolerance

EleCare
Kindergen
Neocate
Pepti-Junior

Severe enteropathy, maldigestion and malabsorptive disorders

Alfaré
Pepti-Junior

Failure to thrive and/or fluid restriction necessary

Infatrini
Also energy supplements:
Poly-Joule
Polycose
Calogen
Liquigen

Low birthweight/premature

Karicare Nutriprem Low Birthweight
S-26 LBW
S-26 LBW Gold
Pre-NAN
FM-85 human milk supplement
Nutricia Breast Milk Fortifier
S-26 Human Milk Fortifier

* These formulas are usually only used in a specialist/hospital setting.

continued

Table 7. Formulas for unwell children

Nutritionally complete formulas for children aged 1 to 6 years

Nutrini

PediaSure

Energy supplements

Carbohydrate supplements:

Poly-Joule

Polycose

Fat supplements:

Calogen – long chain triglycerides

Liquigen – medium chain triglycerides

Oil

nutritionally complete formulas such as Nutrini or PediaSure can be used, or a standard infant formula modified to provide additional energy by either the addition of supplements of carbohydrate (e.g. Poly-Joule, Polycose) or fat (Calogen, Liquigen, ordinary oil) or the use of a more concentrated preparation (Table 7). Most of these products would generally be prescribed in a specialist/hospital setting.

There are standard nutritionally complete formulas available especially for young children (Nutrini, PediaSure), and all of these are low in lactose or lactose-free. Adult formulas may also be used for older children but care must be taken with products high in sodium and protein.

Oral supplements for sick children are available. These differ in their nutritional composition, although most are milk-based. Supplements for adults can be used for most children but again the sodium and protein content may make them unsuitable for younger children, depending on the daily intake.

Conclusion

There are many infant formulas available, all meeting the Australian Food Standards Code, but there is little evidence that any one is better than another for



Figure. There is little evidence that any one of the standard infant formulas for healthy term infants is better than another.

healthy term infants. As the prices of the different formulas and the types of retail outlets selling them have no relation to their quality or nutritional value, formulas for healthy infants may be chosen on the basis of cost and availability. However, frequent changes in the choice of formula for an infant may lead to incorrect formula preparation as the required powder to water ratio differs between products.

The choice of a speciality formula needs to be made on a rational basis that is evidence-based. Formula changes should not be made as spur of the moment decisions for problems such as poor sleep, colic or fussiness in otherwise healthy infants. Formulas with 'new nutrients' need to be evaluated in terms of safety and efficacy as these 'high tech' products cost considerably more. **MT**

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