

NUTRICIA  
**neocate**<sup>®</sup>

# Guide to Neocate<sup>®</sup> Syneo<sup>®</sup> Infant for Healthcare Professionals

## Frequently Asked Questions





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## 1. NEOCATE SYNEO INFANT: DESCRIPTION AND INDICATIONS

### What is Neocate Syneo Infant? For whom is Neocate Syneo Infant indicated?

Neocate Syneo Infant is a hypoallergenic, amino acid-based infant formula specially formulated for the dietary management of infants with cow milk allergy, multiple food allergies and related gastrointestinal and allergic conditions, including food protein-induced enterocolitis syndrome, eosinophilic esophagitis, and gastroesophageal reflux. Neocate Syneo Infant contains **Syneo**, a patented, clinically tested synbiotic (prebiotic + probiotic). The prebiotic blend is a combination of short- and long-chain fructooligosaccharides (scFOS/lcFOS). The probiotic is a *Bifidobacterium* strain called *B. breve* M-16V.\* **Neocate Syneo Infant is intended for use under medical supervision.**

## 2. DIRECTIONS FOR PREPARATION AND STORAGE

### How do I mix Neocate Syneo Infant?

The following instructions are as they appear on the can of Neocate Syneo Infant.

Your baby's health depends on carefully following these directions. Proper hygiene, preparation, dilution and storage are important when preparing infant formula.

We recommend cooled boiled water for preparation and the use of sterilized bottles. Ask your baby's healthcare team if you need to use cooled boiled water for mixing and if you need to boil (sterilize) bottles, nipples, and rings before use.

1. Wash hands thoroughly and clean preparation area.
2. Add 1 unpacked level scoop (4.7g) of powder to each 1 fl oz of water.
3. Cap bottle; shake well. Feed immediately OR refrigerate immediately at 35-40°F (2-4°C) and use within 24 hours. Once feeding begins, use within 1 hour or discard.

Do not boil formula and do not use a microwave oven to prepare or warm formula; serious burns may result.

Amount of water	Amount of Neocate Syneo Infant Powder to add	Approximate final volume
3 fl oz	3 scoops or 14.1g	3.3 fl oz
5 fl oz	5 scoops or 23.5g	5.5 fl oz
8 fl oz	8 scoops or 37.6g	9 fl oz

Use only under medical supervision. Formula dilution will vary depending on the age, body weight and medical condition of the infant. Neocate Syneo Infant is suitable as a sole source of nutrition for infants under one year of age.

### What can happen to the probiotic in Neocate Syneo Infant if I use water warmer than 104°F (40°C)?

Probiotics in powdered formula, including the one in Neocate Syneo Infant (*B. breve* M-16V), survive and retain their benefits when formula is prepared with water that is lukewarm, at less than 104°F (40°C). The probiotic in prepared Neocate Syneo Infant is sensitive to heat, and mixing with water warmer than 104°F (40°C) or warming formula above 104°F (40°C), even for a few seconds, may lessen the benefits of the probiotic cultures.

### How long can Neocate Syneo Infant be kept once prepared?

Freshly prepared Neocate Syneo Infant is best. Formula prepared in advance should be stored in the refrigerator at 35-40°F (2-4°C) and used within 24 hours of preparation. Neocate Syneo Infant formula remaining in the bottle after one hour of feeding should be discarded. If Neocate Syneo Infant is not fed immediately, we recommend a hang time and "counter time" (time at room temperature if the baby has NOT yet started to feed from the bottle) not to exceed 4 hours.

### Can I warm Neocate Syneo Infant that's been refrigerated?

Yes, although we recommend doing so carefully. Warming to too high of a temperature (above 104°F, or 40°C) may lessen the benefits of the probiotic cultures. If you choose to warm Neocate Syneo Infant, we recommend against using a microwave, as we do for all of our formulas, due to the risk of hot spots and burns. Instead, gently warm cold formula using a bottle warmer, a warm water bath, or by holding the bottle under warm, running water. We suggest using a thermometer to ensure the temperature does not exceed 104°F (40°C).

### What is the shelf life of Neocate Syneo Infant? How long can I use Neocate Syneo Infant after the can is opened?

The shelf life of Neocate Syneo Infant from the date of manufacture is 18 months. Sealed cans of Neocate Syneo Infant should be stored in a cool, dry place and used by the expiration date, which is located on the bottom of each can. We recommend that, after the can is opened, it should be used within two weeks. This is because having the can of Neocate Syneo Infant open for more than two weeks, even with the lid on, may lessen the benefits of the probiotic cultures.

### What is the weight of formula powder in one can of Neocate Syneo Infant?

14.1 oz (400g)

### How many fluid ounces of Neocate Syneo Infant can be made from one can?

95 fl oz

### 3. PREBIOTICS AND PROBIOTIC IN NEOCATE SYNEO INFANT

#### What prebiotics and probiotic does Neocate Syneo Infant contain?

The prebiotic blend is a combination of short- and long-chain fructooligosaccharides (scFOS/lcFOS). The probiotic is a *Bifidobacterium* strain called *B. breve* M-16V.\*

#### Why has a probiotic been added to Neocate Syneo Infant?

Infants with cow milk allergy can have an altered gut microbiota\* composition, or dysbiosis\*. Specifically, researchers have found lower levels of bifidobacteria in infants with cow milk allergy, including those on hypoallergenic formula, compared to healthy, breastfed infants. A *Bifidobacterium* strain, paired with prebiotics, may help foster the development of bifidobacteria in the gut microbiota of infants with cow milk allergy to levels closer to those seen in healthy, breastfed infants.

Not all probiotic strains are the same: the most well-known and studied probiotic strains are *Lactobacillus* and *Bifidobacterium* species. Bifidobacteria have been found to be the predominant genus of bacteria in the healthy, breastfed infant gut in the first months of life.

The probiotic *B. breve* M-16V is a specific strain of bifidobacteria that has been widely studied in various allergic populations. We compared the probiotic *B. breve* M-16V to several other probiotics in research and found it offered the greatest compatibility with allergy compared to several other strains of bifidobacteria and lactobacilli.

#### How do I know that the probiotic in Neocate Syneo Infant is safe?

The probiotic (*B. breve* M-16V) used in Neocate Syneo Infant has been in use in nutritional products since 1976. It has been extensively studied by Nutricia as well as other researchers. Some of this research has taken place in healthy infants, in low birth weight infants, and in allergic infants. Specifically, we've studied the probiotic in several clinical trials, all of which showed that it was safe and well-tolerated when added to Neocate.

#### Are the prebiotics and probiotic in Neocate Syneo Infant safe for use by infants with cow milk allergy?

The prebiotic blend in Neocate Syneo Infant is derived from chicory root inulin – a plant-based, non-dairy source. The probiotic in Neocate Syneo Infant is cultured using a dairy-free process that also does not use ingredients derived from other major food allergens. This makes the synbiotic blend suitable for all infants with cow milk allergy.

Neocate Syneo Infant is backed by 4 clinical studies in infants with cow milk allergy. These studies demonstrate that Neocate Syneo Infant is safe and well-tolerated. Neocate Syneo Infant has been shown to be hypoallergenic based on criteria developed by the American Academy of Pediatrics (AAP) subcommittee on Nutrition and Allergic Diseases. Neocate Syneo Infant is made in the same dedicated 100% dairy protein-free facility as our other Neocate powdered products.

### 4. USE OF NEOCATE SYNEO INFANT

#### How do I transition my patient to Neocate Syneo Infant from another product?

If you are ready to switch your patients from another hypoallergenic formula to Neocate Syneo Infant for the added benefits, you might prefer to transition them gradually to Neocate Syneo Infant over the course of a few bottles, days, or even weeks. This way they will be less likely to notice any differences. See our Caregivers' Guide to Transitioning to Neocate Syneo Infant to determine the best way to transition. As with all medical foods, Neocate Syneo Infant should be used under medical supervision.

#### Will there be any differences in stools when transitioning to Neocate Syneo Infant from breast milk or other formulas?

Infants usually adjust to a hypoallergenic formula and settle into a routine after a few days or weeks. The same may be true when adding prebiotics and/or probiotics to the diet – a gradual transition may help.

The research behind Neocate Syneo Infant suggests that there may be some initial changes in stool characteristics (e.g. color and consistency) during the early transition onto this product from a formula without pre- and probiotics. Stools may be softer, more like breastfed infants. In the first days/weeks of use, there may also be more gas or flatulence, which may cause some temporary discomfort or fussiness.

If you are ready to switch your patients from another hypoallergenic formula to Neocate Syneo Infant for the added benefits, you might prefer to transition them gradually to Neocate Syneo Infant over the course of a few bottles, days, or even weeks.

## Can Neocate Syneo Infant be given through a feeding tube?

Neocate Syneo Infant can be given through gastric feeding tubes that empty into the stomach. However, **Neocate Syneo Infant is not recommended for use in post-pyloric feeding tubes**, which bypass the stomach and empty into the small intestine, unless directed or supervised by a healthcare professional. Neocate Syneo Infant is our ideal formulation for most infants who need an amino acid-based infant formula for food allergies and related conditions. For infants with a post-pyloric feeding tube, we recommend Neocate® Infant DHA/ARA.

## Why do you not recommend the use of Neocate Syneo Infant in infants with a central venous catheter (CVC)?

Medical teams are sometimes cautious about using products that contain probiotics in patients with a CVC. There is concern that probiotics could, through improper handling, be introduced to the CVC and cause a serious blood infection. We are not aware of any reports of negative outcomes with the use of *B. breve* M-16V in patients with a CVC. Out of caution, and until we have more data on the use of Neocate Syneo Infant in patients with a CVC, we do not recommend the use of Neocate Syneo Infant in infants with a CVC unless directed or supervised by a healthcare professional.

## Why is Neocate Syneo Infant “not for use in premature infants or infants who are immunocompromised”, as stated on the label?

Neocate Syneo Infant is intended for use in term infants. Premature infants have unique nutritional needs that Neocate Syneo Infant is not designed to meet. Powdered infant formulas are not sterile and, in the United States, are not recommended for use in infants who are immunocompromised unless directed and supervised by a doctor.

## What is Nutricia’s position on the use of Neocate Syneo Infant for patients with short bowel syndrome (SBS)?

Neocate Syneo Infant is not recommended for use in patients with SBS unless a risk and benefit analysis is completed by a healthcare professional and the patient is monitored.

Neocate Infant DHA/ARA will remain available for infants with SBS. Neocate infant formulas without pre- or probiotics have been studied and safely used in infants with SBS worldwide for over 20 years. While there is growing evidence of potential benefits of pre- and probiotics for some patients with SBS, we don’t yet have specific data on the use of Neocate Syneo in infants with SBS. All of the clinical research we’ve conducted for this product to date has involved infants

with cow milk allergy and related allergic conditions as well as healthy infants.

## 5. COMPARISON OF NEOCATE SYNEO INFANT WITH NEOCATE INFANT DHA/ARA

### How does the nutrient profile of Neocate Syneo Infant compare to Neocate Infant DHA/ARA?

These two products are nearly identical in their nutritional profiles, and both are nutritionally complete for infants up to one year of age. There are only slight differences, as Neocate Syneo Infant has added prebiotic oligosaccharides as well as a probiotic, resulting in minor differences in the levels of some vitamins and minerals between the two products.

### Does Neocate Syneo Infant look/smell/taste different from Neocate Infant DHA/ARA?

Neocate Syneo Infant looks, smells, and tastes almost identical to Neocate Infant DHA/ARA. Nutritionally they are almost identical, and the addition of the synbiotic blend hasn’t changed the taste.

### How does the appearance of the Neocate Syneo Infant can differ from the Neocate Infant DHA/ARA can?



Neocate Syneo Infant



Neocate Infant DHA/ARA

The cans are different in appearance, and the two products have different product codes. This different appearance is also obvious on the outer case as well.

### Can I use the same dilution charts for both Neocate infant formulas?

No. While the general mixing instructions for parents are the same for these two products, they have slightly different characteristics (displacement factor, calories per gram). This means each formula has its own dilution chart. The two charts are not interchangeable.

How do the mixing and storage instructions for Neocate Syneo Infant compare to Neocate Infant DHA/ARA?



	Neocate Syneo Infant	Neocate Infant DHA/ARA
Water temperature	Water below 104°F (40°C) to preserve the benefits of the probiotic cultures	Water below 122°F, or 50°C
Consumption	Feed immediately after mixing  Any prepared formula not consumed within an hour of the start of the feeding should be discarded  The hang time and “counter time” (time at room temperature if the baby has NOT yet started to feed from the bottle) is a maximum of 4 hours	
Refrigeration	Prepared formula can be refrigerated at 35-40°F (2-4°C) immediately after mixing and used within 24 hours	
Warming prepared formula	Neocate Syneo Infant that’s been prepared in advance and refrigerated can be warmed carefully to ensure it doesn’t exceed 104°F (40°C) to preserve the benefits of the probiotic cultures	Neocate Infant DHA/ARA that’s been prepared in advance and refrigerated can be warmed carefully to ensure it doesn’t exceed 122°F (50°C)
Shelf life once opened	Use within 2 weeks; This is because having the can of Neocate Syneo Infant open for more than 2 weeks, even with the lid on, may lessen the benefits of the probiotic cultures	Use within 4 weeks

Is the scoop size/volume/color for Neocate Syneo Infant different than the scoop provided with Neocate Infant DHA/ARA?

The scoop included in cans of Neocate Syneo Infant is the same blue scoop (~8.0 mL in volume) that’s included in Neocate Infant DHA/ARA, so they are technically interchangeable, though we recommend using the fresh scoop every time you open a new can. The two formulas also have the same mixing instructions on the can (1 scoop per 1 fluid ounce water at the standard concentration).

However, because the powder densities and energy densities of the two formulas are slightly different, the number of grams of powder per scoop is slightly different (4.6 grams per scoop for Neocate Infant DHA/ARA, 4.7 grams per scoop for Neocate Syneo Infant). This also means that for larger volumes or when concentrating formula, each formula has its own unique dilution instructions.

## 6. NEOCATE SYNEO INFANT: GENERAL INFORMATION

### Is Neocate Syneo Infant halal and/or kosher?

Neocate Syneo Infant has been certified halal by the Halal Food Council of Europe.

Neocate Syneo Infant is certified kosher pareve by the Kashrut Division of the London Beth Din (KLBD).

## 7. GLOSSARY

### Probiotics

Probiotics, often called good or helpful bacteria, are live microorganisms that when administered in adequate amounts confer a health benefit on the host. The probiotic in Neocate Syneo Infant is *Bifidobacterium breve* M-16V.

### Prebiotics

Prebiotics, the food for probiotics, are non-digestible food ingredients that beneficially affect the host by selectively stimulating the growth and/or activity of one or more of a limited number of microorganisms, such as bacteria, in the colon that can improve the host health. Prebiotics used as dietary supplements are usually in the form of carbohydrates, e.g. oligosaccharides. The prebiotic blend in Neocate Syneo Infant is a combination of short- and long-chain fructooligosaccharides (scFOS/lcFOS), which are derived from chicory root inulin – a vegetarian, non-dairy source.

### Gut microbiota

The gut microbiota describes the whole microbial population found in the gut or gastrointestinal tract.

### Gut dysbiosis

The condition in which there is an imbalance in the microbiota compared to a healthy state.

## 8. CONTACT US

For other questions about Neocate Syneo Infant, call 1-800-NEOCATE (1-800-636-2283), Monday - Friday, 8:30 am - 5:00 pm, EST to speak with a Nutrition Specialist.



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Nutricia North America supports the use of breast milk wherever possible.

Neocate® is a family of hypoallergenic, amino acid-based products and must be used under medical supervision. Neocate Syneo Infant is indicated for cow milk allergy, multiple food allergies and related GI and allergic conditions including food protein-induced enterocolitis syndrome, eosinophilic esophagitis and gastroesophageal reflux.

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