Neocate Parent Guide

Short Bowel Syndrome
Acknowledgement
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Note
This book has been prepared as a resource guide for parents whose child has been recommended to use Neocate in short bowel syndrome. The dietary management of short bowel syndrome can differ between individuals. As such, it is strongly recommended that this guide be used in consultation with a healthcare professional. All information provided in this guide is reflective of the most current and relevant recommendations regarding the dietary management of short bowel syndrome with Neocate.

Research publications consulted in developing this piece:

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General Information on Short Bowel Syndrome

What is short bowel syndrome?

Short bowel syndrome (SBS) occurs when a significant portion of the small intestine is removed. The definition of short bowel syndrome is: inadequate length or function of the small bowel (small intestine) to support nutrition and fluid requirements needed for health and growth. The reaction of infants and children to the loss of any section of the small bowel varies and depends on the amount of bowel lost and the part of the small bowel that is lost.

The small bowel, or small intestine, is a very important part of the digestive system. It absorbs a majority of the nutrients and fluids your body needs to function. Loss of any part of the small bowel reduces the area available for absorbing nutrients and fluids. When a part of the small bowel is lost, the route that the nutrients take to get through the intestinal tract is disrupted. This means, it is no longer a smooth process from the stomach to the end of the intestine, which can cause problems for the infant or child.

What are the challenges of short bowel syndrome?

Depending on how much of the small bowel is lost in infants and children, they may need special formulas, medical procedures, and medications to help their body adapt to the reduced length of the small bowel. Children with SBS may experience diarrhea, dehydration, poor growth, and may need to have nutrition given through their veins, which is known as either total parenteral nutrition (TPN) or parenteral nutrition (PN).

Infants and children with SBS may be at increased risk of food allergy. This may be due to damage to the inner lining of the intestine causing the body to react to intact protein.
What causes short bowel syndrome?

In infants and children, the cause of short bowel syndrome can be one of the following:

- Necrotizing enterocolitis: an infection or inflammation of the intestinal system of premature or low birth weight infants that can result in a necrosis (dying) of the intestinal tract
- Mid-gut volvulus: twisting of the bowel upon itself
- Intestinal atresias: malformation where there is a narrowing or absence of a portion of the intestine
- Intussusception: a situation in which a part of the intestine has prolapsed into another section of the intestine, similar to the way in which parts of a collapsible telescope slide into one another
- Aganglionosis: absence of nerve cells in the colon
- Congenital anomaly: condition present at birth that could be hereditary or result from a problem during pregnancy or birth
- Hirschsprungs: absence or marked decrease in the number of nerve endings that cause the bowel to move feces

What are the goals for short bowel syndrome patients?

There are two main goals of nutritional management:

1) **To help the gut adapt to the damage that has been done**
   
   With time, the gut adapts by growing longer, increasing its ability to absorb nutrients and digest formulas and foods normally. Through adaptation, the remaining small bowel will do the work of the lost bowel and absorb nutrients with a smaller work space. Research has shown that enteral nutrition (tube feeding) can help the gut adapt. Special formulas, such as Neocate, may be needed to help with the absorption of nutrients.

2) **Nutritional stability**
   
   Through a diet that agrees with the child with short bowel syndrome, the body can obtain the nutrients and fluids needed for optimal growth. The diet may consist of TPN initially and then advance to enteral (oral or tube) nutrition and use of Neocate. Eventually some children will be able to eat an oral diet and use Neocate as a supplement.
What is Neocate?

The Neocate family is a range of amino acid-based nutrition designed for meeting the needs of growing children at specific ages. Neocate products are specially designed for infants and children for the nutritional management of cow and soy milk allergies, multiple food protein allergy, and food allergy-associated conditions, such as short bowel syndrome. Neocate products are medical foods intended for use only under medical supervision. Neocate provides nutrients required for a child’s growth and development. Neocate has been recommended by your doctor or dietitian because your child has difficulty in tolerating or digesting other formulas.

- **Hypoallergenic**
  The formula is less likely to cause an allergic response.

- **Nutritionally Complete**
  All of the essential nutrients needed to grow are supplied by the formula.

- **Amino Acid-Based**
  Amino acids are the non-allergenic building blocks for all protein.

- **Elemental**
  Protein is present in its simplest form so it is easier for the body to process and absorb.

- **Dairy-Free Manufacturing**
  All Neocate powder formulas are manufactured in a dairy-free environment providing a safe and effective formula for individuals with dairy allergies.
How does Neocate help with SBS?

Neocate is an amino acid-based formula, which means that the proteins are in the most simple form, making it easier for the body to process and digest. Neocate helps in the absorption of nutrients for infants and children with short bowel syndrome by giving the gut time to rest and use energy towards growth and adaptation rather than breaking down nutrients.

Our unique amino acid-based and milk-free formulation makes it different from other standard formulas. Neocate is truly hypoallergenic; it was designed to minimize the possibility of an allergic response and contains no potential harmful allergens, such as milk.

Fat absorption may also be an issue for infants and children with short bowel syndrome. The type of fat used in Neocate consists of a balanced blend of medium chain triglycerides (MCT) and long chain triglycerides (LCT). MCT is more easily digested than other fats which take longer and use more energy to breakdown. This is important for a child with SBS as their GI tract has been compromised and may lead to difficulty in nutrient absorption. LCT is also important for a child with SBS as it helps the gut adapt quickly enabling it to absorb important nutrients for your child to grow and thrive.
Frequently Asked Questions

How long will my child need Neocate?
There is no standard amount of time your child will need Neocate as it greatly varies per individual. The length and the functionality of the remaining bowel along with how quickly the gut adapts will help the physician and/or dietitian determine the amount of time Neocate is needed.

Will Neocate meet all of my child's nutritional needs?
Neocate offers a full range of nutritionally complete, age-specific nutrition for infants and children over 1 year of age to meet their changing needs. If you are concerned that your child is not gaining weight or growing adequately consult your doctor or dietitian. They will be able to assess if nutritional needs are being met and if dietary adjustments are necessary. For children with SBS, it’s important for the healthcare team to monitor nutrient status over time.

Neocate tastes and appears different than other formulas. Is this normal?
Yes, this is quite normal. The protein source in Neocate is different than milk-based or hydrolyzed formulas. The free amino acids give the product its characteristic taste and smell. Our Neocate family of products offers a wide variety of flavors and forms for individuals one year and older to help with compliance. Our flavors include vanilla, strawberry, chocolate, tropical, grape, orange-pineapple, tropical fruit and unflavored.

My child has had a change in stools since starting on Neocate. Is this normal?
Yes, this is perfectly normal! Stools can change in consistency and color when a child is introduced to an elemental formula such as Neocate. This is because Neocate is a low residue formula. Low residue formulas lower the number of bacteria in the gut leading to reduced breakdown of bile. More bile is present in the stool making it darker in color.

What are DHA and ARA?
DHA and ARA are two important fats naturally found in breast milk. Studies have shown a direct consumption of these key ingredients promote brain and eye development.

Will my insurance company cover the cost of Neocate?
Insurance coverage will depend on your policy, as well as the state in which you reside. There are several states that mandate Neocate coverage. For an up-to-date listing of these states visit www.Neocate.com. Hints and tips for successful reimbursement are also available online. For one-on-one, personalized guidance on insurance coverage matters, call Nutricia Navigator at 1-800-365-7354 ext. 1200 or visit Nutricia-NA.com/NutriciaNavigator.

Consult your doctor and/or insurance company to assist you with any specific questions you may have. For additional suggestions and helpful documents that may assist you in obtaining coverage, please contact our Nutrition Department at 1-800-Neocate or www.Neocate.com.

Where can I purchase Neocate?
You can order Neocate directly from Nutricia North America at www.Neocate.com or by calling 1-800-Neocate. Neocate is also available to order through your local pharmacy.

Why is the Neocate range only available from the pharmacy and not through my grocery store?
Neocate products are medical foods intended for use only under medical supervision and are typically recommended by a physician and ordered by a pharmacist. These specialized nutritional products are generally represented and labeled solely to provide dietary management for specific diseases or conditions. Some pharmacies carry Neocate, and any pharmacies can special order Neocate.

Always consult your doctor or dietitian if you have questions or concerns regarding your child’s health.
Neocate Preparation and Nutrient Profile

How do I prepare Neocate Infant?
To make a standard dilution (20 cal/fl oz), add 1 unpacked level scoop (4.6 g) of powder to each fluid ounce of water. Only use the scoop provided. Use a gram scale for the most accurate results. Do not boil formula or use a microwave to prepare or warm formula.

1. Wash hands thoroughly and clean the preparation area.
2. Pour the required amount of cooled, boiled water into a sterilized feeding bottle.*
3. Add the prescribed amount of scoops of Neocate Infant DHA/ARA to the water.
4. Place the cap on the bottle and shake until the powder dissolves.

Important Preparation Information
Freshly prepared formula is best. Formula prepared in advance must be cooled rapidly, stored in the refrigerator and used within 24 hours of preparation. Formula remaining in the bottle after one hour of feeding should be discarded. Tube feeding hang time should not exceed 4 hours.

*Boiling is the preferred method for sterilizing water, bottles, nipples and mixing utensils.
Neocate Infant DHA/ARA Mixing Instructions

How do I make different volumes?

<table>
<thead>
<tr>
<th>Amount of Water</th>
<th>Amount of Neocate Infant Powder to Add</th>
<th>Approximate Final Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 fl oz</td>
<td>3 scoops or 13.8 g</td>
<td>3.3 fl oz</td>
</tr>
<tr>
<td>5 fl oz</td>
<td>5 scoops or 23 g</td>
<td>5.5 fl oz</td>
</tr>
<tr>
<td>8 fl oz</td>
<td>8 scoops or 37 g</td>
<td>9 fl oz</td>
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</tbody>
</table>

Nutricia North America recommends using a gram scale for greatest accuracy.

How can Neocate be stored?

- Prepared formula can be stored in a refrigerator for up to 24 hours
- Once a bottle is introduced to your infant’s mouth, all formula remaining in the bottle should be discarded after one hour
- Opened cans of Neocate with plastic lid securely fastened should be stored in a cool, dry place and used within one month
- Sealed cans of Neocate should be stored in a cool, dry place and used by the expiration date, which is located on the bottom of each can

What is the best way for me to warm the Neocate once it has been prepared?

As with any other formulas, a microwave oven should not be used to reheat Neocate, as this can lead to “hot spots” in the formula. It is recommended to place the prepared bottle either under warm, running water, or in a container filled with warm water.

Neocate Infant DHA/ARA Nutrient Profile

<table>
<thead>
<tr>
<th>Nutrients</th>
<th>Per 100 calories (5 fl oz)</th>
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<tbody>
<tr>
<td>Calories</td>
<td>100</td>
</tr>
<tr>
<td>Protein Equivalent, g</td>
<td>2.8</td>
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<tr>
<td>Fat, g</td>
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<tr>
<td>Carbohydrate, g</td>
<td>10.8</td>
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<tr>
<td>Linoleic Acid, mg</td>
<td>738</td>
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<tr>
<td>Vitamins</td>
<td></td>
</tr>
<tr>
<td>Vitamin A, IU (mcg RE)</td>
<td>280 (84.1)</td>
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<tr>
<td>Vitamin D₃, IU (mcg)</td>
<td>72.9 (1.8)</td>
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<tr>
<td>Vitamin E, IU (mg T.E.)</td>
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<td>Vitamin K, mcg</td>
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<td>Thiamin, mcg</td>
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<td>Sodium, mg</td>
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<tr>
<td>Potassium, mg</td>
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<tr>
<td>Chloride, mg</td>
<td>79.9</td>
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</table>

* Standard dilution = 20 calories/fl oz
Osmolality (standard dilution): 340 mOsm/kg
Ingredients:
Corn Syrup Solids (54%), Refined Vegetable Oil (Medium Chain Triglycerides (6%), High Oleic Sunflower Oil (6%), Sunflower Oil (5%), Canola Oil (4%)), Calcium Phosphate Dibasic (2%), and less than 2% of each of the following: L-Arginine L-Aspartate, L-Leucine, Tripotassium Citrate, L-Lysine Acetate, L-Glutamine, L-Proline, CAEM (an emulsifier), L-Valine, Glycine, L-Isoleucine, L-Threonine, L-Phenylalanine, L-Tyrosine, L-Serine, L-Histidine, L-Alanine, Sodium Chloride, L-Cystine, Magnesium Chloride, L-Tryptophan, Choline Bitartrate, L-Methionine, Tricalcium Citrate, Magnesium L-Aspartate, M. Alpina Oil*, C. Cohnii Oil**, M-Ascorbic Acid, Taurine, Ferrous Sulfate, Zinc Sulfate, L-Carnitine, Uridine 5’-Monophosphate Disodium Salt, Cytidine 5’-Monophosphate, Niacinamide, Inosine 5’-Monophosphate Disodium Salt, Adenosine 5’-Monophosphate, Calcium D-Pantothenate, Guanosine 5’-Monophosphate Disodium Salt, DL-Alpha Tocopherol Acetate, Ascorbyl Palmitate, Manganese Sulfate, Thiamine Chloride Hydrochloride, Pyridoxine Hydrochloride, Cupric Sulfate, Riboflavin, Vitamin A Acetate, DL-Alpha-Tocopherol, Potassium Iodide, Mixed Tocopherols, Folic Acid, Chromium Chloride, Phylloquinone, Sodium Selenite, D-Biotin, Vitamin D3, Cyanocobalamin.

* A source of Arachidonic Acid (ARA).
** A source of Docosahexaenoic Acid (DHA)

Neocate® Choices: Tailored nutrition as children grow

Neocate provides age-appropriate hypoallergenic elemental nutrition choices.

Shown to be effective in the nutritional management of:
- Cow milk allergy and soy allergy
- Multiple food protein allergy
- Food allergy-associated conditions:
  - Short bowel syndrome
  - Eosinophilic esophagitis
  - Malabsorption
  - Gastroesophageal reflux
  - Other gastrointestinal disorders

For product information or to place an order call: 1-800-NEOCATE or visit www.Neocate.com

* Over 100 publications worldwide support the use of Neocate
Visit www.Neocate.com to see the many ways we can help.

Call 1-800-Neocate (1-800-636-2283) for nutrition and reimbursement assistance.

Nutricia leads the development of advanced medical nutrition. Nutricia products and services transform the daily lives of millions of infants, children, adults and seniors.