Karyn, age 7
Diagnosed with eosinophilic esophagitis (EoE)

Neocate® Caregiver Guide
Eosinophilic Esophagitis (EoE)
Dear EoE families,

Feeding your child with EoE can be challenging. While dietary management for EoE has shown to be very effective in identifying the root cause of inflammation, the day to day struggles of meeting nutritional and developmental needs on either an elemental diet or an elimination diet can be difficult. Your child’s healthcare team’s mission is to provide guidance on the diets including what foods to avoid and how to replace those foods to ensure your child is meeting their individual nutrition needs for optimal growth and development while working towards remission. Registered Dietitians are uniquely qualified to educate families on how to read food labels, prevent cross contamination from trigger foods and work with your family to meet your child’s individualized nutritional needs.

Nutritional gaps of key nutrients may exist whether you’re removing 1 food or 10 foods from the diet. Having tools such as the Neocate® line of products can help your child meet their recommended nutrient intakes and help take some of the stress out of eating. The variety in flavors and forms gives choices to children when they have so little control in the foods they are eating.

Neocate is available as either a powder, semi-solid or a liquid ready-to-feed formula. In addition, Neocate provides 10 great-tasting options to meet your child’s taste preferences. Neocate can be given by itself or can be added to recipes to provide a calorie and nutrient boost.

This caregiver guide is an excellent resource which educates families on the various dietary management options for EoE, as well as the appropriate Neocate products that may be used as part of the management plan. This guide should be paired with guidance from your medical team.

Be well,

Sally Schwartz, RD, LDN

ACKNOWLEDGEMENT

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NOTE

This book has been prepared as a resource guide for caregivers whose child has been recommended to use Neocate® for the dietary management of eosinophilic esophagitis. The dietary management of eosinophilic esophagitis can differ between individuals. As such, this guide should be used in consultation with a healthcare professional. All information provided in this guide reflects current recommendations regarding the dietary management of eosinophilic esophagitis with Neocate.
General Information on Eosinophilic Esophagitis

What is Eosinophilic Esophagitis (EoE)?

EoE is one of the various types of Eosinophilic Gastrointestinal Disorders (EGIDs). The category of EGIDs also encompasses eosinophilic gastritis, eosinophilic gastroenteritis, eosinophilic enteritis, and eosinophilic colitis. EoE is characterized by the infiltration of a large number of eosinophils, a type of white blood cell, in the esophagus. Eosinophils travel throughout the body to help fight different types of infections, such as parasites. However, eosinophils are not normally found in the esophagus. When they are present, this is an indication of inflammation, which may be due to food allergens (e.g. milk, soy, egg) or environmental allergens (aero-allergens).

Symptoms vary from one individual to the next and may differ depending on age. EoE symptoms may include vomiting, gastroesophageal reflux, nausea, food aversion (which can lead to pediatric feeding disorder), growth failure (younger children), dysphagia (difficulty and/or pain swallowing), food impaction (food that gets stuck in the throat) and chest and abdominal pain (commonly seen in older individuals).

Diagnosis of this condition is made by endoscopy and biopsy. An endoscopy is a medical procedure that allows your doctor to look inside the digestive tract. A thin, flexible, lighted tube called an endoscope is guided into the mouth and throat, then into the esophagus, stomach and duodenum (beginning of the small intestine). The endoscope allows your doctor to view the inside of this area of the body, as well as to insert instruments through a scope for the tissue biopsy. The biopsy is reviewed under a microscope by your doctor to look for inflammation by counting the number of eosinophils.
Why dietary management?
The goal of dietary management is to identify food triggers that cause inflammation in your child’s esophagus without the need for medications. Dietary management helps determine if your child’s EoE is due to food allergens or something else. Dietary elimination approaches to managing EoE are gaining acceptance by patients and clinicians as a first-line management option. Research has shown an 88-98% success rate (removal of eosinophils) with dietary management. Adult diet trials have shown positive results from use of dietary management as well.

Some clinicians may suggest drug therapies such as steroids to manage EoE. While medications can help, they won’t help uncover the root cause of inflammation. Dietary management is the only approach that helps healthcare teams identify the root cause of EoE: which specific foods are triggering inflammation. After achieving drug-free histologic remission, patients who elect dietary management for EoE are often able to return to a wide and varied diet without exposure to potential side effects of drugs.

There are 2 primary options for dietary management for EoE:

1. Elemental diet:
In this management option, all sources of whole proteins are removed from the diet. This diet involves use of an amino acid-based product (Neocate® Junior, Neocate® Splash, Neocate® Infant DHA/ARA, or Neocate® Syneo® Infant). Simple sugars, salt and oils may be permitted (e.g. 100% apple juice, white grape juice and sugar). Formulas such as Neocate may be given either by mouth or tube feeding depending on your child’s nutritional needs. Your medical team will provide a goal amount of formula for your child to consume to meet 100% of nutritional needs for optimal growth and development.

2. Elimination diet:
Elimination diets involve removing trigger food/s from your child’s diet. The most common EoE food triggers are cow milk, wheat, egg, soy, tree nut, peanut, fish and shellfish. Eliminating foods can make it hard to meet nutrient needs. Neocate can be used to supplement elimination diets to help meet nutritional needs.

If your child has responded positively to dietary management (either an elemental diet or elimination diet), indicated by a decrease in eosinophils and improvement of the lining of the esophagus, the next step would be food reintroduction using food trials.

Food reintroduction: Food trials involve adding back one food at a time to determine which specific foods are causing a reaction. Adding one food at a time for a period of weeks, monitoring for symptoms, and keeping track of foods introduced will help you determine which food(s) may be causing the inflammation. This process takes time. In a child that was on an elemental formula only, this may take months for them to return to a normal diet. An elemental formula can be used to ensure that the nutritional needs (vitamins, minerals and calories) of your child are being met during food elimination. This will be important for optimal growth and development during this critical time. It is important to work with your registered dietitian to ensure your child is meeting their individual nutrition needs.

Whether your child is on an elemental diet, elimination diet or a combination of both, the Neocate family of products can help meet nutrient needs and has been shown to improve EoE symptoms as part of an elimination or elemental diet.
What is Neocate?

Neocate is a family of amino acid-based, hypoallergenic products effective in the dietary management of cow milk allergy, multiple food allergies and related GI and allergic conditions, including eosinophilic esophagitis. Neocate is specifically developed to meet the nutritional needs of growing children. Neocate is for use under medical supervision so ask your child’s healthcare professional about Neocate before use.

Neocate products are:

- **Amino acid-based**: Amino acids are the non-allergenic building blocks for all proteins
- **Elemental**: Amino acid-based products are sometimes also referred to as elemental formulas. Ingredients are in simple forms so they are easier for the body to process and digest
- **Hypoallergenic**: Amino acid-based formulas like Neocate are less likely to cause an allergic response than other formula types
- **Nutritionally complete**: Neocate Infant DHA/ARA, Neocate Syneo Infant, Neocate Junior, and Neocate Splash provide all of the essential nutrients needed to grow when consumed in adequate amounts
- **Tailored nutrition**: Neocate products are designed to support the growth and nutritional needs through key stages of the journey

Neocate Choices:

Neocate’s consistent innovation provides age-appropriate, hypoallergenic, amino acid-based nutrition choices that may help improve adherence and fight flavor fatigue.
What makes Neocate different from other formulas?

Neocate contains free amino acids, the tiny building blocks of protein, and that makes it different to other products. Amino acids are non-allergenic and do not have any protein links to trigger an allergic reaction.

Our unique amino acid-based and milk-free formulation makes it different from other products. Neocate is truly hypoallergenic; ingredients for Neocate are carefully selected to minimize the possibility of an allergic response. Neocate is the only hypoallergenic amino acid-based formula in the US that does not contain soy oil.

To learn more about Neocate and its ingredients, visit our Living with Food Allergies Blog at www.neocate.com/living-with-food-allergies-blog.

Remington, age 20
Diagnosed with eosinophilic esophagitis (EoE)
Eliminating common EoE triggers from the diet can create nutritional gaps by putting key nutrients at risk of low intake, which can contribute to growth problems. Neocate can safely supplement elimination diets and help close nutrition gaps so your child can thrive.

WHEAT  EGG  PEANUT  TREE NUTS  MILK  FISH  SHELLFISH  SOY

ARE YOU EATING ENOUGH?

YES

NO

Ask your RD about AAF &/or micronutrient supplementation

Keep an eye out for possible symptoms. Your doctor will keep track of your growth.

"A common example is the 4-food elimination diet: milk, soy, wheat, and egg.
Neocate® is a family of hypoallergenic, amino acid-based medical foods for use under medical supervision and is indicated for cow milk allergy, multiple food allergies and related GI and allergic conditions. AAF = amino acid-based formula.

EOSINOPHILIC ESOPHAGITIS

DIETARY MANAGEMENT - Dietary management may allow for prolonged, drug-free remission. Work with a Registered Dietitian (RD) to manage your EoE diet.

ELIMINATION DIET

1. Empiric (1-8 foods)*
2. Test-directed - See an Allergist

COMBINATION

Elimination diet + supplement AAF

ELEMENTAL DIET (AAF)

NEOCATE® PROVIDES THE MOST OPTIONS

0-12 months 6+ months 1+ years

Neocate® Infant Neocate® Nutra‡ Neocate® Splash

Neocate® Infant DHA/ARA Neocate® Junior Neocate® Junior‡

Individual needs as directed by healthcare professional.
Neocate Nutra is a hypoallergenic semi-solid food - not suitable as sole source of nutrition.

^{*}Following diagnosis: Discuss goals & pros/cons of all dietary management options with your doctor.
Formula Preparation Guide

Neocate Splash Preparation

• Shake well before opening. Best served chilled.

Neocate Junior, Neocate Infant DHA/ARA, and Neocate Syneo Infant Preparation

1. Clean hands and preparation area
2. Add 1 unpacked level scoop of powder to 1 fl. oz water*
3. Stir or cover and shake well

Feed immediately OR refrigerate immediately. Keep prepared formula refrigerated for no longer than 24 hours.

Discard leftover formula 1 hour after feeding starts.

Tube feeds can be safely kept at room temperature for up to 4 hours.

STORAGE

CANS: Store unopened and opened cans in a cool, dry place. Avoid extreme temperatures. Once opened, use within one month (two weeks for Neocate Syneo Infant).

LIQUIDS: Store unopened product in a cool, dry place. Once opened, store in a refrigerator and keep no longer than 24 hours. Do not freeze.

Neocate Nutra Preparation

• Clean hands, bowl and preparation area.
• Add the recommended amount of formula. Slowly add the required amount of water while stirring. Mix until thickened.
• Neocate Nutra should be prepared immediately prior to feeding. Remaining prepared product should be discarded within 1 hour.

*Yields 20 kcal/fl. oz or 30 kcal/fl. oz for infant or junior formulations, respectively. For Neocate Syneo Infant: Mixing with water warmer than 104°F (40°C) or warming formula above 104°F (40°C) may lessen the benefits of the probiotic cultures. We recommend cooled, boiled water for preparation and the use of sterilized bottles.
Vanilla Orange Pineapple Fruit Blast

What You Need:
- 1 ¾ cups gluten-free all-purpose flour substitute
- ½ cup of sugar
- 2 tsp baking powder
- ¼ tsp salt
- ½ tsp xanthan gum (optional)
- ½ tsp nutmeg (optional)
- ¾ cup non-dairy margarine (or allowable fat substitute), cold and cut into pieces
- ¾ cup blueberries, fresh
- 1 Tbsp egg replacer mixed with ¼ cup water
- 2 tsp real or imitation vanilla extract
- ½ cup Neocate Splash, Tropical Fruit

Directions:
1. Crush ice and frozen pineapple in blender.
2. Add Neocate Junior and blend for a few seconds.
3. Add orange juice and pineapple juice. Blend till evenly mixed.
4. Pour in glass and serve. Add a pineapple slice as a garnish.

Blueberry Scones

What You Need:
- 1 ¾ cups gluten-free all-purpose flour substitute
- ½ cup of sugar
- 2 tsp baking powder
- ¼ tsp salt
- ½ tsp xanthan gum (optional)
- ½ tsp nutmeg (optional)
- ¾ cup non-dairy margarine (or allowable fat substitute), cold and cut into pieces
- ¾ cup blueberries, fresh
- 1 Tbsp egg replacer mixed with ¼ cup water
- 2 tsp real or imitation vanilla extract
- ½ cup Neocate Splash, Tropical Fruit

Directions:
1. Preheat the oven to 400°F.
2. Line baking sheet with parchment.
3. Whisk together the flour substitute, sugar, baking powder, salt, and xanthan gum and nutmeg, if using.
4. Work in the cold margarine till the mixture is crumbly with a pastry cutter or fork.
5. Stir in the blueberries.
6. Whisk together the Splash Tropical Fruit, egg substitute, and vanilla till frothy.
7. Add to the dry ingredients, stirring till well blended. The dough should be cohesive and very sticky.
8. Drop dough by using rounded tablespoons onto the baking sheet. Let the scones rest for 15 minutes.
9. Bake for 15 to 20 minutes, until golden brown.
10. Remove from the oven and let rest for 5 minutes or so before serving.
Trying a new formula can be challenging, but here are some tips to help you and your child get started

- **Serve chilled.** Neocate is best served cold.
- **Use a special cup.** Serve Neocate in a cup that is different than what they are used to. Try a fun cup with a straw and lid, or use your child’s favorite cup.
- **Try Neocate Splash.** Looks like a store-bought drink box that’s easy to pack for on-the-go.
- **Give it time.** Easier said than done, but be patient – research shows that children may need up to 20 exposures to a new food before they try it.
- **Be encouraging.** Don’t make any comments about the formula before your child drinks it – remember, kids are always listening and watching!
- **Make it fun.** Create a game to help your child finish drinking the formula. Take one sip, then two sips, then three and so on. After five sips, win a prize!
- **Add Neocate to prepared foods.** For example: Mix dry Neocate powder into recipes like smoothies or warm soups or moist foods like mashed potatoes or casseroles. Wait until hot food is cool enough to eat before you add Neocate.

As always, be sure to talk to your healthcare team about what works best for you and your child.

Let us help you find Neocate coverage

Navigator is a FREE assistance program for families to help navigate insurance reimbursement and access. Our experts will stand by your side until all coverage and access options are explored.

Over 15,000 patients from families like yours have found support through Navigator

- **Phone:** 1-800-Neocate (1-800-636-2283)
- **Website:** Neocate.com/Reimbursement
- **Email:** NutriciaNavigator@Nutricia.com

As always, be sure to talk to your healthcare team about what works best for you and your child.
Frequently Asked Questions

When will I see an improvement after starting an elimination diet with Neocate?
If your child has been experiencing allergy symptoms for some time, his or her condition may take time to improve. Severe allergies can cause inflammation and irritation to the affected areas. In a clinical trial, a Neocate elimination diet has been shown to start managing EoE within as little as two weeks.

How long will my child need Neocate?
There is no standard amount of time your child will need Neocate. It greatly varies per individual and depends on the amount and type of foods your child is able to tolerate. Your child's physician and/or registered dietitian will determine the amount of time Neocate is needed.

Will Neocate help my child meet their nutritional needs?
Neocate Junior, Neocate Splash, Neocate Infant DHA/ARA, and Neocate Syneo Infant have been formulated to meet daily nutritional requirements of infants and children. For children with food restrictions or on elemental diets, fiber is often lacking. Neocate Syneo Infant and Neocate Junior safely add prebiotic fiber into the diet to help with overall gut health. Neocate Nutra, unlike the rest of the range, is not nutritionally complete but can supplement essential nutrients in children on elimination diets. If you are concerned that your child is not gaining weight or growing adequately, consult with your doctor and/or registered dietitian. Healthcare professionals will be able to assess if nutritional needs are being met and if dietary adjustments are necessary.

Neocate tastes and appears different than other formulas. Is this normal?
Yes, this is quite normal. Neocate contains 100% amino acids, which is different to milk-based and hydrolyzed formulas. The free amino acids give the product its characteristic taste and smell. For children over the age of 1, Neocate is the only range with 10 great-tasting options to help support adherence.

What is Neocate Nutra and how will it help with EoE?
Neocate Nutra is the only semi-solid amino-acid based medical food for children ages 6 months and older. Neocate Nutra makes a soft cereal-style consistency that adds texture and variety into the diet. Nutra can help with EoE by providing an allergen-free food option for those on an elimination diet or elemental diet. Note: Neocate Nutra is not intended for bottle or tube feeding. Other foods or formula must be consumed for a complete diet.

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. 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 or visit Nutricia-NA.com/NutriciaNavigator. For additional suggestions and helpful documents that may assist you in obtaining coverage, please contact our Nutrition Services Department at 1-800-Neocate or nutritionservices@nutricia.com.

Where can I purchase Neocate?
Neocate can be ordered 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 Neocate only available through the pharmacy and not on my grocery store shelf?
Neocate products are medical foods intended for use only under medical supervision and are typically recommended by a physician and requested by a pharmacist. These specialized nutritional products are generally represented and labeled solely to provide dietary management for specific diseases or conditions.

Always consult your doctor or registered dietitian if you have questions or concerns regarding your child's health.
Neocate® is a family of hypoallergenic, amino acid-based medical foods for use under medical supervision and is indicated for cow milk allergy, multiple food allergies and related GI and allergic conditions. Talk to your healthcare provider about product recommendations.

Contact Nutricia North America at:
1-800-Neocate (1-800-636-2283) 8:30 AM-5 PM ET

Visit neocate.com/junior and neocate.com/splash for more information

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