

NUTRICIA
neocate[®]

Quinn, Age: 16 months
Diagnosed with cow milk allergy

NEOCATE[®] SPLASH CASE STUDY BOOKLET

Clinical cases to support dietary management of food allergies with Neocate Splash

Foreword

Nearly 6 million or 8% of U.S. children have food allergies with young children affected most¹. This case study booklet was designed to share management strategies by healthcare professionals who have successfully managed food allergies and gastrointestinal (GI)-related conditions such as **cow milk allergy, multiple food allergies, food protein-induced enterocolitis syndrome (FPIES) and eosinophilic esophagitis (EoE)** using Neocate® Splash. These cases demonstrate the importance of dietary elimination as an essential tool in the management of these conditions that may be temporary or life-long.

The potential for nutritional risks associated with elimination diets are well documented, especially in children who avoid multiple foods²⁻⁴. Food allergic children are often smaller than their peers²⁻⁴ and can have suboptimal nutrient intake⁴⁻⁶. Moreover, patients with food allergies who are managed by a multidisciplinary team that includes a dietitian are less likely to incur the potential negative nutritional impact of dietary elimination¹.

Awareness of the individual risks and challenges of an elimination diet can optimize your patients' care and their health⁷⁻⁹. It is important for healthcare professionals to be mindful of the broad, life-altering impacts of dietary avoidance. These impacts affect patients of all ages—including a toddler, who may have been diagnosed with cow milk allergy and later developed multiple food allergies with secondary feeding difficulties and growth failure, to a young adult with an eosinophilic disorder who is entering college and needs to successfully navigate cafeterias and social situations.

This case study booklet provides a range of case studies, written by healthcare professionals who have demonstrated the effective use of Neocate products in the nutritional management of food allergies.



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CASE 1: Neocate® Splash Allows a Toddler with FPIES to Gain Feeding Independence and Decrease Reliance on Tube Feeding

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Patient History:

A now 20 month old toddler with a history of gastroesophageal reflux disease (GERD), food protein-induced enterocolitis syndrome (FPIES), IgE-mediated cow milk allergy, delayed gastric emptying, constipation, poor weight gain and poor intake requiring use of a feeding tube is presented.

Nutrition/Medical Management:

Since birth, a full-term infant received a standard, cow milk based-formula and as early as 2 weeks of age she experienced blood in her stools. She trialed an extensively hydrolyzed formula for 2 weeks, yet remained symptomatic. At 4 weeks of age she was referred to a pediatric gastroenterologist for evaluation of possible GERD and cow milk allergy. She was transitioned to an amino acid-based formula (AAF), Neocate® Infant in addition to continuing a medication to manage GERD. Over the course of the next several months, she was able to maintain the recommended weight gain of 15-21 g/day. However, she continued to experience frequent vomiting and irritability despite medical management for both GERD and delayed gastric emptying.

At 6 months of age, while continuing on Neocate Infant, her parents began introducing solid foods.

She experienced delayed, profuse vomiting with a number of foods including oat, pea, carrot, banana, green beans, pear, and apple. It was difficult to determine the cause of her frequent emesis in the face of persistent GERD, which did not seem to be adequately controlled. Over the next several months this infant had numerous hospital admissions for feeding refusal, extreme dehydration, diarrhea, and multiple respiratory illnesses.

During the hospital admission when she was 8 months of age, all solid foods were removed from her diet and she was exclusively fed Neocate Infant by bottle. Although this resulted in a vast improvement of most of her symptoms, she continued to have difficulty meeting her daily nutritional needs orally because she was unable to drink the recommended volume.

Due to ongoing feeding refusal, vomiting and difficulty tolerating age-appropriate formula volumes, a nasogastric (NG) tube was inserted and used for supplemental feedings. This allowed her to take ad lib oral feedings during the day and receive the remainder of her daily required AAF volume as a continuous NG feeding overnight.

Her repeated episodes of delayed, profuse vomiting after specific foods made her healthcare provider suspect she may have FPIES. At 10 months of age she was referred to a pediatric allergist. The diagnosis of FPIES was confirmed and the family was counseled by a registered dietitian on how to systematically reintroduce solid foods based on the current FPIES guidelines¹⁰.

Although she began to show more interest in table foods, she would put these foods in her mouth, chew, and then expel without swallowing. She had also become averse to all pureed foods, which made conducting food trials extremely difficult. In addition, she became very rigid around her mealtime routine. For example, she began taking formula orally only when she was at home in a particular chair and only tolerated having her NG tube in place while sleeping. This rigidity combined with having to reinsert the NG tube each night became increasingly stressful for the entire family. She began to decrease her oral intake of AAF during the day, thus requiring the majority of her enteral feedings to be administered via overnight continuous NG feedings that negatively impacted her sleep.

At 12 months of age it was recommended that her parents establish care with a pediatric feeding team to begin working on the behavioral issues contributing to her food refusal. She received oral motor skill assessment by a speech language pathologist. Under the guidance of a registered dietitian, efforts were made to continue introducing foods that have a low likelihood of causing a FPIES reaction.

Due to her now severe oral food aversion, perhaps made worse because of daily NG tube reinsertion, and continued need for enteral feedings, a gastrostomy tube (G-tube) was placed as a more permanent solution. She was also transitioned from Neocate Infant to a powdered Junior AAF, which is formulated specifically to meet the nutritional needs of children aged 1 year and above. Shortly after placement of the G-tube, her oral intake of both food and AAF volume improved, but remained inconsistent. While continuing on supplemental G-tube feedings for the majority of her nutritional needs, she was able to participate in systematic food trials in hopes of expanding the variety of foods and textures accepted orally. The registered dietitian provided ongoing monitoring of growth and nutrition-related laboratory tests, guided food trials and recommended adjustments to AAF volumes. The

primary nutrition and feeding therapy goal was to ingest an age-appropriate diet along with the volume of AAF necessary to foster growth and development without the use of her G-tube.

Her volume of powdered junior AAF taken orally continued to fluctuate, making it difficult for her to wean off overnight G-tube feedings. The dietitian suggested introducing her to Neocate® Splash, a nutritionally complete, ready-to-drink AAF in an attempt to achieve consistent oral AAF intake. She trialed all 4 Neocate Splash flavors in order to “find her flavor fit” and picked Neocate Splash, Orange-Pineapple as her favorite. Her oral intake of Neocate Splash, Orange-Pineapple significantly increased, which allowed for a reduction in the volume of AAF needed overnight. To simplify this toddler’s overnight G-tube feeding regimen, Neocate® Splash, Unflavored replaced powdered junior AAF to alleviate the burden of mixing formula. The feeding team continued to work with her to increase her acceptance of “safe foods” offered to her in various textures, increase her willingness to try new foods, and improve her overall feeding skills and behaviors.

✓ Conclusion:

The acceptance of Neocate Splash, Orange-Pineapple allowed this toddler to more easily achieve her daily nutritional goals orally, thus reducing her dependency on tube feedings. Its ready-to-drink format and easy-to-decant packaging offered convenience by negating the need to mix formula and prevented the spills that unintentionally occurred while her parents administered her tube feeding in the dark (to prevent their daughter from waking). Neocate Splash has increased the family’s quality of life and has allowed this toddler to progress closer to achieving age-appropriate meals, snacks and enhanced feeding independence.

How Neocate Splash was used:	Overview of symptoms & conditions:
<ul style="list-style-type: none"> • Sole source and supplemental enteral support administered via NG and G-tube feedings • Oral supplement to an elimination diet 	<ul style="list-style-type: none"> • IgE-mediated cow milk allergy • Gastroesophageal Reflux Disease (GERD) • Delayed gastric emptying • Poor weight gain • Inadequate oral intake to meet nutritional needs, thus requiring tube feedings • Food Protein-Induced Enterocolitis Syndrome (FPIES) • Behavioral feeding difficulties

The opinions expressed are those of the author of this case study and not necessarily reflective of the views of Nutricia North America. Formula choices were made independently prior to the author’s development of this patient case report.

CASE 2: Eosinophilic Esophagitis (EoE), Multiple Food Allergies and Feeding Difficulties: Improving Nutritional Intake with Neocate® Splash

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Patient History:

This case focuses on a 9 yo male who was diagnosed with EoE at 4 years of age. Like many young children with EoE, he was an extremely picky eater as a toddler. His food refusal and feeding aversion ultimately resulted in a diet consisting primarily of chocolate milk and oyster crackers. His parents sought help from a feeding therapist when he was 3 ½ years old. The feeding therapist felt that his history was more complex than just a picky eater, and suspected an underlying medical etiology.

Similar to many patients with EoE, this boy had IgE-mediated egg and peanut allergies diagnosed by an allergist at 13 months of age.

Despite continued feeding issues and food allergies, his linear growth remained on track, but his weight gain was disproportionately low, thus his body mass index (BMI) z-score fell below -1.0 for his age.

Nutrition/Medical Management:

At the recommendation of the feeding therapist, the pediatrician referred this patient to a pediatric gastroenterologist. He underwent an endoscopy with biopsies after 8 weeks on a high-dose proton pump inhibitor. Histologically, his esophageal biopsies revealed 45 eosinophils per high-powered field and clinically he was experiencing symptoms of esophageal dysfunction, which were likely a contributor to his feeding issues. Having met current consensus criteria

for an EoE diagnosis, the management options for this patient included swallowed, topical corticosteroids or the empiric six food elimination diet (SFED), which involves the exclusion of milk, egg, wheat, soy, peanuts and tree nuts, fish and shellfish.

Because of his ongoing feeding issues and a very limited diet consisting exclusively of milk and wheat-based products, the family initially chose medical management using swallowed topical steroids. Unfortunately, the twice daily topical steroid regimen was not a feasible because he refused to take the medicine, thus he embarked on the SFED. The family received instruction on the SFED from a registered dietitian who took into account the few foods he was willing to eat as well as those that had to be avoided.

This posed significant nutritional challenges. Not only does implementing the SFED involve excluding his preferred foods, his intake was also constrained by his limited repertoire of accepted food textures. These only included crunchy, starchy foods like cereal, chips, pretzels and crispy french fries. He has had a longstanding aversion to more difficult textures like meats that require considerable chewing. He also exhibited early satiety and had adopted a grazing feeding pattern typical of many children with feeding issues.

Owing to the poor nutritional quality of his diet, which was deficient in calories, fat, protein, calcium, and vitamins A and D, the dietitian recommended supplementation with two 8 fl oz servings of Neocate® Junior, Tropical powder daily in order to fill the nutritional gaps in his diet. This provided 30% of his estimated daily calorie needs and 90% of his estimated protein requirement, which was particularly important considering his high carbohydrate and low protein-based diet. He experienced adequate weight gain while adhering to the SFED, averaging the recommended 8 grams of weight gain per day for his age.

After 3 months on the SFED, he returned to the gastroenterologist for a follow-up endoscopy. Esophageal biopsies showed complete histologic and symptom resolution of EoE while on the SFED. He “passed” the SFED.

He started food trials right away, but unfortunately failed due to recurrent symptoms, first with soy that caused abdominal pain and vomiting, then with cow's

milk that caused abdominal pain and food refusal. As a result, the family decided to postpone food reintroductions and focus on feeding therapy. He made great progress since the initiation of feeding therapy, and became a feeding therapy graduate by age 7. He was able to discontinue taking Neocate Junior, Tropical as a supplement and was receiving 100% of his nutritional needs from foods.

Over time, the family encountered some pitfalls related to having their son on the SFED. Elimination diets typically require intense planning, label reading, meal preparation, and additional shopping at specialty grocery stores and online purchasing to acquire SFED friendly food alternatives, allergen-free snacks and baking mixes. While home cooked meals can be modified into a SFED, they are not always portable. For patients and families who find themselves constantly on the go, take-out meals and dining out while adhering to the SFED may reduce the feasibility of adhering to the diet.

When this patient turned 9 years old and became more active in school and social activities, it became difficult for him to meet his daily nutritional needs from food alone. Therefore, the dietitian recommended reintroducing an amino acid-based formula to supplement his diet. The family chose nutritionally complete, ready-to-drink Neocate Splash for convenience and portability. After trialing the different flavors he selected Neocate Splash, Tropical Fruit as his favorite flavor. He required two 8 fl oz ready-to-drink boxes per day that provided 20% of his daily calorie needs and 40% of daily protein requirements. Neocate Splash supplementation allowed him to achieve 100% of his daily nutritional needs when combined with his SFED food intake. After one month on supplemental Neocate Splash, his weight improved, averaging the recommended 6 grams of weight gain per day.

Age (years)	Milestone	Weight kg (%ile)	Weight z-score	Height cm (%ile)	Height z-score	BMI kg/m ² (%ile)	BMI z-score
4	EoE diagnosis	13.8 (7)	-1.51	100 (28)	-0.59	13.8 (3)	-1.93
4.5	After successful 3-month initiation of the SFED supplemented with Neocate Junior	15.0 (10)	-1.27	104 (34)	-0.42	14.0 (5)	-1.62
7	Feeding therapy graduate	20.2 (16)	-1.01	119 (29)	-0.56	14.3 (15)	-1.05
9	Currently adhering to the SFED supplemented with Neocate Splash	27.9 (43)	-0.17	132 (39)	-0.28	16.1 (46)	-0.09

✓ Conclusion:

This case illustrates the nutritional challenges associated with dietary elimination therapy in an active school aged child diagnosed with multiple food allergies, EoE and feeding issues. This case also demonstrates how amino acid-based formulas like Neocate Splash serve as a useful, portable tool that can fill nutritional gaps and can ease families' concerns about the growth of their child while following an allergy-restricted diet.

How Neocate Splash was used:	Overview of symptoms & conditions:
<ul style="list-style-type: none"> • Oral supplement to an elimination diet 	<ul style="list-style-type: none"> • Eosinophilic Esophagitis (EoE) • Growth failure or Faltering growth • Multiple food allergies • Gastrointestinal symptoms • Feeding issues

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CASE 3: Quality of Life and Dietary Management of Eosinophilic Esophagitis with Neocate® Splash

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Medical Center



Background:

Children with eosinophilic esophagitis (EoE) often follow challenging elimination diets that involve avoidance of multiple foods¹¹. These dietary restrictions negatively impact participation in family meal times, school activities, and social functions, thus affecting one's quality of life (QoL). Children and adolescents with EoE have lower health-related QoL and poorer psychosocial functioning compared to healthy children and children with other chronic illnesses^{12,13}. Additionally, mothers of children with EoE report higher levels of parenting stress than mothers of healthy children¹².

Patient History:

This 15-year old male was diagnosed with EoE at age 9 and his presenting symptoms included failure-to-thrive, vomiting, and abdominal pain. His body mass index (BMI) at diagnosis was <5th percentile for age.

This teen, his family and health care providers agreed to initially trial a dietary antigen elimination approach for EoE. Under the direction of a registered dietitian, he implemented the empiric six food elimination diet (SFED) restricting all cow's milk, soy, egg, wheat, peanut/tree nut, and fish/shellfish. His follow-up endoscopy with biopsies showed persistent eosinophilic-related inflammation. Unfortunately, repeat endoscopy revealed persistent

EoE. Swallowed topical steroids were prescribed in combination with a dietary antigen elimination approach. Regardless, the combined pharmacologic and dietary approach failed to resolve this teen's symptoms and eosinophilic inflammation.

Medical/Nutritional Management:

At age 13, this teen, his family and health care providers agreed that an elemental diet was the best management choice for his persistent EoE. He was given an opportunity to orally consume his elemental diet, but was unable to routinely consume the volume necessary to promote growth and weight gain. A gastrostomy tube (G-tube) was placed that allowed the delivery of Neocate® Junior with Prebiotics, Unflavored. The combination of G-tube feedings and ready-to-feed (RTF) Neocate® Splash, Tropical Fruit intake met his complete nutritional needs. Esophageal biopsies taken after an elemental diet trial showed complete histologic resolution of EoE. Both growth and weight gain improved while on an elemental diet. His BMI exceeded the 25th percentile and he reported feeling energized.

After successful histologic EoE resolution with an elemental diet, this teen attempted single, sequential food trials to rebuild his diet. However, progress was slow because of recurring esophageal inflammation and symptoms with reintroduction of particular foods. Over time, this teen successfully tolerated apple, rice, pork, and carrot without recurrence of eosinophilic inflammation.

As a teen, this patient's life became hectic with increased school demands and extracurricular activities. As a result, both he and his mother expressed their escalating stress that was directly associated with administering his tube feedings (finding time to mix formula for his bolus feeds), especially before his after-school sports practices and events.

To simplify this teen's tube feeding regimen, the registered dietitian recommended nutritionally complete, RTF Neocate® Splash, Unflavored as an alternative for powdered Neocate Junior with Prebiotics, Unflavored. He used one RTF drink box for each of his gravity boluses, and two RTF drink

Diet Recall and G-tube Feeding Regimen:

8 AM:	1 medium apple, 1 cup puffed rice + 8 fl oz unflavored rice milk
10 AM:	240 mL gravity G-tube bolus: Neocate Splash, Unflavored
12 PM:	1 slice home-cooked ham + ¼ cup carrot sticks, 1 ounce plain potato chips + 1 8 fl oz Neocate Splash, Tropical Fruit
3 PM:	1 serving rice crackers, 8 fl oz apple juice
4 PM:	240 mL gravity G-tube bolus: Neocate Splash, Unflavored
6 PM:	3 slices bacon, 1 cup oven fries with 1 tsp refined oil, ½ cup applesauce, 1 8 fl oz Neocate Splash, Tropical Fruit
10 PM to 6 AM	Continuous feeds of Neocate Splash, Unflavored: 50 mL/hr

boxes for his overnight feeds. The switch from powder to liquid RTF formula with easy-to-decant packaging made feeding administration much easier for his mother and even allowed this teen to dispense his own G-tube bolus feeds, thus increasing self-efficacy and confidence in managing his own care. Use of the RTF amino acid-based formula,

Neocate Splash, alleviated the burden of having to mix and refrigerate formula; eliminated safety concerns, and the need to locate water and find a clean and suitable location to prepare formula while on-the-go.

✓ Conclusion:

Children and adolescents with chronic illnesses such as EoE often report lower QoL compared to healthy children. This teen's case is no exception and it highlights the importance of simplifying complex medical regimens. Using ready-to-feed Neocate Splash, Unflavored streamlined this teen's G-tube feeding regimen, allowing him to self-administer his tube feedings and gain autonomy in his own care. Use of RTF Neocate Splash taken orally and tube-fed also reduced caregiver burden and allowed the family to venture from home safely and more frequently despite needing to adhere to his daytime bolus feeding schedule.

How Neocate Splash was used:	Overview of symptoms & conditions:
<ul style="list-style-type: none"> • Oral supplement to an elimination diet • G-tube bolus feedings 	<ul style="list-style-type: none"> • Eosinophilic Esophagitis (EoE) • Stress due to managing diet restrictions that affected the patient and his family's quality of life • Multiple food allergies • Growth failure • GI symptoms

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CASE 4: Tube Feeding a Nine Year Old Boy with Eosinophilic Esophagitis

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Pediatric Dietitian

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North Carolina



Patient History:

A nine-year-old boy with a history of asthma and allergic rhinitis was diagnosed with eosinophilic esophagitis (EoE) at age 5 based on his clinical history and results of an endoscopy with biopsies. Biopsies were obtained while patient was on high dose proton pump inhibitor (PPI) therapy, ruling out PPI-responsive esophageal eosinophilia (PPI-REE). Symptoms prior to the management of his EoE included abdominal pain, gastroesophageal reflux disease (GERD), dysphagia, cough, chronic diarrhea (thought to be toddler’s diarrhea) and nausea. Atopy patch testing was conducted and results were used together with the history of symptoms to develop a tailored elimination diet.

Nutritional Management:

The patient and his parent were counseled on a tailored elimination diet by a registered dietitian. After following this tailored elimination diet, the patient did not show improvement in his esophageal histology, eosinophil count or symptoms. Based on clinical evidence and patient history, additional foods were removed from his diet, including all of the top eight food allergens. Concurrent therapy of topical swallowed steroids with an elimination diet was initiated in the hopes of achieving histologic and symptom resolution, specifically his extreme abdominal pain. After six weeks of combined dietary elimination and swallowed topical steroid therapy, symptoms still had not improved.

Due to persistent eosinophilic inflammation despite combined diet and steroid therapy, an elemental diet taken orally was initiated using flavored powdered amino acid-based formula. Caloric needs were assessed and 56 ounces of formula (at 30 kcal per fluid ounce) were required to meet the patient’s daily recommended nutrient intakes. After several weeks, consumption of the required daily volume became too difficult to consume orally, therefore a nasogastric (NG) tube was placed. The insertion of a feeding tube was also deemed necessary due to his lack of weight gain.

The challenge of meeting formula volume goals by mouth was decreased after NG tube placement. After eight weeks of NG tube feedings, a gastrostomy G-tube was placed as a more permanent solution. Consultation prior to the G-tube placement was provided to the patient and his family by a registered dietitian. Arrangements were made with a durable medical equipment company to obtain supplies and arrange feeding pump training. While the daily formula volume goal was achieved, other obstacles the patient faced included:

- Difficulty finding container with a pourable spout to hold pre-mixed formula for school personnel to administer
- Clumping and clogging of the formula causing feeding pump errors that were not able to be resolved by the nurse
- Potential for mixing errors
- Warming the cold refrigerated formula to room temperature before placing in the feeding bag in the hopes of minimizing stomach cramping

In an effort to overcome feeding-related obstacles at home and school, the patient was offered Neocate Splash, Unflavored, a ready-to-feed, nutritionally complete formula that did not require warming to room temperature.

Since the 12 week initiation of the elemental diet and continued high-dose proton pump inhibitor therapy, symptoms have been eliminated, and tissue integrity improved. However, mild eosinophilic inflammation persisted, perhaps due in part to the failure to manage environmental allergens during this diet trial.



Conclusion:

The introduction of Neocate Splash, Unflavored, an amino acid-based ready-to-feed, nutritionally complete formula has improved this family’s quality of life and gave the patient greater independence. Formula preparation and administration issues were remedied, and the patient was now able to administer his own feeds. This allowed the patient to spend more time in the classroom instead of in the nurses’ office. When planning for time outside of the home, carrying the supplies necessary for his G-tube feedings were minimal and required little planning.

How Neocate Splash was used:	Overview of symptoms & conditions:
<ul style="list-style-type: none"> • Sole source of nutrition administered via a G-tube that was necessary to successfully adhere to an elemental diet 	<ul style="list-style-type: none"> • Eosinophilic Esophagitis (EoE) • Gastroesophageal Reflux Disease (GERD) and other gastrointestinal symptoms • Growth impairment due to difficulties meeting nutritional needs through oral intake

The opinions expressed are those of the author of this case study and not necessarily reflective of the views of Nutricia North America. Formula choices were made independently prior to the author’s development of this patient case report.

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Landon, Age: 9
Diagnosed with FPIES



NUTRICIA
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Ashton, Age: 9
Diagnosed with EoE

Neocate® Splash Case Study Booklet

For 30 years and counting, Neocate has delivered evidence-based, hypoallergenic nutritional solutions to meet the many different nutritional needs of infants and children globally.

Our commitment remains unyielding with a “best-in-class” portfolio driven by science, guided by research, and dedicated to children worldwide.

Neocate Splash is the latest addition to our portfolio. The 4 flavors of Neocate Splash are the first and only nutritionally complete, ready-to-feed hypoallergenic formula for the dietary management of cow milk allergy, multiple food allergies and other related gastrointestinal and allergic conditions, including food protein-induced enterocolitis syndrome (FPIES) and Eosinophilic Esophagitis (EoE) when an amino acid-based formula is recommended.

This case study booklet contains case studies written by healthcare professionals that illustrate their use of Neocate Splash in various clinical settings.

