

# DiaResQ™

## PRODUCT INFORMATION

### FOOD FOR SPECIAL DIETARY USE

DiaResQ® is a Food for Special Dietary Use that contains immune factors, micronutrients, and macronutrients that work with the body to address the underlying cause of diarrhea.

### DESCRIPTION

Each DiaResQ packet (7g net weight) contains a light-colored powder consisting of bovine (cow) colostrum, egg solids, silicon dioxide, vanilla flavor, and sucralose. DiaResQ is suitable for vegetarians. It is gluten-free, soy-free, and dye-free.

### DIRECTIONS FOR USE

Take at the first sign of diarrhea. Fill enclosed cup with water to the 30ml line. Add powder from one packet. Secure lid and shake until the contents are fully dispersed. Immediately drink the entire contents of the cup. Take additional packets as needed, up to three packets per day.

### FOOD ALLERGY PRECAUTION

DiaResQ contains ingredients derived from milk and eggs, therefore patients who have an allergy to milk, eggs, or any component of DiaResQ should not take this product.

### DRUG AND FOOD INTERACTIONS

No drug interactions with DiaResQ have been reported.

### SAFETY OF INGREDIENTS

The safety of bovine colostrum has been extensively reviewed.<sup>1,2</sup> All other ingredients in DiaResQ are approved food additives or generally recognized as safe (GRAS), which is a statutory safety standard defined by the FDA.

| <b>Nutrition Facts</b>   |                      |            |
|--|----------------------|------------|
| Serving Size 1 packet (7g)   |                      |            |
| Servings per Container 3   |                      |            |
| Amount Per Serving   |                      |            |
| <b>Calories</b> 35   | Calories from Fat 15 |            |
| % DV Children 4 Years of Age & Older*  |                      |            |
| <b>Total Fat</b> 2g  |                      | <b>2%</b>  |
| Saturated Fat 1g   |                      | <b>5%</b>  |
| Trans Fat 0g   |                      |            |
| <b>Cholesterol</b> 60mg  |                      | <b>19%</b> |
| <b>Sodium</b> 30mg   |                      | <b>1%</b>  |
| <b>Total Carbohydrate</b> 1g   |                      | <b>0%</b>  |
| Dietary Fiber less than 1g   |                      | <b>1%</b>  |
| Sugars less than 1g  |                      |            |
| <b>Protein</b> 3g  |                      | <b>7%</b>  |
| % DV Children Under 4  |                      |            |
| <b>Protein</b>   | 26%                  | 7%         |
| <b>Vitamin A</b>   | 4%                   | 2%         |
| <b>Vitamin C</b>   | 0%                   | 0%         |
| <b>Calcium</b>   | 6%                   | 4%         |
| <b>Iron</b>  | 2%                   | 2%         |
| *Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: |                      |            |
| Calories:  | 2,000                | 2,500      |
| Total Fat  | <65g                 | <80g       |
| Saturated Fat  | <20g                 | <25g       |
| Cholesterol  | <300mg               | <300mg     |
| Sodium   | <2,400mg             | <2,400mg   |
| Total Carbohydrate   | 300g                 | 375g       |
| Dietary Fiber  | 25g                  | 30g        |
| Protein  | 50g                  | 65g        |

| <b>Bovine Colostrum</b>   | <b>Egg Solids</b>  | <b>Inactive Ingredients</b>  |
|---|--|--|
| The first milk produced by dairy cows, colostrum is rich in nutrients, immune factors, and protective proteins. | Provides a source of high-quality bioavailable protein and immune factors. | <b>Silicon dioxide:</b> Anti-caking agent<br><b>Vanilla flavoring:</b> Flavoring<br><b>Sucralose:</b> Artificial sweetener |

## SAFETY OF DIARESQ IN CHILDREN

DiaResQ is safe for children 1yr+. The safety of DiaResQ has been evaluated in over 590 children in three clinical trials. No serious adverse events attributable to the product have been reported.

### Safety of DiaResQ in pediatric clinical trials

| Year | Study Size | Number of Serious Adverse Events Attributed to DiaResQ |
|------|------------|--|
| 2015 | 140        | 0  |
| 2017 | 325        | 0  |
| 2017 | 125        | 0  |

## SAFETY OF DIARESQ IN ADULTS

The safety of DiaResQ has been evaluated in 72 adults. No serious adverse events attributable to the product have been reported.

### Safety of DiaResQ in adult clinical trials

| Year | Study Size | Number of Serious Adverse Events Attributed to DiaResQ |
|------|------------|--|
| 2018 | 72         | 0  |

## EFFICACY

DiaResQ has been investigated in clinical trials conducted in some of the most challenging environments for addressing diarrhea.

### Study 1

| Study Site | Participants | Description   |
|------------|--------------|---|
| Guatemala  | 325 children | Study 1 was a randomized, double-blind, placebo-controlled trial that enrolled 325 children with acute non-bloody diarrhea. Study groups were computer randomized to receive three daily doses of DiaResQ or placebo. |

### Study 2

| Study Site   | Participants | Description  |
|--------------|--------------|--|
| Phillippines | 128 children | Study 2 was a randomized trial that enrolled 128 children with acute watery non-bloody diarrhea. Half (n=64) were systematically assigned to the control group who received standard therapy, and the other half to the treatment group who received a daily dose of DiaResQ for three consecutive days. |

## FREQUENTLY ASKED QUESTIONS FROM PATIENTS

### *Once mixed, do I need to drink DiaResQ right away?*

Yes, it's recommended to consume the product immediately after mixing.

### *What does it taste like? Will my child take it?*

DiaResQ is vanilla flavored and formulated to be palatable to young children and adults.

### *What is bovine colostrum?*

Bovine colostrum is the first milk from dairy cows. It is rich in nutrients, immune factors, and protective proteins that work with the body to address the underlying cause of diarrhea.

### *Can DiaResQ be consumed with ORS (Oral Rehydration Solutions)?*

Yes, DiaResQ can be consumed in addition to ORS (Oral Rehydration Solution). ORS addresses dehydration which may accompany diarrhea.

### *When should I contact my doctor?*

If there is no improvement after 24 hours, a doctor should be consulted. Medical care should be sought immediately if any of the following warning signs are present:

- Temperature over 101° F
- Signs of dehydration (such as thirst, dark urine, less frequent urination, listlessness, or irritability)
- Blood in the stool

### *Is DiaResQ safe for children?*

Yes, it is safe for ages one and up.

### *Is DiaResQ gluten-free?*

Yes, DiaResQ is gluten-free.

### *What is a food for special dietary use?*

A food for special dietary use supplies particular dietary needs due to disease, physical or physiological condition, age, or weight. DiaResQ is a food for special dietary use that provides beneficial nutrients for those with diarrhea.

## HOW SUPPLIED/STORAGE AND HANDLING

| Product* #    | Description        | Size              |
|---------------|--------------------|-------------------|
| 52870-0004-63 | Children's DiaResQ | 3 packets per box |
| 52870-0004-64 | Adult DiaResQ      | 3 packets per box |

\*PanTheryx, Inc. does not represent this product code to be a National Drug Code (NDC) number. The assigned product code is formatted according to standard industry practice to meet the formatting requirements of pharmacy and health insurance computer systems.

Store packets in a cool dry place. DiaResQ is shelf stable for 30 months.

**References:** 1. Struff WG and Sprotte G. Int J Clin Pharmacol Ther. 2007;45:193-202. 2. Struff WG and Sprotte G. Int J Clin Pharmacol Ther. 2008;5:211-225.

For more information, visit  
www.DiaResQ.com or call  
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