



## **CeraLyte: Frequently Asked Questions (FAQ) and Approved Answers**

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*CeraLyte® is classified in the United States as a “MEDICAL FOOD”, in a classification that is considered generally safe, but should be used under medical supervision. If diarrhea is severe or prolonged, or if there is any swelling of hands or feet, a physician should be consulted immediately for advice. Cera Products provides the information as educational only and does not treat patients.*

### **Legal / Medical Disclaimer**

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### **Storage and Stability**

#### **Question #1**

**How long can a reconstituted product be stored and under what conditions should it be stored?**

Keywords: storage, stability, reconstituted

#### Answer

CeraLyte should be used within several hours if stored at room temperature and can be stored up to 24 hours after reconstituting (dissolving) the powder if it is stored in a clean sealed container in the refrigerator. Any remaining quantities should be discarded. The product can become contaminated from bacteria or mold in the air or water and become unsuitable to drink if the allowed to stand for longer periods.

Reconstituted product can be stored frozen for up to a week.



## **Storage and Stability**

### **Question #2**

**Is CeraLyte still good if it is left out of the refrigerator for a few hours?**

Keywords: storage, stability

### **Answer**

Although the ingredients in CeraLyte are chemically stable, leaving it at room temperature after reconstitution could make it more susceptible to increased microbial contamination and growth much like milk. CeraLyte should be used within several hours if stored at room temperature.

## **Storage and Stability**

### **Question #3**

**How long can you keep an opened packet of CeraLyte? How long can you safely keep an opened liquid of ready-to-drink CeraLyte?**

Keywords: storage, stability, packet, liquid, ready-to-drink

### **Answer**

**Packet:** The ingredients in an opened packet of CeraLyte (but not yet mixed with water) are chemically stable. The remaining powder can be stored up to a week in the refrigerator if the packet is folded over and then stored in a sealed plastic bag. Opened packets should not be used beyond a day if they are left in an unsealed container at room temperature.

**Ready-to-drink:** CeraLyte ready to drink is packaged in easy to use single use containers. Opened containers should be consumed within several hours of opening. This will ensure product quality and minimize the chance for potential microbial contamination after opening the containers, much in the same way as milk or milk products are treated.



## **Dosage and Administration**

### **Question #4**

**When do you use the CeraLyte-50 versus the CeraLyte-70?**

Keywords: CeraLyte-50, CeraLyte-70, use

### **Answer**

Your physician or pharmacist can assist in deciding whether CeraLyte-50 or 70 is more appropriate for you. However, in general, CeraLyte-50 is appropriate to prevent or treat mild dehydration when diarrhea or vomiting is mild to moderate in nature. CeraLyte-70 contains a higher level of sodium and is appropriate for moderate to significant dehydration and can be given where more significant levels of electrolytes have been lost.

Medical treatment should be sought right away if any of the following warning signs are present:

- \* Severe diarrhea, possibly including vomiting
- \* Dehydration symptoms, including
  - \* sunken eyes or, for infants, sunken fontanel ("soft spot" at the top of the head)
  - \* Excessive thirst or dry mouth
  - \* Decreased urine or no urine
  - \* Very ill appearance, listless or fainting
- \* High temperature (over 103°F)
- \* Blood in the stool; severe abdominal cramps

## **Dosage and Administration**

### **Question #5**

**What is the minimum age for use of CeraLyte?**

Keywords: use, pediatric, child, elderly, chronic diarrhea

### **Answer**

CeraLyte can be used for any age, including infants. Young children, the elderly and those with chronic conditions are most at risk. Dehydration can occur quickly in young children and should be monitored closely.

Start giving CeraLyte right away by giving the child small sips of CeraLyte, and follow-up with



the pediatrician if the diarrhea persists, especially in children under 3 months of age.

It is usually easier for the child to begin by sipping and then continue taking small quantities (such as a sip from a spoon) more frequently than larger quantities all at once. This will help avert vomiting the solution.

### **Dosage and Administration**

#### **Question #6**

**How much CeraLyte should be given to a child? Is pediatric dosing based on age and/or weight? How long can pediatric dosing be continued?**

Keywords: use, age

#### **Answer**

Give CeraLyte with the goal of replacing lost fluids. A quick rule of thumb is to give young children 2 to 4 oz after every loose stool. Greater amounts may be needed if large amounts of fluid are lost with the diarrhea or if vomiting is involved. A general rule is to continue taking CeraLyte until the urine is a pale yellow with good flow every two to four hours.

If the child is vomiting it may be better to initially give CeraLyte in small quantities (tablespoonfuls or sipping) and increasing the amounts when possible. The idea is "if you lose a cup, drink a cup."

Oral fluids should not be withheld from anyone who is thirsty (unless medically necessary) since this is a typical sign that the patient is not adequately hydrated. Patients who are severely dehydrated may not be able to drink or they may drink poorly.

Encourage continued eating of regular food and water. Eating helps speed recovery. Small amounts may be more easily tolerated. For infants, breastfeed or give formula, as usual.

The duration of CeraLyte use depends upon the type of illness. Some patients (including pediatric patients) suffering from chronic ailments, and under the supervision of their physician, will rely on CeraLyte throughout their lives.



## **Dosage and Administration**

### **Question #7**

**How much per day should be given to an adult? What is the normal length of use?**

Keywords: use, adult

### **Answer**

The goal is to replace the amount of fluid lost (if you lose a cup drink a cup). An average person 10 years of age or older with diarrhea should slowly drink the contents of one ready to drink package (11 ounces) or the contents of one 10 gram packet dissolved in about 7 ounces of water after every loose stool. Greater amounts may be needed if large amounts of fluid are lost with the diarrhea or if vomiting is involved. A general rule is to continue taking CeraLyte until the urine is a pale yellow with good flow every two to four hours. An initial starting dose of approximately one liter over one to two hours is often an adequate starting point.

Oral fluids should not be withheld from anyone who is thirsty (unless medically necessary) since this is a typical sign that the patient is not adequately hydrated. Patients who are severely dehydrated may have difficulty drinking.

The duration of CeraLyte use depends upon the type of illness. Some patients (including pediatric patients) suffering from chronic ailments, and under the supervision of their physician, will rely on CeraLyte throughout their lives.

## **Dosage and Administration**

### **Question #8**

**What should be done if diarrhea continues?**

Keywords:

### **Answer**

If the patient's diarrhea continues for more than one or two days or gets worse they should seek medical attention.

Medical treatment should be sought right away if any of the following warning signs are present:



- \* Severe diarrhea, possibly including vomiting
- \* Dehydration symptoms, including
  - \* sunken eyes or, for infants, sunken fontanel ("soft spot" at the top of the head)
  - \* loss of skin turgor, rapid pulse with low blood pressure, cold clammy extremities
  - \* excessive thirst or dry mouth
  - \* decreased urine or no urine or dark urine (it should be pale in color)
  - \* very ill appearance, listless or fainting
- \* High temperature (over 103°F)
- \* Blood in the stool; severe abdominal cramps

### **Dosage and Administration**

#### **Question #9**

**Can CeraLyte be administered through an NG tube?**

Keywords: administration, NG, naso-gastric tube

#### **Answer**

CeraLyte can be given via an NG tube or gastrostomy ("G" tube) but should be done so only under close medical supervision. The amount to be given should match the amount lost by diarrhea. The best way to judge adequate dose is good urine flow (50-100 ml/hour) with pale colored urine. Initially, in moderate dehydration, the dosage should be 20 ml/kg/hour for 2 - 3 hours to match losses. Check for residual fluid in the stomach if patient becomes distended or vomits. Slow the rate of infusion if residuals are more than 50 ml until the residuals diminish.

### **Dosage and Administration**

#### **Question #10**

**What recommendations do you have for accidental ingestions/exposures?**

Keywords: overdose

#### **Answer**

It is nearly impossible to overdose on CeraLyte. Children or adults with normal cardiovascular systems and kidneys will dispose of any excess with no side effects except increased urine output and some edema (swelling) if an large amount is taken (2 - 4 liters) within a short period of time,



such as one to two hours. If someone has heart failure or kidney failure then they should consult their physician who may prescribe a diuretic and measure blood potassium levels.

For persons who must restrict their intake of sodium, there is a chance that they may absorb too much salt if they drink large amounts of CeraLyte. The symptoms of too much sodium being absorbed would typically include swelling of feet, eyelids and face.

### **Dosage and Administration**

#### **Question #11**

**Can CeraLyte be administered to pregnant women?**

Keywords: pregnancy, pregnant women

#### **Answer**

CeraLyte is classified as a medical food by the Food and Drug Administration and is labeled for use under medical supervision. Clinicians considering recommending CeraLyte for pregnant women should do so after careful evaluation of the ingredients of CeraLyte.

### **Instructions for Use & Mixing**

#### **Question #12**

**What liquids can the powder be mixed with? Can CeraLyte be mixed with something other than water? Do not like flavor. What other flavors does it come in?**

Keywords: reconstitute, mix, water, flavor

#### **Answer**

It is best to dissolve the CeraLyte powder in water. Other fluids that are low in sodium (unsalted soup, herbal teas, and diet powder drinks such as Crystal Light) can also be used. Diet soft drinks without caffeine such as diet ginger ale or diet lemon lime sodas can also be used but CeraLyte should be added and mixed slowly due to excessive “fizzing”. Liquids such as sugar sweetened soft drinks, coffee, fruit drinks and sugar or honey sweetened tea should NOT be used. Some of these liquids can cause increased fluid loss or osmotic diarrhea. \_

CeraLyte is available in lemon, mixed berry and natural flavors.



## **Availability & Purchase**

### **Question #13**

**Is CeraLyte available in Canada or other countries?**

Keywords: Canada, international, countries

#### **Answer**

Yes. For international sales information, contact Cera Products at 410-309-1000.

## **Availability & Purchase**

### **Question #14**

**Where can I purchase this? My pharmacy does not carry it. Can I order it directly?**

Keywords: purchase, pharmacy

#### **Answer**

*Physician Response: You can purchase directly from Cera Products at 410-309-1000 (1-888-237-2598) or from Cumberland Pharmaceuticals at its Corporate offices at (615) 255-0068.) and one of these companies can assist you, or other distributors listed on the Cera Products website ([www.ceraproductsinc.com](http://www.ceraproductsinc.com)) under the “CeraStore.”*

*Pharmacist Response: Call your wholesaler or contact Cera Products at 410-309-1000 for wholesaler information.*

*Wholesaler Response: Call Cera Products at 410-309-1000 .*

*Consumer Response: You can use your VISA or MASTERCARD to purchase CeraLyte directly from Cera Products (1-888-237-2598) or 410-309-1000 or on its website at [www.ceraproductsinc.com](http://www.ceraproductsinc.com) or call to find a pharmacy near you. Any pharmacy in the USA CAN buy CeraLyte, either direct from Cera Products or from one of our distributors or wholesale companies.*



## **Availability & Purchase**

### **Question #15**

**How do I get in touch with a sales representative for CeraLyte?**

Keywords:

#### Answer

Please contact Cera Products at 410-309-1000 or [sales@ceraproducts.us](mailto:sales@ceraproducts.us) or see the website at [www.ceraproductsinc.com](http://www.ceraproductsinc.com)

You can also call Cumberland Pharmaceuticals corporate offices at 615-255-0068.

## **Components & Ingredients**

### **Question #16**

**Does it contain sugar, lactose, salicylate, or gluten?**

Keywords: lactose, gluten, salicylate, sugar

#### Answer

CeraLyte has been specially formulated and contains NO lactose, gluten or salicylate. Only CeraLyte Lemon ready-to-drink contains added sucrose (9 grams per 11 ounce serving) as a natural sweetener. All CeraLyte products contain a mix of carbohydrates from the rice syrup solids.

## **Components & Ingredients**

### **Question #17**

**What is the source for the flavorings and dyes? Are the flavorings natural or artificial?**

Keywords: flavoring, flavor, dye, natural, artificial

#### Answer

CeraLyte comes in natural, lemon, and mixed berry flavors. The natural contains no flavors or colors. The lemon ready to drink contains natural and artificial flavors and no added colors while the mixed berry and lemon powders contain natural and artificial flavors and colors.



## **Other**

### **Question #18**

**What is CeraLyte 90? When is it appropriate to use CeraLyte 90? How can I order/buy CeraLyte 90?**

Keywords: CeraLyte 90

#### **Answer**

CeraLyte 90 is similar to CeraLyte 50 and 70 but contains the highest level of sodium, 90 milliequivalents per liter. CeraLyte-90 is for heavy purging, such as in short gut or other patients with significantly reduced absorption capacity.

CeraLyte 90 can be used where the greatest levels of sodium are lost.

You can use your VISA or MASTERCARD to purchase CeraLyte-90 directly from Cera Products at 410-309-1000 or 1-888-237-2598.

## **Other**

### **Question #19**

**Should CeraLyte be given if the patient is vomiting?**

Dehydration occurs more rapidly if the patient has diarrhea and vomiting. Treatment with CeraLyte should be initiated or continued unless other medical complications exist that would preclude oral treatment. Sipping small quantities frequently will allow more CeraLyte to be ingested and retained whereas ingesting larger volumes of fluids including CeraLyte could increase bouts of vomiting.

Oral fluids should be avoided if the patient is unconscious or nearing unconsciousness and the patient should seek immediate medical attention.

## **Other**

### **Question #20**

**Are there any contraindications for CeraLyte?**

**Contraindications:**



May include certain kidney and heart conditions, where excretion of water and electrolytes such as sodium and potassium is impaired.

If the patient develops swelling of eyelids, face, or feet, stop CeraLyte for a few hours, call your physician or medical center and inform them.