

PRESCRIBING INFORMATION

GASTROLYTE

(electrolyte and dextrose oral powder)

Diarrhea Therapy

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GASTROLYTE®

(electrolyte and dextrose oral powder)

Diarrhea Therapy

DESCRIPTION

The composition of GASTROLYTE stimulates intestinal water absorption.

Each sachet contains:

Dextrose Monohydrate.....	3.56 g
Disodium Citrate.....	0.53 g
Sodium Chloride.....	0.47 g
Potassium Chloride.....	0.30 g

One litre made up of 5 sachets x 200 mL contains:

Sodium	60 mmol
Potassium	20 mmol
Chloride	60 mmol
Citrate	10 mmol
Dextrose (Anhydrous)	90 mmol

Non-medicinal ingredients - Fruit: aspartame (as sweetening agent), silicon dioxide, grapefruit flavour, pineapple flavour.

Non-medicinal ingredients - Regular: aspartame (as sweetening agent), silicon dioxide.

INDICATIONS

Gastrolyte is a source of electrolytes and glucose to help restore/replace water/fluid and electrolytes lost in cases of (acute/watery) diarrhea and/or vomiting (due to acute gastroenteritis).

Gastrolyte is indicated for the:

- prevention of dehydration caused by (acute/watery) diarrhoea and/or vomiting (due to acute gastroenteritis)
- maintenance of hydration status/electrolytes and fluid balance in cases of (acute/watery)

diarrhea and/or vomiting (due to acute gastroenteritis)

RISK INFORMATION

CONTRAINDICATIONS

Hypersensitivity to active substances or to any of the ingredients.

PRECAUTIONS

For oral administration only. GASTROLYTE should not be reconstituted in diluents other than water. Each sachet should always be dissolved in 200 mL of water. A weaker solution than recommended will not contain the optimum dextrose and electrolyte concentration while a stronger solution than recommended may give rise to electrolyte imbalance.

With intractable vomiting, adynamic ileus (inhibition of bowel motility), intestinal obstruction of perforated bowel, nothing should be administered orally.

If the diarrhea does not improve promptly, the patients should be reassessed. If nausea and vomiting are present with the diarrhea, small but frequent amounts should be drunk at first.

WARNINGS

Medical supervision is recommended if you are breast-feeding or pregnant.

Infants should continue to receive breast milk or their usual formula in addition to oral rehydration solution (ORS). Children who are no longer nursing and adults should continue to eat solid food in addition to ORS.

GASTROLYTE shall not be used for treatment in infants below the age of 24 months without medical supervision.

GASTROLYTE should not be used for self-treatment by patients with: chronic or persistent diarrhea, liver or kidney disease, diabetes, on low potassium or sodium diets or patients, intestinal obstruction. Patients with these conditions should be supervised by a physician.

Continue to give/take solution until diarrhea stops.

Consult a health care practitioner if:

- diarrhea/vomiting worsen or persist longer than 24 hours.
- signs of dehydration occur: changes in mental status such as irritability, lack of interest or inactivity, reduced urine output, dry mouth, increased heart and/or breathing rate, decreased tears and/or sunken eyes
- signs of electrolyte imbalance occur such as: disproportionate thirst, muscle weakness, or swelling of the hands, face and/or feet

Seek medical attention if the diarrhea is bloody, is accompanied by a high fever, jaundice (yellow skin), or persistent vomiting, or if dehydration does not improve despite the use of GASTROLYTE.

DOSAGE AND DIRECTIONS FOR USE

1. **Reconstitution:** The contents of each sachet should be dissolved in sufficient drinking water to make 200 mL (approximately 7 fl. oz.). An infant's feeding bottle is a convenient measure of this volume. The solution should be made up immediately prior to feeding and any solution remaining an hour after reconstitution should be discarded. However, the solution may be used for up to 24 hours if stored in a refrigerator immediately after reconstitution. The reconstituted solution must not be boiled.
2. **Dosage:** For oral administration and occasional use only. A basic principle of treatment of diarrhea is to replace fluid loss and then to maintain sufficient fluid intake to replace further loss from stools.

For toddlers, older children and adults, GASTROLYTE solution may be given freely until the thirst is satisfied.

The following dosage and regrading scheme are only a general guide and the volume of the product given and the speed of re-introduction of the normal feeds is at the discretion of the physician.

General Dosage Guide

Age	Amount
Children under 2 years*	50–100 mL (¼ to ½ cup) after each episode of diarrhea
Children 2 to 9 years	100–200 mL (½ to 1 cup) after each episode of diarrhea
Persons 10 years or older	As much as wanted per episode of diarrhea, up to approximately 2 L (8½ cups) a day

* GASTROLYTE shall not be used for treatment in infants below the age of 24 months without medical supervision (see WARNINGS).

In those patients who are vomiting at the start of treatment, it may be advisable to give very small volumes initially until vomiting is under control. Infantile diarrhea is uncommon in breast-fed infants. However, if treatment with this product becomes necessary, it is suggested that for each feeding the chosen regimen be followed and the infant be given the appropriate volume of the solution for that feeding and then breast-fed until satisfied.

OVERDOSAGE

In case of significant overdose, serum electrolytes should be evaluated as soon as possible. Steps should be taken to correct any abnormalities and levels should be monitored until return to normal values. This is particularly important in the very young and in cases of severe hepatic or renal failure.

RECOMMENDED STORAGE

Store between 15°C and 25°C. Keep unused solution in refrigerator for a maximum of 24 hours.

HOW SUPPLIED

Boxes containing 10 foil/laminate sachets.
Available in fruit and regular flavour.

ADDITIONAL INFORMATION

This document can be found at www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-800-265-7927.

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