

DATA SHEET

1 PRODUCT NAME

Gastrolyte Electrolyte Hydration

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sachet, each 5.1g sachet contains: Sodium chloride 470mg, potassium chloride 300mg, sodium acid citrate 530mg, glucose 3.56g.

Tablet, each tablet contains: Sodium chloride 117mg, potassium chloride 186mg, citric acid 384mg, sodium bicarbonate 336mg, glucose 1.62g.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution

Effervescent Tablet

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Oral correction of fluid and electrolyte loss in infants, children and adults. The product has been formulated to treat fluid and electrolyte loss associated with acute dehydration in infantile diarrhoea, but is also appropriate for the treatment of older children and adults.

Gastrolyte Electrolyte Hydration is also indicated for the correction of dehydration due to traveller's gastroenteritis and vigorous and prolonged exercise.

4.2 DOSE AND METHOD OF ADMINISTRATION

For oral administration only.

Reconstitution: The powder contents of one sachet or two effervescent tablets should be made up to 200ml with fresh drinking water. (For infants, the water should be freshly boiled and cooled before mixing with Gastrolyte Electrolyte Hydration). 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.

Dosage: The volume of reconstituted Gastrolyte Electrolyte Hydration needed per day should be determined by the physician, taking into account the weight of the patient and severity of the condition.

Toddlers and older children:

For toddlers and older children, Gastrolyte Electrolyte Hydration may be given freely until their thirst is satisfied or frequently while diarrhoea persists.

Infants:

A number of different regimens are recommended for the treatment of infantile diarrhoea, but the basic principle is to provide enough fluid to rehydrate the infant. Further fluid is then given to allow for ongoing losses until the diarrhoea settles. During the first 12-24 hours of rehydration, milk and solid feeds can be omitted, but these should be rapidly reintroduced to avoid malnutrition. Milk feeds may be half-strength initially, but full-strength feeds should be given within 24 hours. If the diarrhoea persists or is worsened by the milk, then the possibility of a temporary intolerance to lactose should be considered. If confirmed, a low lactose formula can then be offered.

Infantile diarrhoea is uncommon in breast-fed infants. However, if treatment with Gastrolyte Electrolyte Hydration becomes necessary, it is suggested that for each feed the chosen regimen is followed such that the infant is given the appropriate volume of Gastrolyte Electrolyte Hydration for that feed and then put to the breast until satisfied. Expression of residual milk from the breasts may be necessary during this period.

In those patients who are vomiting at the start of treatment, it may be advisable to offer very small volumes initially until vomiting is under control. If the vomiting and diarrhoea show no sign of moderating, the patient should be reassessed.

The dosage and regrading schemes are only a general guide and the volume of Gastrolyte Electrolyte Hydration given and the speed of reintroduction of the normal feeds is at the discretion of the physician.

Mild Cases (no dehydration):

During the first 12-24 hours the infant is offered Gastrolyte Electrolyte Hydration solution in the same quantities as are used for the usual feeds. For the next 12 to 24 hours, the infant can be given half strength feeds of the usual formula mixed with an equal volume of water. Following this, full strength feeds should be recommenced. Ordinary solid feeds should be continued throughout.

Dosage: Volume of fluid required over 6 hours for the prevention of dehydration

Patient's weight (kg)	Volume of Gastrolyte Electrolyte Hydration (mL) in 6 hours
5	150 – 210

10	300 – 420
15	450 – 630
20	600 – 840
30	900 – 1260

For patients over 30kg, fluid replacement should be 5-7mL/kg/hr plus replacement of any additional losses.

More Severe Cases (dehydration):

Prompt medical attention should be sought if dehydration is suspected. Signs of dehydration include documented weight loss, reduced urine output, and diminished skin turgor. A suggested regimen for the treatment of infantile diarrhoea with marked dehydration based on bodyweight in kilograms is given.

Dosage: Volume of fluid required over 6 hours for the treatment of dehydration

Patient's weight (kg)	Volume of Gastrolyte Electrolyte Hydration (mL) in 6 hours
5	200 – 400
10	400 – 800
15	800 – 1000
20	900 – 1500
30	1000 – 2000

After 6 hours, fluid replacement should be 5 – 7 mL/kg/hour plus replacement of any additional losses.

If the condition worsens, or the diarrhoea has not stopped within 6 hours in infants under 6 months, within 12 hours for children under 3 years, 24 hours in children 3-6 years of age or 24-36 hours in children over 6 years of age, or the child has decreased urinary output, the clinician should ensure patients and parents are aware of the risk and early warning signs of dehydration in young children and infants.

If the condition further worsens or fails to improve, IV fluid replacement is required.

Dosage: Treatment of dehydration in older children and adults

	Child	Adult
Approx. number of sachets	1 sachet after each loose motion or 6-12 sachets per 24 hours	1 or 2 sachets after each loose motion or 8-16 sachets per 24 hours

Diet Day1	Limited food if desired
Diet Day 2	Gradually return to normal diet by slowly reducing the amount of Gastrolyte Electrolyte Hydration and increasing the amount of food (Light solids at first, e.g. cereals, toast, etc.)

4.3 CONTRAINDICATIONS

Gastrolyte Electrolyte Hydration should not be used in patients with hypersensitivity to active substances or to any of the excipients.

There may be a number of conditions where treatment with Gastrolyte Electrolyte Hydration will be inappropriate, e.g. intestinal obstruction requiring surgical intervention.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Use water **ONLY** to mix Gastrolyte Electrolyte Hydration powder or effervescent tablets. Never dilute with lemonade, soft drinks, cordials or any other fluid than water.

Gastrolyte Electrolyte Hydration powder is available with either sodium saccharin or aspartame as a sweetening agent. Phenylketonurics are warned that this product, in some forms, contains phenylalanine. Please refer to the packaging for information relating to the sweetening agent used.

For oral administration only. The contents of one sachet or two effervescent tablets should always be made up to 200ml with water (the product must not be reconstituted in diluents other than water, e.g. must not be included in milk solutions). A weaker solution than recommended will fail to provide adequate sugar and electrolytes and a stronger solution than recommended may give rise to hypernatraemia. If nausea and vomiting are present with the diarrhoea, small but frequent amounts should be drunk. Intravenous rehydration is required for dehydrated children with shock, very large stool losses (>10mL/kg/hour), severe vomiting that interferes with oral fluid replacement, or glucose malabsorption. Patients with gastroenteritis should be monitored carefully to ensure that their condition does not deteriorate. In particular, young infants may become severely dehydrated in a short time. Patients and/or parents should be advised to seek medical advice if the condition worsens. Gastrolyte Electrolyte Hydration should not be used in infants below the age of 24 months without medical supervision. Clinicians should particularly ensure patients are aware of the risk of dehydration in young children and infants. Early warning signs of impending dehydration should be discussed.

Seek medical advice if diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children aged 6 months to 3 years, 24 hours in children aged 3 to 6 years and 24-36 hours in children over 6 years of age and adults.

Gastrolyte Electrolyte Hydration should not be used for self-treatment by patients with:

- Chronic or persistent diarrhoea
- Liver or kidney disease
- Diabetes
- On low potassium or on low sodium diets
- Intestinal obstruction

The use of Gastrolyte Electrolyte Hydration with these conditions should be supervised by a physician.

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

No information available

4.6 FERTILITY, PREGNANCY AND LACTATION

There is no contraindication to the use of Gastrolyte Electrolyte Hydration in pregnancy and lactation. However, pregnant or lactating women with gastroenteritis should only use under medical supervision.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not applicable

4.8 UNDESIRABLE EFFECTS

None reported.

Reporting suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to <https://nzphvc.otago.ac.nz/reporting/>.

4.9 OVERDOSE

In case of significant overdose, serum electrolytes should be evaluated as soon as possible. Appropriate 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.

For information on the management of overdose, contact the New Zealand National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Compound sodium chloride and glucose oral powder and effervescent tablet. Total osmolarity is 240mOsm/L.

Sachet: 1 L of made up solution (5 sachets, 5x200mL) contains sodium (Na⁺) 60mmol, potassium (K⁺) 20mmol, chloride (Cl⁻) 60mmol, citrate 10mmol and glucose 90mmol.

Tablet: 1 L of made-up solution (10 tablets, 5x200mL quantities) contains sodium (Na⁺) 60mmol, potassium (K⁺) 25mmol, chloride (Cl⁻) 45mmol, citrate 20mmol and glucose 90mmol.

5.2 PHARMACOKINETIC PROPERTIES

No information available

5.3 PRECLINICAL SAFETY DATA

No information available

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Oral glucose electrolyte preparations

Sachet: silicon dioxide, saccharin sodium, orange flavour

Tablet: saccharin sodium, blackcurrant flavour, lemon flavour, raspberry flavour.

6.2 INCOMPATIBILITIES

No information available

6.3 SHELF LIFE

Sachets and Tablets: 36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Sachets and Tablets: Store at or below 25°C

Sachets and Tablets: Once reconstituted 24 hours if refrigerated, 1 hour if not refrigerated

6.5 NATURE AND CONTENTS OF CONTAINER

Sachets Saccharin: Orange flavour: 5.1g, 10's

Tablets, effervescent: Blackcurrant: 2s & 20's, Lemon and Raspberry flavours: 20's

Reconstitution: The powder contents of one sachet or two effervescent tablets should be made up to 200ml with fresh drinking water. (For infants, the water should be freshly boiled and cooled before mixing with Gastrolyte Electrolyte Hydration). An infant's feeding bottle is a convenient measure of this volume. The solution should be made up immediately prior to feeding

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements

7 MEDICINE SCHEDULE

General Sale

8 SPONSOR

sanofi-aventis new zealand limited

Level 8, 56 Cawley Street
Ellerslie, Auckland
New Zealand
Toll Free Number (medical information 0800 283 684)

9 DATE OF FIRST APPROVAL

Orange Oral Powder Sachets: 5 April 1990

Blackcurrant, Raspberry and Lemon Effervescent Tablets: 27 January 2011

10 DATE OF REVISION OF THE TEXT

26 July 2017

SUMMARY TABLE OF CHANGES

SECTION	ADDITIONAL TEXT ADDED
2	Active ingredient altered to match TPDR
4.2	Length of time changed to seek medical advice for children older than 6 years to 24-36 hours
4.3	Gastrolyte Electrolyte Hydration should not be used in patients with hypersensitivity to active substances or to any of the excipients
4.4	If nausea and vomiting are present with the diarrhoea, small but frequent amounts should be drunk.
4.4	Gastrolyte Electrolyte Hydration should not be used in infants below the age of 24 months without medical supervision.
4.4	Length of time changed to seek medical advice for children older than 6 years and adults to 24-36 hours
4.4	Gastrolyte Electrolyte Hydration should not be used for self-treatment by patients with: chronic or persistent diarrhoea, liver or kidney disease, diabetes, on low potassium or on low sodium diets and intestinal obstruction, The use of Gastrolyte Electrolyte Hydration with these conditions should be supervised by a physician.
4.6	Only use under medical supervision in pregnancy and lactation
4.9	In case of serious overdose, serum electrolytes should be evaluated as soon as possible, Appropriate 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.
10.	Revision of text date changed to 26 July 2017