COMPOSITION

Active ingredients per sachet:

- Pre-cooked rice (Oryza sativa) powder: 6g
- Sodium Citrate: 580mg
- Sodium Chloride: 350mg
- Potassium Chloride: 300mg

Content of electrolytes in the reconstituted preparation:

- Na (sodium): 60 mmol/L
- Cl (chloride): 50 mmol/L
- K (potassium): 20 mmol/L
- Citrate: 10 mmol/L (or 30 Meq/L)

Osmolarity of electrolytes: 140mosm/L
Total osmolarity of solution: 226mosm/L

Excipients: Gastrolyte-R sachets also include hypromellose, apricot flavouring and aspartame. Phenylketonurics should be warned that this product contains phenylalanine.

DESCRIPTION

Yellowish, granular powder with faint odour of apricot.

PHARMACOLOGY

Gastrolyte-R contains a balanced amount of electrolytes, starch and proteins in water. Oral dehydration therapy with Gastrolyte-R enables a dehydrated subject to be rehydrated rapidly. The presence of pre-cooked rice in the formulation enables watery stools to return to normal more rapidly.

The advantages of Gastrolyte-R are bound with its composition.

- Water: the appropriate amount is essential to correct dehydration.
- Starch: low osmotic capacity (unlike pure glucose) thus preventing any additional loss of fluid through the stools. Rice starch contains 20% amylose and 80% amylopectin.
- Proteins: specific nutritional properties.
- Electrolytes: essential for restoring the ionic equilibrium. The role of citrate is to correct the acidosis that occurs as a result of diarrhoea. Citrate also enhances the absorption of sodium and is more stable than bicarbonate.
**INDICATIONS**

- Oral correction of fluid and electrolyte loss in infants from 3 months of age, children and adults.
- Treatment of watery diarrhoea of various aetiologies including gastro-enteritis in all age groups from 3 months upwards. (Use in infants less than 3 months of age only under medical supervision.)
- Gastrolyte-R is particularly recommended in the case of too loose or frequent stools where it enables over-loose stools to revert to normal.

**CONTRA-INDICATIONS**

Gastrolyte-R should not be used in patients with phenylketonuria as it contains aspartame.

Treatment with Gastrolyte-R may be inappropriate in conditions such as intestinal obstruction requiring surgical intervention and cases of severe renal or hepatic impairment.

**PRECAUTIONS**

- For oral administration only.
- Gastrolyte-R should be mixed only with water. Never dilute with lemonade, soft drinks, cordials or any other fluid than water.
- Each sachet should always be mixed in 200ml water.
- A weaker solution than recommended will fail to provide adequate sugar and electrolytes and a stronger solution than recommended may give rise to hypernatraemia. 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 gastro-enteritis 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. 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.
- Gastrolyte-R should not be administered to infants under 3 months unless under medical supervision.
- Seek medical advice if diarrhoea persist for more than 6 hours in infants under 6 months, 12 hours in children aged 6 months to 3 years of age, 24 hours in children aged 3 to 6 years and 48 hours in children over 6 years.
- No specific precautions are necessary in the elderly. However, care should be taken when administering Gastrolyte-R solution in cases of severe renal or hepatic impairment or other conditions where normal electrolyte balance may be disturbed.
Interactions

No known interactions with other medicaments or other forms of interaction.

Use in Pregnancy and Lactation

Gastrolyte-R is not contraindicated in pregnancy or lactation but should be used only on medical advice.

ADVERSE REACTIONS

None known.

DOSAGE AND ADMINISTRATION

For oral administration only.

Reconstitution

Pour the contents of one sachet into fresh 200mL of drinking water. Stir vigorously to mix all powder. Note: Gastrolyte-R powder will not dissolve completely. The correctly mixed solution will be milky.

Drink the whole volume. For infants and where drinking water is not available the water should be freshly boiled and cooled. The solution should be made up immediately before use.

Dosage: Volume of Fluid Required over 6 hours for the Prevention of Dehydration

<table>
<thead>
<tr>
<th>Patient’s weight (kg)</th>
<th>Volume of Gastrolyte-R (mL) in 6 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>150 – 210</td>
</tr>
<tr>
<td>10</td>
<td>300 – 420</td>
</tr>
<tr>
<td>15</td>
<td>450 – 630</td>
</tr>
<tr>
<td>20</td>
<td>600 – 840</td>
</tr>
<tr>
<td>30</td>
<td>900 – 1260</td>
</tr>
</tbody>
</table>

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

Dosage:

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

For toddlers and older children, Gastrolyte-R should be given freely until thirst is satisfied or frequently while diarrhoea persists.

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 breastfed infants, however in such cases it is recommended to continue breast-feeding. If treatment with Gastrolyte-R becomes necessary it is suggested that the infant is given the appropriate volume of Gastrolyte-R 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-R given and the speed of reintroduction of the normal feeds is at the discretion of the physician.

**Infants from 3 months to one year under medical advice**

In the event of diarrhoea and depending on the extent of dehydration (loss of weight assessed at less than 10%), 150 to 200mL/kg/24 hours of Gastrolyte-R may be given.

⇒ half the volume is to be given during the first 8 hours, and the other half during the next 16 hours.
⇒ in the event of vomiting accompanying the diarrhoea, the amount administered can be divided up (5 to 10mL every 5 minutes) and this may be gradually increased until the infant can drink normally.

Gastrolyte-R is not recommended for infants less than 3 months of age unless under medical supervision. Use in infants from 3 months to 1 year only on medical advice.

**Mild cases (no dehydration)**

During the first 12 to 24 hours of illness, the infant can be offered Gastrolyte-R 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.

**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 rehydration is given in the following table.

**Dosage : Volume of Fluid Required over 6 hours for the Treatment of Dehydration**

<table>
<thead>
<tr>
<th>Patient's weight (kg)</th>
<th>Volume of Gastrolyte-R (mL) in 6 hours</th>
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<tr>
<td>15</td>
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<tr>
<td>20</td>
<td>900 - 1500</td>
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<tr>
<td>30</td>
<td>1000 - 2000</td>
</tr>
</tbody>
</table>

After 6 hours, fluid replacement should be 7mL/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 48 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.

**STORAGE**

Store below 25°C in dry place.

**PRESENTATION**

Cartons of 2 and 10 7.5g sachets

**SPONSOR**

Aventis Pharma Pty Ltd

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[Approved by Therapeutic Goods Administration 15th December 2000]