

Oral Rehydration Salts (Natural)

DESCRIPTION

Enerlyte Oral Rehydration Salts (Natural).

White to off white colour granules, produce a clear to slightly turbid solution when dissolved in water.

COMPOSITION

Each sachet contains sodium chloride 650mg, trisodium citrate 725mg, potassium chloride 375mg and glucose anhydrous 3.375gm. When reconstituted (1 sachet in 250ml water), the ionic concentration is as follows: Na+75, K+20, Cl⁻65, Citrate 10, Glucose 75 and total lonic strength 245.

INDICATION

For replacement of water and electrolyte loss associated with diarrhoea and vomiting.

PHARMACODYNAMICS

Oral rehydration salts are given orally to prevent or treat dehydration due to actue diarrhoea. Essential water and salts are lost in stools and vomitus, and dehydration results when blood volume is decreased because of fluid loss from the extracellular fluid compartment. Preservation of the facilitated $\dot{\text{glucose-sodium}}$ contransport system in the small-bowel mucosa is the rationale of oral rehydration therapy. Glucose is actively absorbed in the normal intestine and carries sodium with it in about an equimolar ration. Therefore, there is a greater net absorption of an isotonic salt solution with glucose than one without it. Potassium replacement during acute diarrhoea prevents below-normal serum concentrations of potassium, especially in children, in whom stool potassium losses are higher than in adults. Citrate are effective in correcting the metabolic acidosis caused by diarrhoea and dehydration.

PHARMACOKINETICS

The basis for oral rehydration is the glucose-facilitated sodium absorption in the small intestines. In severe diarrhoea, passive sodium diffusion and the active sodium pump mechanism are not functioning properly. However, the glucose-facilitated sodium absorption remains intact, as long as glucose concentrations do not exceed 160mmol/l. Time to peak effect is between 8 to 12 hours.

DOSAGE

Add 250ml of boiled, cooled water to the contents of one sachet of **Enertyte** Oral Rehydration Salts (Natural). Stir or shake well for 2 to 3 minutes to dissolve

Use as advised by your medical practitioner. As a general guideline, the following regime may be used:

	Serving in the 1st 2 hours	Serving in the 24 hours
Adults anf children over 10 years	4	12
Children (2 to 10 years)	3	6
Children (up to 2 years of age)	1	3
	(Each serving equals 250ml reconstituted Enertyte Oral Rehydration Salts (Natural))	

If nausea or vomiting are present, and in infants or young children, drink the solution slowly in sips at shorter interval.

PATIENT COUNSELLING NOTES

- Do not boiling solution.
- Making and using fresh solution each day.
- Infants and small children to drink solution slowly and frequently in small amounts of oral rehydration fluid.
- Giving breast milk to breast-fed infants between doses of solution.
- Eat soft foods, such as cereals, bananas, cooked peas, beans and potatoes to maintain nutrion.
- Drink water between doses of rehydration solution.

OVERDOSAGE

If puffy eyelids are observed, this is a symptom or over-hydration and therapy may need to be discontinued temporarily.

UP-TO-DATE INFORMATION ON THE TREATMENT OF OVER DOSAGE CAN BE OBTAINED FROM THE NATIONAL POISON CENTRE, UNIVERSITI SAINS MALAYSIA

TOXICOLOGY

Pregnancy/Reproduction

Problems in humans have not been documented.

148.5mm(w) x 210mm (h)

Black 100%

BREASTFEEDING

Problems in humans have not been documented. Continued breast feeding using the treatment and maintenance phases of oral rehydration therapy is vital for the management of diarrhoea.

PAEDIATRICS

Although oral rehydration therapy appears to be safe and effective in neonates, it has not been evaluated in premature infants. The range of sodium concentrations recommended is 40 to 60mEq per litre for maintenance solutions and 75 to 90mEq per litre for rehydration solutions. To allow adequate intake of free water in the prevention of hypernatreamia with the use of Enerlyte Oral Rehydration Salts (Natural) feeding (including breast milk) may continue and / or the infant may be given a separate feeding of plain water after every 2 doses of Enerlyte Oral Rehydration Salts (Natural) solution.

GERIATRICS

Carbohydrate and electrolyte solutions are well tolerated by elderly patients.

SIDE EFFECTS

Mild vomiting may occur when oral therapy has begun, but therapy should be continued with frequent, small amounts of solution administered slowly. Rarely, symptoms of hypernatreamia (dizziness, fast heartbeat, high blood pressure, irritability, muscle twitching, restlessness, seizures, swelling of feet or lower legs, or weakness) may be experienced.

CONTRAINDICATION

Precise parenteral administration of water and electrolytes is recommended in the following conditions and the use of oral rehydration should not be used except under special circumstances:

Anuria or oliguria, severe dehydration with symptoms of shock, severe diarrhoea, inability to drink, severe and sustained vomiting.

Diarrhoea is exacerbated and dehydration worsened when oral rehydration solutions are given to patients with glucose malabsorption; volume of stool is greatly increased and contains large amounts of glucose. Rehydration therapy should be discontinued. In patients with intestinal obstruction, paralytic ileus or perforated bowel, delayed passage of carbohydrate and electrolytes solution through the gastrointestinal tract may increase the risk of gastrointestinal irritation.

DRUG INTERACTIONS

None reported.

PRECAUTIONS

To be used with care in patients with impaired renal function, high blood pressure, diabetes or heart ailments. In some cases, patient monitoring may be especially important. These include monitoring of blood pressure, body weight, serum electrolytes and serum pH, glucose malabsorption tests, signs or rehydration, and stool volume measurements.

PRESENTATION

Pack of 50's sachets Not all pack sizes are available locally.

STORAGE CONDITIONS

Store in a dry place below 30°C. Protect from light.
Keep out of reach of children.
Jauhi daripada kanak-kanak.

Shelf life: please refer to outer package. **Route of administration: Oral.**

Product Registration Holder:

DUOPHARMA MARKETING SDN. BHD. Lot No 2, 4, 6, 8 & 10, Jalan P/7, Section 13,

Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor, Malaysia.

Manufacturer:

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