

ORAL REHYDRATION SALTS I.P. ORAL REHYDRATION SOLUTION

ELECTRAL®

COMPOSITION

Electral 4.4 g Sachet

Each sachet of 4.4 g contains	
Sodium Chloride IP	0.52 g
Potassium Chloride IP	0.30 g
Sodium Citrate IP	0.58 g
Dextrose Anhydrous IP	2.70 g
Excipients	q.s.

Electral 21.8 g Sachet

Each sachet of 21.8 g contains	
Sodium Chloride IP	2.60 g
Potassium Chloride IP	1.50 g
Sodium Citrate IP	2.90 g
Dextrose Anhydrous IP	13.50 g
Excipients	q.s.

Electral 200 ml Ready-to-drink pack

Each 200 ml pack contains	
Sodium Chloride IP	0.52 g
Potassium Chloride IP	0.30 g
Sodium Citrate IP	0.58 g
Dextrose Anhydrous IP	2.70 g
Excipients	q.s.

DOSAGE FORM

Electral 4.4 g Sachet: Oral powder for reconstitution
Electral 21.8 g Sachet: Oral powder for reconstitution
Electral 200 ml Ready-to-drink pack: Oral liquid

PHARMACOLOGY

Pharmacodynamics

The ORS formulation is based upon the well accepted WHO oral rehydration solution (ORS). Dextrose has been shown to greatly enhance the absorption of salts and water. Sodium, Potassium and Chloride are included to replace electrolytes lost in the stool. Sodium Citrate combats metabolic acidosis.

The key constituents of ORS are sodium and glucose. The central principle of oral rehydration therapy (ORT) is the utilization of sodium-glucose co-transport in the small intestine, a phenomenon which remains largely unaffected during acute infectious diarrhea. Thus the success of ORT is largely dependent on glucose-driven sodium absorption (transcellular route) leading to passive absorption of water by the paracellular route. The clinical result is usually rapid rehydration and correction of acidosis.

Pharmacokinetics

Sodium absorption

Sodium absorption is accomplished by three different processes, the energy required being generated by the 'sodium pump' situated on the basolateral membrane of the enterocyte.

1. 'Electrogenic' non-nutrient coupled sodium absorption appears to be present both in the small and large intestine. Sodium ions enter the cell passively through selective ion channels down the electrochemical gradient.
2. 'Neutral' NaCl absorption occurs mainly in the ileum and appears to be accomplished through the action of a pair of linked ion exchangers.
3. The final mechanism of sodium entry into the enterocyte is coupled non-electrogenic sodium absorption which operates in both the jejunum and ileum and is the most important therapeutically. Sodium absorption is coupled to the absorption of a variety of organic solutes including glucose, amino acids, bile salts, water-soluble vitamins and organic acids. Carrier proteins responsible for sodium entry are situated in the brush border membrane and one of the best characterized is the Na-glucose symporter. This carrier protein utilizes the potential energy released as sodium ions enter the epithelial cells down their electrochemical gradient to drive the 'uphill' movement of glucose in the same direction. The 'downhill' electrochemical gradient for sodium is, as stated above, maintained by the Na⁺-K⁺ ATPase of the basolateral enterocyte membrane. The configuration of the symporter is such that it is only operative when the sodium- and glucose-binding sites are occupied. Sodium efflux occurs via the sodium pump while solute leaves the cell via means of facilitated diffusion across the basolateral membrane.

Chloride absorption

Chloride ions cross the epithelium transcellularly through the action of the coupled ion exchangers but are also absorbed by the paracellular route down the electrical gradient generated by the 'electrogenic' and 'coupled' mechanisms of sodium entry.

Potassium absorption

In the small intestine, potassium ions are absorbed passively via the paracellular route.

Water transport

Water transport occurs by the passive route and is always secondary to the active transport of electrolytes or other solutes, increasing directly in proportion to the amount of solute transported.

INDICATIONS& USAGE

Oral replacement therapy of electrolyte and fluid loss in children and adults arising from dehydration associated with acute diarrhoea.

DOSAGE & METHOD OF ADMINISTRATION

Reconstitution:

Product	Directions for reconstitution
Electral 4.4 g sachet	Adults and children: The content of each sachet should be dissolved in approximately 200 ml of cool, fresh, clean drinking water. Infants: The water should be boiled then cooled before reconstitution as above.
Electral 21.8 g sachet	Adults and children: The content of each sachet should be dissolved in approximately 1000 ml (1 liter) of cool, fresh, clean drinking water. Infants: The water should be boiled then cooled before reconstitution as above.
Electral 200 ml Ready-to-drink	No reconstitution is required.

The reconstituted cooled solution should be used immediately and the unused remainder discarded, or stored in a refrigerator for no longer than 24 hours. Do not boil after reconstitution. The product must only be used at the recommended dilution.

Contents of Electral 4.4 g sachet dissolved in 200 ml water will provide:

Electrolyte	mmol/L
Sodium	75
Potassium	20
Chloride	65
Citrate	10
Glucose	75
Osmolarity	245 mOsmol/L

Similarly, contents of Electral 21.8 g sachet dissolved in 1000 ml (1 liter) water will provide:

Electrolyte	mmol/L
Sodium	75
Potassium	20
Chloride	65
Citrate	10
Glucose	75
Osmolarity	245 mOsmol/L

Dosage:

Oral fluid replacement and maintenance therapy must be tailored to individual patient needs. The volume of solution used will depend on the weight and age of the patient, using the basic principle of firstly rehydrating the patient by replacing lost fluid and thereafter maintaining fluid replacement in line with the volume of fluid lost from stools or vomiting plus normal daily requirements. As a basic guide, a daily intake of 150 ml/kg bodyweight for infants (under 2 years of age) or 20-40 ml/kg for adults and children is needed.

Replacement of fluid losses with ORS solution:

Infants (under 2 years of age): Reconstitute sachets according to directions and administer at 1-1.5 times usual feed volume. No milk (other than breast milk) or solids should be given during the first 24 hours. In breast-fed infants, ORS should be given before the feed. The re-introduction of normal feeding should only take place when symptoms of diarrhoea are abating and should be added gradually to make up the total daily fluid requirements.

Children: 200 ml after every loose motion, up to 2.4 liters in 24 hours.

Adults: 200-400 ml after every loose motion, up to 3.2 liters in 24 hours.

Elderly person: As for adults but care must be taken not to over-hydrate.

In adults and children ORS can be given in amounts necessary to satisfy thirst. As with infants, solids should be avoided during the first day, but may be gradually resumed as necessary during day 2.

It is extremely difficult to over-hydrate by mouth, thus when there is normal renal function, it is better to give more ORS than less.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

Oral treatment is inappropriate in such conditions as severe dehydration, which requires parenteral fluid therapy or intestinal obstruction.

It is necessary for medical supervision in the presence of renal disease, including anuria or prolonged oliguria, severe and persistent diarrhoea and vomiting, inability to drink or retain oral fluids.

WARNINGS & PRECAUTIONS

Infants under the age of 2 years with severe diarrhoea/vomiting should be seen by a doctor as soon as possible.

If symptoms persist for longer than 24-48 hours, a doctor should be consulted.

The solution must be made up without adding extra sugar or salt. In treating diabetics with gastro-enteritis, the sugar content must be noted.

Solutions of greater concentration may result in hyponatraemia. Those of greater dilution may result in inadequate replacement.

DRUG INTERACTIONS

None known.

PREGNANCY & LACTATION

The dose is the same as adult dose. Breast feeding can be continued as normal. If vomiting is a problem then ORS solution should be taken in frequent small volumes.

ORS is not contraindicated in pregnancy or lactation but should be used on medical advice.

ADVERSE REACTIONS

Vomiting can occur after administration of oral rehydration solution, and may be an indication that it was administered too quickly. If vomiting occurs, administration should be halted for 10 minutes, then resumed in smaller, more frequent, amounts.

The risk of hyponatraemia or overhydration after administration of oral rehydration solutions is low in patients with normal renal function. Overdose of oral rehydration solutions in patients with renal impairment may lead to hyponatraemia and hyperkalaemia.

Reporting of suspected adverse reactions

To report SUSPECTED ADVERSE REACTIONS, contact FDC Limited at 1800 266 9347 or drug.safety@fdcindia.com or report online at http://www.fdcindia.com/adverse_form.php.

OVERDOSE

In oral electrolyte replacement therapy, toxicity is rare in previously healthy people. In subjects with renal impairment, hyponatraemia and hyperkalaemia might occur.

In the event of significant overdose serum electrolytes should be evaluated by means of full biochemical profile under hospital conditions and the physician should take the appropriate measures. This is particularly important in the very young and in cases of severe hepatic or renal failure.

INCOMPATIBILITIES

None stated.

SHELF-LIFE

- 1) Sachet of 21.8 g and 4.4 g - 24 Months
- 2) Tetra Pack of Orange Flavour 200 ml - 15 Months
Tetra Pack of Mango and Apple Flavour 200 ml - 18 Months

PACKAGING INFORMATION

- 1) Sachet of 21.8 g
- 2) Sachet of 4.4 g in following flavours:
(Orange, Blackcurrant, Mango, Lime, Lychee and Pineapple)
- 3) Tetra Pack of 200 ml (Orange, Mango and Apple flavours)

STORAGE AND HANDLING INSTRUCTIONS

- 1) Sachet of 21.8 g and 4.4 g - Store protected from moisture.
- 2) Tetra Pack of 200 ml - Store at temperature not exceeding 30°C.

DATE OF PREPARATION OF PACK INSERT

03rd Feb 2025

Manufactured by:

FDC Limited

Regd. Office: B-8, MIDC Industrial Area,
Waluj, Aurangabad - 431 136, Maharashtra.

® Registered Trademark of FDC Limited