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Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

ELECTRAL (Oral Rehydration Salts BP).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 21.8 g sachet contains:
Sodium Chloride BP …… 2.60 g
Potassium Chloride BP ……. 1.50 g
Sodium Citrate BP …… 2.90 g
Anhydrous Glucose BP ……. 13.50 g
Excipients …….. q.s.

3. PHARMACEUTICAL FORM

Oral powder (for reconstitution with 1 litre water).

Description

White to off white granular free flowing powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

ELECTRAL is used for oral correction of fluid and electrolyte loss in infants, children and adults. ELECTRAL is also indicated in treatment of watery diarrhoea of various aetiologies including gastro-enteritis, in all age groups.

4.2 Posology and Method of Administration

Daily intake may be based on a volume of 150 ml/kg body weight for infants up to the age of 2 years and 20 to 40 ml/kg body weight for adults and children. More may be required initially to ensure early and full volume repletion.

Oral: For fluid and electrolyte loss in diarrhoea.

- Infant 1 to 11 months: 1 to 1½ times of usual feed volume.
- Children 1 to 11 years: 200 ml to be given after every loose motion.
- Adolescents 12–17 years: 200 to 400 ml to be given after every loose motion, dose according to fluid loss.
- Adults: 200 to 400 ml to be given after every loose motion, dose according to fluid loss.

When vomiting is present with the diarrhoea, it is advisable that small amounts of ELECTRAL/ORS be given frequently. However, it is important that the whole amount of the required volume of ORS be taken by patient. Where the kidneys are functioning normally, it is difficult to over-hydrate by oral route and where there is doubt about the dosage, more rather than less should be taken. If no improvement is seen within 24 to 48 hours it is recommended that the patient be seen by a physician.

Method of Administration

Reconstitute/dissolve all content of 21.8 g sachet with 1000 ml (1 litre) of water. Use fresh drinking water for adults and children. For infants, preferably, freshly boiled and cooled water to be used for preparing ORS solution. After reconstitution with water, the solution itself must not be boiled.

The solution should be made up immediately before its use. The reconstituted solution may be stored and used for up to 24 hours when kept in a refrigerator. Any unused solution should be discarded after an hour of its preparation when stored at normal conditions or after 24 hours if it is stored in a refrigerator.
For reconstitution, use plastic or glass or stainless steel container only. Don't use copper utensils/vessel for reconstitution and storage of the ORS solution.
Important Note: Continue feeding the child during diarrhoea. If diarrhoea persists after 2 days or the child shows sign of dehydration take the child to the nearest health facility.
Or, as directed by the Physician.

4.3 Contraindications

ELECTRAL is contraindicated in patient with hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
There are no known contraindications to ELECTRAL/ORS. However, there may be a number of conditions where treatment with ELECTRAL will be inappropriate e.g., intestinal obstruction requiring surgical intervention and severe dehydration requiring parenteral fluid therapy.

4.4 Special Warnings and Precautions for Use

- 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 to 48 hours, consult doctor immediately.
- The solution must be made up without adding extra sugar or salt. In treating diabetics with gastro-enteritis, the sugar content must be noted.
- Depressed renal function, severe continuing diarrhoea or other critical fluid losses may need supplementation with other parenteral fluids along with ORS.
- Solutions of greater concentration may result in hypernatremia. Those of greater dilution may result in inadequate replacement.
- Medical supervision is necessary in the presence of renal disease including anuria or prolonged oliguria, severe and persistent diarrhoea and vomiting, and inability to drink or retain oral fluids.

In patients with following conditions, ORS should not be used for self-treatment by patients; therapy should be supervised by a physician:

- Chronic or persistent diarrhea.
- Liver or kidney disease.
- Diabetes.
- Low potassium or sodium diets.
- Intestinal obstruction.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

None known.

4.6 Fertility, Pregnancy and Lactation

ELECTRAL can be administered to pregnant women and breastfeeding mother. Medical supervision is recommended for use during pregnancy and lactation. Breastfeeding can be continued as usual. If vomiting is a problem during pregnancy then solution should be taken frequently in small volumes.

4.7 Effects on Ability to Drive and Use Machines
ELECTRAL could not be expected to affect the ability to drive or use machines.

4.8 Undesirable Effects
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 and then resumed in smaller and more frequent amounts.
The risk of hypernatraemia or overhydration after administration of oral rehydration solutions is low in patients with normal renal function. Overdosage of oral rehydration solutions in patients with renal impairment may lead to hypernatraemia and hyperkalaemia.

Reporting of Suspected Adverse Reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

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4.9 Overdose
In oral electrolyte replacement therapy, toxicity is rare in healthy people. In subjects with renal impairment, hypernatraemia and hyperkalaemia might occur.
In the event of significant overdose, serum electrolytes should be evaluated as soon as possible, appropriate steps taken to correct an abnormalities and levels monitored until return to normal levels is established. This is particularly important in the very young and in cases of severe hepatic of renal failure.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties
Pharmacotherapeutic Group: Electrolytes with carbohydrates.
ATC Code: A07CA.

Mechanism of Action
Sodium, potassium, and chloride replace lost electrolytes through loose motions (dehydration) whereas glucose enhances the absorption of salt/sodium and water from the intestine. Sodium citrate combats metabolic acidosis.

Pharmacodynamic Effects
ELECTRAL is a WHO approved formulation of low-osmolarity oral rehydration salts (ORS). Combination of electrolytes stimulates water and electrolyte absorption from the gastrointestinal tract (GIT) and therefore prevents or reverses dehydration caused by diarrhoea.
After reconstitution of all contents of ELECTRAL 21.8 g sachet with 1,000 ml (1 litre) of water, total osmolarity of the reconstituted solution become 245 mOsmol/L.

Electrolytes	Concentration (mmol/L)
Sodium	75
Potassium	20
Chloride	65
Citrate	10
Glucose	75
Osmolarity of the solution - 245 mOsmol/L	

5.2 Pharmacokinetic Properties

Sodium and glucose are actively transported via the membrane into the enterocytes. Sodium is then extruded into the intercellular spaces and the resulting osmotic gradient causes water and electrolytes to be drawn from the gut and then into the circulation.

5.3 Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Anhydrous Citric Acid, Neotame, Pinacolada DSC 244 or Trusil Pinacolada RS 16122 and Trusil Orange FRS

6.2 Incompatibilities

ORS solution is not compatible with copper pot/container; don't use copper utensils for preparing and storing ORS solution.

6.3 Shelf-life

24 months

6.4 Special Precautions for Storage

Store in a dry place at a temperature not exceeding 30°C

6.5 Nature and Contents of Container

21.8 g of ELECTRAL (ORAL REHYDRATION SALTS BP) filled in a sachet of 3 ply laminate. 20 such sachets are packed in a carton along with pack insert.

21.8g of ELECTRAL (ORAL REHYDRATION SALTS BP) filled in a sachet of 3 ply laminate. 100 such sachets are packed in a Carton along with pack insert.

6.6 Special Precautions for Disposal and Other Handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Registered Office:

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8. MARKETING AUTHORISATION NUMBER(S)
Certificate No; 05373/07186/REN/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Mar 23, 2016.

10. DATE OF REVISION OF THE TEXT
August 2023.