SUMMARY OF PRODUCT CHARACTERISTICS.

1. Name of the medicinal product

Oral rehydration Salts (ORS)

2. Qualitative and quantitative composition

Each sachet contains: Anhydrous glucose BP 13.5gm, Sodium chloride BP 2.6gm, Trisodium citrate dihydrate BP 2.90gm, Potassium chloride BP 1.50gm and full list of excipients see Section 6.1.

3. Pharmaceutical form

Powder for oral solution.
White fine powder.

4. Clinical particulars

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Oral Administration

- Use clean and safe water to prepare the ORS solution. The water should be treated or boiled and cooled.
- Measure half a Litre of water (500ml soda bottle) and pour it into a clean container.
- Add the entire content of one ORS sachet into the jar of water.
- Stir well until the powder is completely dissolved.
- Give the child ORS solution to drink after every stool.

For children up to 2 years: give ½ a cup.
For children 2 year and above: give full cup.
If the child vomits, wait for 10 minutes and continue giving the ORS solution sip by sip.
Use ORS within 12 hours of preparation.

4.3 Contraindications

- Oral rehydration salts (ORS) is contraindicated in conditions like continued vomiting, severe dehydration
- Hypersensitivity to any of the salts or any excipients.
- ORS might also be contraindicated in people who are in hemodynamic shock due to impaired airway protective reflexes. Short-term vomiting is not a contraindication to receiving oral rehydration therapy. In persons who are vomiting, drinking oral rehydration solution at a slow and continuous pace will help the person avoid vomiting.

4.4 Special warnings and precautions for use

Use with caution in patients with pre-existing blood disorders, gout, dental disease, liver disease or heart disease. These are not appropriate for patients with gastrointestinal obstruction, oliguric or anuric renal failure oral rehydration salts should be reconstituted only with water.

4.5 Interaction with other medicinal products and other forms of interaction

No data regarding the interactions of oral rehydration salts (ORS) was found.

4.6 Fertility, pregnancy and lactation

This medication is classified as pregnancy category C and should be used during pregnancy or lactation only if clearly needed.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

The severe or irreversible adverse effects of Oral Rehydration Salts (ORS), which give rise to further complications include Radio sensitization effect on thorax, Skin inflammation, Esophageal inflammation.
Oral Rehydration Salts (ORS) produces potentially life-threatening effects which include Hyperkalemia, Hyperkalemia, and Hypernatremia. Which are responsible for the discontinuation of Oral Rehydration Salts (ORS) therapy.
The signs and symptoms that are produced after the acute over dosage of Oral Rehydration Salts (ORS) include Severe vomiting, Mucositis, Diarrhea, Severe myelosuppression, Hyperkalemia, Hypernatremia.
The symptomatic adverse reactions produced by Oral Rehydration Salts (ORS) are more or less tolerable and if they become severe, they can be treated symptomatically, these include Nausea, Vomiting, Alopecia, Diarrhea, Mucositis, Fever, Myalgia, Abdominal pain, Reaction at injection site, Alopecia.

4.9 Overdose
In oral electrolyte replacement therapy, toxicity is rare in previously healthy people. In subjects with renal impairment, hypernatremia and hyperkalemia 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.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Oral Rehydration Salts Formulations.
ATC code: A07CA.

5.2 Pharmacokinetic properties
Fluid from the body enters the intestinal lumen during digestion. This fluid is isosmotic with the blood because it contains a high concentration of sodium (approx. 142mEq/L). A healthy individual secretes 2000–3000 milligrams of sodium per day into the intestinal lumen. Nearly all of this is reabsorbed so that sodium levels in the body remain constant. In a diarrheal illness, sodium-rich intestinal secretions are lost before they can be reabsorbed. This can lead to a life-threatening hyponatraemia within hours. This is the motivation for sodium and water replenishment in ORT.
Sodium absorption occurs in two stages. The first is via intestinal epithelial cells. Sodium passes into these cells by co-transport with glucose, via the SGLT1 protein. From the intestinal epithelial cells, sodium is pumped by active transport via the sodium potassium pump through the basolateral membrane into the extracellular space.
The sodium–potassium ATPase pump at the basolateral cell membrane moves three sodium ions into the extracellular space, while pulling into the cell two potassium ions. This creates a "downhill" sodium gradient within the cell. SGLT proteins use energy from this downhill sodium gradient to transport glucose across the apical membrane of the cell against the glucose gradient. The co-transporters are examples of secondary active transport. The GLUT uniporters then transport glucose across the basolateral membrane. Both SGLT1 and SGLT2 are known as symporters, since both sodium and glucose are transported in the same direction across the membrane.
The co-transport of glucose into epithelial cells via the SGLT1 protein requires sodium. Two sodium ions and one molecule of glucose (as galactose) are transported together across the cell membrane via the SGLT1 protein. Without sodium, intestinal glucose is not absorbed. This is why oral rehydration salts (ORS) include both sodium and glucose. For each cycle of the transport, hundreds of water molecules move into the epithelial cell, slowly rehydrating the patient.

5.3 Preclinical safety data
None stated.

6. Pharmaceutical particulars
6.1 List of excipients
- Aspartame
- Orange powder Flavour
- Tartrazine soluble colour

6.2 Incompatibilities
None known.

6.3 Shelf life
36 months in the sealed sachet, not more than 24 hours after reconstitution.

6.4 Special precautions for storage
Stored in a dry place below 30ºC, Protected from light.
Keep all medicine out of reach of children.

6.5 Nature and contents of container
Filled in 20.6g/10.3g aluminium foil sachet packed in a unit box of 1 Litre & 500ml.

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 and Manufacturing Site Addresses.

Marketing Authorization Holder:

Company Name: LABORATORY & ALLIED LTD
Address: Plot No. 209/10349, Opposite Sameer Business Park, next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi,
Country: Kenya
Telephone: +254 20 8040306
Telefax: +254 20 8040309
E-Mail: info@laballied.com.

Manufacturing Site Address:

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Country: Kenya
Telephone: +254 20 8040306
Telefax: +254 20 8040309
E-Mail: info@laballied.com

8. Marketing Authorization Number:
Registration No; Kenya: H2007/147

9. Date of first Registration/ Renewal of the Registration:
Date of Registration: 28/03/2007
Renewal: Retained Annually.

10. Date of revision of the text.
June 2024.

11. Dosimetry (if applicable)
Not Applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)
Not Applicable.