

Oral Rehydration Salts BP

WHO-recommended formula

ORANGE
FLAVOR

Composition:

Each sachet contains:

Sodium Chloride BP.....	2.6 g
Potassium Chloride BP.....	1.5 g
Sodium Citrate BP.....	2.9 g
Glucose (Anhydrous) BP.....	13.5 g
Excipients.....	q.s.

Pharmaceutical form:

Oral powder.

Therapeutic indications:

ORS is indicated for the treatment of acute diarrhea and the treatment and prevention of dehydration, replenishing fluids and electrolytes lost due to diarrhea.

Dosage and method of administration:

Dosage:

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

Oral: For fluid and electrolyte loss associated with diarrhea.

- Infants aged 1 to 11 months: 1 to 1½ times the usual feeding volume.
- Children aged 1 to 11 years: 200 ml to be administered after each bowel movement.
- Adolescents aged 12 to 17 years: 200 to 400 ml to be administered after each bowel movement; dose according to fluid loss.
- Adults: 200 to 400 ml to be administered after each bowel movement; dose according to fluid loss.

When vomiting accompanies diarrhea, it is advisable to administer small amounts of ORS frequently. However, it is important that the patient consumes the full required volume of ORS. Where kidney function is normal, oral overhydration is unlikely; if there is doubt regarding dosage, it is better to administer more rather than less. If no improvement is observed within 24 to 48 hours, it is recommended that the patient be examined by a physician.

Method of administration:

For oral administration after reconstitution.

Reconstitution:

Reconstitute/dissolve the entire contents of the sachet in 1000 ml (1 liter) of water. Use fresh potable water for adults and children. For infants, preferably use water that has been freshly boiled and cooled to prepare the ORS solution. Once reconstituted with water, the solution itself must not be boiled.

The solution should be prepared immediately before use. The reconstituted solution may be stored and used for up to 24 hours if kept in a refrigerator. Any unused solution must be discarded one hour after preparation if stored under normal conditions, or after 24 hours if stored in a refrigerator.

Use only plastic, glass, or stainless steel containers for reconstitution. Do not use copper utensils or containers for the reconstitution and storage of the ORS solution.

Contraindications:

ORS is contraindicated in patients with phenylketonuria or in those with hypersensitivity to any of the ingredients in the formulation.

Severe and persistent diarrhea must be treated under medical supervision. If symptoms persist for more than 24 to 48 hours, medical advice should be sought.

Inability to drink or retain fluids requires medical supervision.

Children:

• Rehydration treatment should only be administered to children under 1 year of age under medical guidance.

• If a young child (particularly one under 6 months of age) has diarrhea and/or vomiting, advice should be sought from a pharmacist, doctor, or other healthcare professional. If the diarrhea and/or vomiting is severe, the child should be examined by a doctor as soon as possible.

Renal impairment:

• Medical supervision is required for patients with kidney disease, including anuria and prolonged oliguria.

Hepatic impairment: low-potassium or low-sodium diets; diabetes:

- Treatment must be supervised by a doctor.

Drug interactions:

Sodium bicarbonate:

It increases lithium excretion, resulting in reduced plasma lithium concentration.

Potassium chloride:

ACE inhibitors (hyperkalemia); cyclosporine (increased risk of hyperkalemia).

Potassium-sparing diuretics, where hyperkalemia may result. No known interactions with other active ingredients.

Pregnancy and lactation:

ORS may be used during pregnancy and lactation, as there are no known adverse effects.

Undesirable effects:

Unknown.

Overdose:

If significant overdose occurs, serum and electrolyte levels should be assessed.

Corrective measures should be taken and levels monitored until a return to normal levels is achieved.

Storage:

Store below 30°C in a dry place; protect from light.

Keep the medication out of the reach of children.

Presentation:

10 sachets are packed in a printed box along with the package insert.

Manufactured by:

