

Peditral

Oral Rehydrated Salt (ORS) Orange Flavor (Sachet)

COMPOSITION

Each 30 gm sachet contains:
sodium chloride 3.5g; potassium chloride 1.5g; sodium citrate 2.9 g; dextrose anhydrous 20g.
Excipients: citric acid anhydrous, saccharin sodium, orange durarome flavor.

THERAPEUTIC INDICATIONS

For the treatment of acute diarrhea and the treatment and prevention of dehydration by replacing fluids and electrolytes lost through diarrhea.

DOSAGE AND METHOD OF ADMINISTRATION

Adults, the elderly, and children over 12 years:

The contents of one or two sachets to be taken after each loose motion.

Children 1 to 12 years:

The contents of one sachet to be taken after each loose motion.

Infants under 1 year:

Not to be given unless instructed by a doctor, in which case one to one and a half the usual 24 hour feed volume should be given.

During the first 24 hours of illness ORS should replace normal feeds in bottle fed babies, gradually resuming normal feeds as the baby gets better. In breast fed babies, firstly the recommended amount of ORS should be given and then breast fed until satisfactory.

Response to treatment should be evaluated after 2 months. In patients with inadequate initial response, additional response after this time is unlikely. The therapeutic benefit should be reassessed regularly (at least every three months).

Reconstitution

The contents of each sachet should be dissolved in 200 ml (7 fluid ounces) of fresh drinking water (adults and children). Freshly boiled and cooled water should be used for infants and when fresh water is not available. The solution should be made up immediately before use and used within one hour. If refrigerated the solution can be kept for up to 24 hours.

A doctor should be consulted if symptoms persist for longer than 24 – 48 hours.

Method of administration

For oral use.

CONTRAINDICATIONS

Contraindicated in patients with phenylketonuria or those with hypersensitivity to any of the ingredients.

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

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Severe and persistent diarrhoea should be treated under medical supervision. If symptoms persist for more than 24 — 48 hours, medical advice should be sought. Inability to drink or retain fluids requires medical supervision.

Children

Rehydration treatment should only be given to children under 1 year of age on medical advice.

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

Renal Impairment

Medical supervision is necessary in patients with renal disease, including anuria and prolonged oliguria.

Hepatic Impairment: Low potassium or Sodium diets: Diabetes

Treatment should be supervised by a physician.

This product contains dextrose. Patients with rare-glucose-galactose malabsorption should not take this medicine.

Pregnancy & Lactation:

May be used during pregnancy and lactation as there are no known adverse effects.

Effect on Drive & operation machine:

This product has no effects on ability to drive and use machines.

consult with the doctor/pharmacist:

- If you have liver problems
- If you have kidney problems, including producing little or no urine
- If you have severe and persistent diarrhoea and sickness
- If you are unable to drink fluids, or are unable to keep fluids down
- If you have diabetes
- If you are on a low salt (sodium) diet
- If you are on a low potassium diet

DRUG INTERACTIONS

No data regarding the interactions of Oral Rehydration Salts (ORS) was found.

HIGH RISK GROUPS

ORS should not be given to patients suffering from Kidney dysfunction, and Neonates.

Adverse Drug Reactions

This medicine is not expected to cause side effects. The symptomatic adverse reactions may 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. In case you get any side effects or any undesirable event, talk to your doctor, pharmacist or nurse or can report at email: pv@searlecompany.com. By reporting side effects you can help provide more information on the safety of this medicine

OVERDOSE

The signs and symptoms that are produced after the acute overdosage of Oral Rehydration Salts (ORS) include Severe vomiting, Mucositis, Diarrhea, Severe myelosuppression, Hyperkalemia, Hypermnatremia.

SHELF LIFE

30 months from manufacturing date. The reconstituted solution should be discarded after 1 hour. Unused solution should be stored in a refrigerator and discarded 24 hours after preparation.

PRECAUTIONS

Store below 25°C. Store in a dry place.

Keep this medicine in a safe place out of the sight and reach of children. Use by the date on the end flap of the carton.

REGISTRATION NUMBER

Peditral Sachet (Orange): R.N. 061351

MANUFACTURE BY:

THE SEARL COMPANY LIMITED
Plot No. F-319, S.I.T.E. Area, Karachi, Pakistan.

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