Oralite Orange Oral Rehydration Salt®

Active Substances and Excipients:

Glucose Anhydrous	3.24 g
Sodium Chloride	0.624 g
Potassium Chloride	0.36 g
Trisodium Citrate Dihydrate	0.696 g
Orange flavour	0.03 g

Description:
Oralite Orange Oral Rehydration Salt® is a white orange flavoured powder pack in 4.95 g aluminium sachet.

Pharmacodynamics:
Administration of fluid and electrolytes by mouth to prevent or treat acute diarrhoea due to fluid and electrolytes lost through diarrhoea, vomiting and of normal losses due to respiration, sweating and urination which are especially high in infants. Acute diarrhoea leads to loss of essential water and salts and unless these are adequately replaced dehydration will develop. Prevention of dehydration is therefore the first appropriate response to diarrhoea. It is firmly established that, regardless of the causative agent of diarrhoea or the age of the patient, an oral rehydration solution containing glucose and essential salts is adequately absorbed and replaces both previous and continuing fluid and salts loses. It does not stop the diarrhoea, but the diarrhoea usually continues for only a limited time.

Pharmacokinetics:
Glucose accelerate the absorption of sodium and water from the small intestine and this process is not impaired during acute diarrhoea. Sodium chloride is readily absorbed from the gastro-intestinal tract. It is present in all body fluids but is mainly found in the extracellular fluid. The amount of sodium chloride normally lost in the sweat is small and the osmotic equilibrium is maintained by the excretion of surplus amounts in the urine. Potassium salts other than the phosphate, sulphate, and tartrate are generally readily absorbed from the gastro-intestinal tract. Potassium is excreted mainly by the distal tubules of the kidney; 5 to 10 mmol a day maybe excreted in the faeces, and some in perspiration.

The urinary excretion of potassium continues even when intake is low and faecal losses may be large in the presence of diarrhoea. Glucose is absorbed from the gastro-intestinal tract. Three pathways of metabolism are established: glycolysis leading to the formations of pyruvate (aerobic) or lactate (anaerobic), followed by the Krebs tricarboxylic acid cycle (citric acid cycle), leading to metabolism to carbon dioxide and water, a pentose phosphate pathway leads also to carbon dioxide and water. Energy is released in these processes. Glucose is also stored as glycogen in the liver and muscle. Blood-glucose concentrations are maintained, on healthy persons, within normal limits by the insulin, which facilitates the passage of glucose through cell membranes, and other homeostatic mechanisms. The body can metabolise about 800 mg per kg body-weight hourly. Glucose facilitates the absorption of sodium from the intestinal tract.

Indication:
Oralite Orange is used for replacement of body fluids and electrolytes lost after diarrhoea and vomiting.

Dose/Use Instruction:
Dissolve total content of a sachet completely in 8 oz (240 ml / feeding bottle or one glass) of cooled boiled water.

Adults: Depending on the amount of lost fluid, generally 200 to 400 ml of oral rehydration solution for every loose motion.

Children: 200 ml for every loose motion.

Infants: 1 to 1.5 times their usual feed volume. Normal feeding can continue after the initial fluid deficit has been corrected. Breast feeding should continue between administration of oral rehydration solution.

Contraindications:
Oral rehydration solutions are not appropiate for patients with gastrointestinal obstruction, oliguric or anuric renal failure, or when parenteral rehydration therapy is indicated as in severe dehydration or intractable vomiting.
Any portion of the prepared solution which remains unused after 24 hours should be discarded.

Do not add extra salt or sugar. Do not use if salts are wet. Consult doctor if condition does not improve.

Warnings and Precautions:
Sodium salts should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema and in toxaemia of pregnancy. Potassium salts should be administered by mouth in well-diluted solution. Intravenous injection should be given slowly as high blood concentrations may affect cardiac function. Potassium salts should be given cautiously to patients with renal or adrenal insufficiency, acute dehydration or heat cramp. Care should be exercised if potassium salts are given concomitantly with potassium sparing diuretics. Glucose tolerance may be impaired in patients with renal failure and in the early post traumatic state or in those with severe sepsis.

Interactions with Other Medications:
N/A

Usage during Pregnancy and Lactation:
N/A

Adverse Effects/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 then resumed in smaller, more frequent, amounts.

The risk of hypernatraemia or overhydration is low in patients with normal renal function. Overdosage of oral rehydration solution in patients with renal impairment may lead to hypernatraemia and hyperkalaemia.

Overdose and Treatment:
In the event of overdosage, hypernatraemia or hyperkalaemia could occur. Hypernatraemia requires the use of sodium-free fluids and the cessation of excessive sodium intake. Very occasionally dialysis has been needed in severe hypernatraemia. Iso-osmotic overload is managed by sodium and water restrictions plus measures to increase renal sodium and water loss such as loop diuretics (e.g. frusemide) or, in specific circumstances, antimineralcorticoid agents.

Mild hyperkalaemia may be treated with sodium polystyrene sulphonate, administered by mouth or as an enema. In severe hyperkalaemia, treatment with haemodialysis or peritoneal dialysis may become necessary. Hyperkalaemia associated with hyponatraemia may respond to treatment with infusions of sodium salts.

Dosage Forms and Packaging:
4.95 g powder packed in a aluminium sachet and packaged in paper carton box, each containing 50 and 100 sachets.

Manufacturer:
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