PACKAGE INSERT TEMPLATE FOR ORAL REHYDRATION SALT (ORS)

Brand or Product Name
[Product name] Powder for Oral Solution
[Product name] Liquid in the form of solution/suspension

Name and Strength of Active Substance(s)
Sodium chloride ……(12.683% w/v)
Glucose, anhydrous……...(65.854% w/v)
Potassium chloride……..…...(7.317% w/v)
Trisodium citrate, dihydrate ….(14.146% w/v)

Product Description

[Visual description of the appearance of the product (eg colour etc)]
*Eg:*A white to off-white colour granules, when dissolved in water, forms an orange colour solution.

Pharmacodynamics

The reconstituted solution contains a mixture of sodium and potassium salts along with glucose, which facilitates the absorption of sodium and potassium from the intestine. Water is drawn from the bowel by the osmotic effect. As well as "drying up" the stools, the dehydration and loss of electrolytes caused by the diarrhoea is corrected by the water and electrolytes absorbed.

Pharmacokinetics

Glucose
After oral administration glucose is completely absorbed by a sodium dependent uptake mechanism exhibiting saturation kinetics. Blood levels return to normal within two hours of ingestion.

Potassium Chloride
No specific control mechanisms limit absorption of potassium, which is usually complete. Potassium is excreted largely by the kidneys, though 10% is excreted by the colonic mucosa. Potassium excretion is reduced in patients with renal impairment and in the elderly, so extreme caution should be used in treating such patients with potassium salts.

Sodium Bicarbonate
Kinetics are determined by the physiological state of the patient at the time.

Sodium Chloride
Readily absorbed from the gastrointestinal tract. Gut absorption, particularly in the jejunum is enhanced by the addition of glucose. Under conditions of sodium balance, the excretion of sodium in the urine will match intake.

Indication

Oral rehydration salt is indicated for the treatment of diarrhoea and fluid loss due to diarrhoea in infants, children and adults.

Recommended Dosage

Dissolve contents in 250ml-1000ml of boiled, cool water and to be taken orally. Unused solution should be stored in a refrigerator and discarded 24 hours after preparation.

Infants
One litre over a period of 24 hours. 1 to 1.5 times their usual feed volume. Administer with care to infants.

Children
One litre over 8 to 24 hours, according to age. 250ml for every loose motion.

Adults
Drink freely as required, or as directed by the physician.250 to 1000ml of oral rehydration solution for every loose motion has been suggested.

Normal feeding can continue after the initial fluid deficit has been corrected. Breast feeding should continue between administrations of oral rehydration solution.

Mode of Administration

Oral powder

Contraindications

Oral Rehydration Salts are contraindicated in patients exhibiting the following conditions:- cirrhosis of the liver, congestive cardiac failure, nephrotic syndrome, acute and chronic renal failure, ischaemic heart disease, adrenocortical insufficiency, hyperkalaemic periodic paralysis, hyperkalaemia, hypoventilatory states, chloride depletion due to continuous gastric fluid loss, metabolic or respiratory alkalosis, hypocalcaemia, hyperosmolar states in anuria or oliguria, oedematous sodium retaining conditions, hypertension, peripheral or pulmonary oedema or toxaemia of pregnancy, severe vomiting, diarrhoea and dehydration requiring fluid therapy, dextrose malabsorption, in cases of diabetes mellitus, thiamine deficiency, severe under-nutrition, haemodilution, hypophosphataemia, sepsis and trauma. Oral rehydration salts are also contraindicated for use in patients undergoing treatment with the following:- sodium retaining drugs (e.g. corticosteroids, NSAID's, carbenoxolone), diuretics known to produce hypochloraemic alkalosis.

Warnings and Precautions

Administer with care in cases of acute dehydration, heat cramps, extensive tissue destruction or if patients are receiving potassium-sparing diuretics. Concurrent use with other potassium containing drugs may precipitate hyperkalaemia.
It is very important to dissolve oral rehydration salts in water of the correct volume. A weak solution will not contain optimum glucose and electrolyte concentration and a strong solution may give rise to electrolyte imbalance.Diarrhoea can have very serious consequences in children under 3 years old. Immediate medical advice should be sought. In other age groups, if symptoms persist for more than

24 - 48 hours, consult a doctor. If nausea and vomiting are present with the diarrhoea, small and frequent amounts of Oral Rehydration Salts should be drunk first. In infants, immediate medical assistance should be obtained. Use within one hour of reconstitution, or within 24 hours if stored in a refrigerator.

Interactions with Other Medicaments

Sodium Bicarbonate
Increases excretion of lithium, resulting in a reduced plasma-lithium concentration.

Potassium Chloride
ACE inhibitors (hyperkalaemia); cyclosporin (increased risk of hyperkalaemia). Potassium sparing diuretics where hyperkalaemia may result. No known interactions to other actives.

Statement on Usage During Pregnancy and Lactation
Use in patients with pre-eclampsia is contraindicated. The product should only be administered if the expected benefit to the mother is thought to outweigh any possible risk to the foetus or neonate.

Adverse Effects / Undesirable Effects

The following adverse effects have been reported although more commonly following excessive amounts:- hypernatraemia, oedema, nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation, lachrymation, sweating, fever, tachycardia, renal failure, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching, coma, convulsions, hyperkalaemia, gastro-intestinal ulceration, metabolic alkalosis, muscle hypertonicity, flatulence, dehydration and raised blood pressure.

Overdose and Treatment

Iso-osmotic overload is managed by restricting sodium, potassium and water intake plus measures to increase renal sodium, potassium and water output by using “loop diuretics” e.g. frusemide.

Storage Conditions
[eg: Store below 30° C, protect from light and moisture]

Dosage Forms and Packaging Available
[Packaging type & pack size]

Name and Address of Manufacturer
[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder
[Name & full address of marketing authorization holder]

Date of Revision of Package Insert
[day/month/year]