Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Name: Multiple Electrolytes and Dextrose Injection Type I USP - Kidrolyte
Strength: Not applicable
Pharmaceutical form: Solution for intravenous infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No.	Name of Ingredients	Specifications	Qt. in mg/100 mL	Used As
1.	Sodium Acetate	USP	0.320	Active Ingredient
2.	Potassium Chloride	USP	0.130	Active Ingredient
3.	Dibasic Potassium Phosphate	USP	0.026	Active Ingredient
4.	Magnesium Chloride	USP	0.031	Active Ingredient
5.	Dextrose monohydrate Eq. to Dextrose Anhydrous	USP	5.500 5.000	Active Ingredient
6.	Sodium Metabisulphite	USP	0.020	Anti-oxidant
7.	Hydrochloric Acid	USP	q.s. to pH	pH adjustment
8.	Water for Injection	USP	q.s.to 100 mL	Vehicle

3. PHARMACEUTICAL FORM

Solution for intravenous infusion

4. CLINICAL PARTICULAR

4.1 Therapeutic indication

This solution is indicated for use in adults as a source of electrolytes, calories and water for hydration and as an alkalinizing agent.

4.2 Posology and method of administration

Dosage:

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

When a hypertonic solution is to be administered peripherally, it should be slowly infused through a small bore needle, placed well within the lumen of a large vein to minimize venous irritation. Carefully avoid infiltration.

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Administration:

This solution is for intravenous use only.

4.3 Contraindications

Solutions containing dextrose may be contraindicated in patients with hypersensitivity to corn products.

4.4 Special warnings and precautions for use

Precaution:

This solution should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, impending or frank cardiac decompensation.

Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.

Additional essential electrolytes, minerals, and vitamins should be supplied as needed. Care should be exercised in administering solutions containing sodium or potassium to patients with

renal or cardiovascular insufficiency, with or without congestive heart failure, particularly if they are postoperative or elderly.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels.

Solutions containing potassium or magnesium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease.

Solutions containing acetate should be used with caution. Excess administration may result in metabolic alkalosis. Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result. If administration is not controlled by a pumping device, refrain from applying excessive pressure (>300mmHg) causing distortion to the container such as wringing or twisting. Such handling could result in breakage of the container.

This solution is intended for intravenous administration using sterile equipment.

Use only if solution is clear and container and seals are intact.

Warning:
Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

4.5 Interaction with other medicinal products and other forms of interaction

Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotropin, or to other salt-retaining patients.

Administration of barbiturates, narcotics, hypnotics, or systemic anesthetics should be adjusted with caution in patients also receiving magnesium-containing solutions because of an additive central depressive effect.

Parenteral magnesium should be administered with extreme caution to patients receiving digitalis preparations.

4.6 Pregnancy and lactation

Pregnancy:

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Multiple Electrolytes and Dextrose Injection. It is also not known whether Multiple Electrolytes and Dextrose Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Multiple Electrolytes and Dextrose Injection should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Caution should be exercised when Multiple Electrolytes and Dextrose Injection is administered to a nursing woman.

Labor and Delivery:

As reported in the literature, Dextrose and electrolyte solutions have been administered during labor and delivery. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

4.7 Effects on ability to drive and use machines

Not known

4.8 Undesirable effects

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

Too rapid infusion of hypertonic solutions may cause local pain and venous irritation. Rate of administration should be adjusted according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended.

Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential. Hypernatremia may be associated with edema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiacarrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation. If infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

Abnormally high plasma levels of magnesium can result in flushing, sweating, hypotension, circulatory collapse, and depression of cardiac and central nervous system function. Respiratory depression is the most immediate threat to life. Magnesium deficits can result in tachycardia, hypertension, hyperirritability and psychotic behaviour.

Phosphorus deficiency may lead to impaired tissue oxygenation and acute hemolytic anemia. Relative to calcium, excessive phosphorus intake can precipitate hypocalcemia with cramps, tetany and muscular hyperexcitability.

The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

4.9 Overdose

In the event of a fluid or solute overload during parenteral therapy, reevaluate the patient's condition, and institute appropriate corrective treatment.

In the event of over dosage with potassium-containing solutions, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

- Dextrose Injection USP, 10% or 25% containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.
- Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
- Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

Over-aggressive phosphate replacement may precipitate hypocalcemic tetany. To prevent hypocalcemia, calcium supplementation should always accompany phosphate administration.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group and ATC code: B05B B02 – Solution affecting electrolyte balance

5.2 Pharmacokinetic properties

Multiple Electrolytes and Dextrose Injection provides electrolytes and calories, and is a source of water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Potassium, the principal cation of intracellular fluid, participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Magnesium, a principal cation of soft tissue, is primarily involved in enzyme activity associated with the metabolism of carbohydrates and protein. Magnesium is also involved in neuromuscular irritability.

Phosphate is a major intracellular anion which participates in providing energy for metabolism of substrates and contributes to significant metabolic and enzymatic reactions in almost all organs and tissues. It exerts a modifying influence on calcium levels, a buffering effect on acid-base equilibrium and has a primary role in the renal excretion of hydrogen ions.

Acetate is an organic ion which is a hydrogen ion acceptor and contributes bicarbonate during its metabolism to carbon dioxide and water, and in sufficient quantities may serve as an alkalinizing agent.

Dextrose provides a source of calories. Dextrose is readily metabolized, may decrease losses of body protein and nitrogen, promotes glycogen deposition and decreases or prevents ketosis if sufficient doses are provided.

5.3 Preclinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite USP
Hydrochloric Acid USP
Water for Injection USP

6.2 Incompatibilities

Not known

6.3 Shelf life

24 Months from the date of manufacturing

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

Multiple Electrolytes and Dextrose Injection Type I USP - Kidrolyte is available as 500 mL in Plastic Bottle.

6.6 Special precautions for disposal

To be used with a pyrogen free IV administration set with aseptic technique.
For Intravenous administration. Keep in a cool place away from light.

7. APPLICANT/SUPPLIER

Otsuka Pharmaceutical India Private Limited
Survey No.199 to 201 & 208 to 210,
Village – Vasana – Chacharwadi,
Tal- Sanand,
Dist: Ahmedabad – 382 213, India.

8. FDA APPLICATION NUMBER

FDA/SD.203-09757

9. DATE OF REGISTRATION/ RENEWAL OF REGISTRATION

Renewal of registration: 25th September 2020

10. DATE OF TEXT REVISION OF THE TEXT

1st October 2020