POTAXINE INJECTION 10%W/V (10 ML AMPOULE)

COMPOSITION: Each ml contains Potassium Chloride 0.1 gm. Each ampoule contains Potassium Chloride 1 gm / 10 ml.

DESCRIPTION: A clear, colourless or almost colourless liquid.

PHARMACODYNAMICS: After intravenous administration, potassium is actively transported from extracellular fluid into cells where concentrations reach up to 40 times that of extracellular fluid. Potassium ion is the principal intracellular ion of most body tissues. Potassium ions are involved in a number of essential physiological processes, including the maintenance of intracellular tonicity, the transmission of nerve impulses, the contraction of cardiac, skeletal, and smooth muscle and the maintenance of normal renal function.

PHARMACOKINETICS: Secretion of potassium occurs via the kidneys and normally any amounts given in excess of intracellular requirements are rapidly eliminated.

INDICATION: The treatment of potassium depletion in patients with hypokalaemia. Treatment of digitalis intoxication. The I.V. route is indicated when the patient is unable to take potassium orally or if hypokalaemia is severe.

RECOMMENDED DOSAGE:

1. For I.V. administration only, dilute before infusing.

   Potaxine Injection is administered as a dilute solution by slow intravenous infusion. The dose and rate of injection are dependent upon the individual patient's condition. In patients whose serum potassium concentration is above 2.5 mEq / L, the rate of infusion should not exceed 10 mEq / hour in a concentration less than 30 mEq / L. The total dose should not exceed 200 mEq/24 hours.
   If urgent treatment is required (serum potassium concentration less than 2 mEq / L with ECG changes or paralysis), infuse potassium in a suitable concentration at a rate of 40 mEq / hour, up to a rate of 400 mEq / 24 hours period. In critical states potassium may be infused in saline (unless saline is contraindicated) rather than in glucose solutions, as the latter may decrease serum potassium concentrations.

2. Usually not more than 3 mEq / kg / day should be administered to young children. Infants may require 2 to 3 mEq / kg / day or 40 mEq / m^2 / day. Potassium may be added in low concentrations to peritoneal dialysis solutions.

ROUTE OF ADMINISTRATION: For I.V. infusion only

CONTRAINDICATIONS: Potaxine Injection is contraindicated in hyperkalaemia, severe burns, acute dehydration, heat cramps, severe renal failure, Addison's disease, metabolic disorders, ventricular fibrillation and AV or intraventricular heart block.

PRECAUTIONS / WARNINGS: The use of potassium salts in patients with chronic renal disease, adrenal insufficiency or any other conditions which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment. Hypokalaemia should not be treated by the concomitant administration of potassium salts and potassium-sparing diuretic (eg. spironolactone or triamterene), since the simultaneous administration of these agents can produce severe hyperkalaemia.
In patients on a low-salt diet, particularly, hypokalaemic hypochloraemic alkalosis is a possibility that they require chloride as well as potassium supplementation.
The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease or acidosis, requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the ECG and the patient's clinical status. Potaxine Injection should be used with caution in disease associated with heart block since increased serum potassium may increase the degree of block.

Warnings: Solutions of Potaxine Injection **must be diluted** before use. Careful and thorough mixing of solution after dilution is essential.
In patients with impaired mechanisms for excreting potassium, administration of potassium salts can produce hyperkalaemia and cardiac arrest. This is of particular concern in patients given I.V. Potaxine Injection. Potentially fatal hyperkalaemia can develop rapidly and be asymptomatic.

DRUG INTERACTIONS: Potassium sparing diuretics, including triamterene, spironolactone, amiloride and ACE inhibitors including enalapril and captopril may produce hyperkalaemia when administered concurrently with Potaxine Injection.

INCOMPATIBILITY: Potaxine Injection is incompatible with amphotericin. Incompatibilities have also been reported with amikacin sulphate, dobutamine hydrochloride and fixed oil emulsions.

SIDE EFFECTS / ADVERSE REACTIONS: The symptoms and signs of potassium intoxication include paraesthesia of the extremities, flaccid paralysis, listlessness, mental confusion, weakness and heaviness of the legs, fall in blood pressure, cardiac arrhythmias and heart block. Hyperkalaemia may exhibit the following ECG abnormalities: disappearance the P-wave, widening and slurring of QRS complex, changes of the S-T segment, tall-peaked T-waves, nausea, vomiting, diarrhoea and abdominal discomfort have been reported.

SYMPTOMS AND TREATMENT FOR OVERDOSE:
Overdosage: Hyperkalaemia due to overdosage is indicated by listlessness, mental confusion, paraesthesia of the extremities, weakness of the legs, flaccid paralysis, fall in blood pressure, cardiac depression, arrhythmias and heart block. Potassium levels of 8-11 mmol / L may result in death from cardiac depression, arrhythmias or arrest.

Treatment: Discontinue administration of Potaxine Injection and potassium chloride sparing diuretics. Parenteral frusemide with substantial doses of sodium chloride and bland fluids will assist excretion of excess potassium through the kidneys.
In renal failure, a cation exchange resin may be given eg. sodium polystyrene sulphonate 15 g four times daily by mouth or 30 g in 200 ml water as an enema.
In severe hyperkalaemia, treatment with haemodialysis or peritoneal dialysis may become necessary. Intravenous infusion of sodium bicarbonate 45-150 mEq over 5 minutes (repeated after 15 to 20 minutes if necessary) has been recommended to correct acidosis.

PACK SIZES: 10's x 10 ml ampoules.

STORAGE CONDITION: Store below 30ºC.
KEEP OUT OF REACH OF CHILDREN. *JAUHKAN DARIPADA KANAK-KANAK.*

SHELF LIFE: Please refer to outer package.

PRODUCT REGISTRATION HOLDER & MANUFACTURER:
DUOPHARMA (M) SDN BHD
Lot 2599 Jalan Seruling 59 Kawasan 3 Taman Klang
Jaya, 41200 Klang Selangor Darul Ehsan MALAYSIA

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