POTASSIUM CHLORIDE INJECTION DEMO 10% W/V

COMPOSITION
Each 10ml ampoule contains 1g of potassium chloride which is equivalent to 13.4 mmol K+ (13.4mEq).

PRODUCT DESCRIPTION
A clear colourless solution.

ACTIONS & PHARMACOLOGY
Potassium is an essential electrolyte in the body. It is the main intracellular action and is involved in numerous vital physiological processes including nerve conduction, muscle contraction and carbohydrate metabolism. The body contains about 40-50mmol of potassium per kg bodyweight, of which approximately 95% is found intracellularly. The normal concentration of potassium in intracellular fluid is about 150mmol/liter and that in plasma is 3.5 to 5.5mmol/liter.
Normally about 80% to 90% of potassium intake is excreted in the urine with some eliminated in the faeces and, to a small extent, in perspiration. The kidneys do not conserve potassium well, even when there is severe depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

INDICATIONS:
Prevention and treatment of moderate or severe potassium deficit when oral replacement therapy is not feasible

CONTRAINDICATIONS:
Severe renal impairment characterized by azotemia, oliguria or anuria, untreated Addison's disease, familial periodic paralysis, acute dehydration, heat cramps, hyperkalemia from any cause, early post-operative oliguria except during GI drainage.

PRECAUTIONS / WARNINGS:
Since plasma levels are not indicative of tissue levels, potassium replacement therapy should be administered with close medical supervision with frequent ECG monitoring and evaluation of the patient's clinical status and serum electrolytes. This is particularly important in patients with cardiac disease and those on digitalis therapy. Caution should also be exercised in patients with metabolic acidosis, renal or adrenal insufficiency, presence of conditions which predispose to hyperkalemia (such as prolonged or severe diarrhoea with vomiting, potassium-sparing diuretics), extensive tissue destruction (eg severe burns), hyponatremia and myotonia congenita.

Warnings
Concentrated potassium solutions are for IV admixtures only. Do not use undiluted. Direct injection may be instantaneously fatal.
Potassium intoxication: Do not infuse too rapidly because high plasma concentrations of potassium may cause death through cardiac depression, arrhythmia or arrest. Potassium replacement therapy should be closely monitored by frequent evaluation of ECG and patient's clinical status and serum electrolytes levels.
Renal impairment or adrenal insufficiency may increase the risk of potassium intoxication. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. Use with great caution, if at all.
In patients with renal insufficiency secondary to dehydration or shock, normal renal function should be reestablished before starting potassium replacement therapy.
Discontinue potassium-containing solutions if signs of renal insufficiency develop during infusions.
Metabolic alkalosis: Potassium depletion is usually accompanied by an obligatory loss of chloride, resulting in hypochloremic metabolic alkalosis. In such cases, administration of IV potassium chloride should be accompanied by treatment of the underlying cause of potassium depletion.
Metabolic acidosis: If hypokalemia is accompanied by metabolic acidosis (eg in renal tubular acidosis), the hypokalemia should be treated with an alkalizing potassium salt such as potassium bicarbonate, potassium acetate, potassium citrate or potassium gluconate.
Musculoskeletal/cardiac effects: In patients with low serum sodium or calcium concentrations, moderate elevation of serum potassium may cause toxic effects on the heart and skeletal muscle. Weakness and later paralysis of voluntary muscles, with consequent respiratory distress and dysphagia are generally late signs, sometimes significantly preceding dangerous or fatal cardiac toxicity.
Use in pregnancy: It is not known whether potassium salts can cause fetal harm when administered to a pregnant women. As such, potassium salts should not be used in pregnant mothers unless the potential benefits outweigh the potential risks to the fetus.
Use in lactation: Caution should be exercised when administering to nursing mothers, and the potential benefits versus potential risks to the nursing infant should be considered.
Use in elderly: No additional precautions are necessary for administration to elderly patients.

DRUG INTERACTIONS:
ACE inhibitors: Concurrent use may result in elevated serum potassium concentrations in certain patients.
Potassium-sparing diuretics/potassium-containing salt substitutes: Concurrent use will increase potassium retention and can produce severe hyperkalemia especially in patients with renal insufficiency.
Digitalis therapy: In patients receiving digitalis therapy, too rapid lowering of plasma potassium levels may result in digitalis toxicity. Thus, caution should be exercised when discontinuing a potassium preparation in patients maintained on digitalis therapy.

SIDE EFFECTS / ADVERSE REACTIONS:
Adverse reactions involve the possibility of potassium intoxication. Signs and symptoms include: paresthesia of extremities, flaccid paralysis, heaviness, muscle weakness, listlessness, mental confusion, hypotension, ECG abnormalities, cardiac arrhythmias, heart block and cardiac arrest.

ADMINISTRATION AND DOSAGE:

Do not administer undiluted potassium.

Potassium preparations must be diluted with suitable large volume parenteral solutions, mixed well and given by slow IV infusion. Too rapid infusion of hypertonic solutions may cause local pain and rarely, vein irritation. Adjust rate of administration according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended.

Dose and infusion rate varies according to urgency and degree of hypokalaemia. The range of potassium levels that constitute mild, moderate or severe hypokalaemia also vary according to the institution. A general rule is the following:

- For mild hypokalaemia, 40mmol in 1000ml of 0.9% sodium chloride or 5% glucose infusion administered peripherally (or centrally) over at least 4 hours, ie 10mmol/1000 ml/h.
- For severe hypokalaemia, 40mmol in 500ml of 0.9% sodium chloride infusion administered peripherally (or centrally) over at least 4 hours, ie 10mmol/500ml/h.
- In the ICU only, via a central line with continuous ECG monitoring of rate and rhythm, 40mmol in 100ml 0.9% sodium chloride infusion administered over at least 2 hours, ie 20mmol/100ml/h.

The maximum rate for general ward areas is 10mmol/h. Faster administration rates are only advisable if central line and cardiac monitoring are available. In these situations, a maximum rate of 20mmol/h is recommended.

Glucose 5% may cause trans-cellular shift of potassium into cells. As such, sodium chloride 0.9% is the preferred infusion fluid.

Pain or phlebitis may occur during IV administration of solutions containing 30mmol or more potassium/1000ml.

Avoid "layering" of potassium by proper agitation of the prepared IV solution. Do not add potassium to an IV bottle in the hanging position.

Dosage should be individualized in terms of dosage and rate of infusion based on ECG and serum electrolyte determinations.

Children: IV infusion up to 3 mEq/kg or 40 mEq/m^2/day. Adjust volume of administered fluids to body size.

OVERDOSAGE AND TREATMENT:

Mild (<5.5 to 6.5 mEq/L) to moderate (>6.5 to 8 mEq/L) hyperkalemia may be asymptomatic and manifested only by increased serum potassium concentration and characteristic ECG changes. Other symptoms include muscular weakness, progressing to flaccid quadriplegia and respiratory paralysis; however, these generally do not develop unless potassium concentrations exceed 8 mEq/L. Dangerous cardiac arrhythmias often occur before onset of complete paralysis. Hyperkalemia, when detected, must be treated immediately because lethal levels can be reached in a few hours. Note that hyperkalemia produces symptoms paradoxically similar to those of hypokalemia. ECG abnormalities include progressive increase in height and peaking of T waves, lowering of the R wave; decreased amplitude and ultimate disappearance of P waves; prolongation of PR interval and QRS complex; shortening of the QT interval and finally, ventricular fibrillation and death.

Treatment:

Discontinue potassium therapy.

Monitor ECG.

Infusion of combined dextrose and insulin in a ratio of 3g dextrose to 1 unit regular insulin may be administered to shift potassium into cells.

Administer sodium bicarbonate 50 to 100 mEq IV to reverse acidosis and also to produce an intracellular shift.

Give 10 to 100 ml calcium gluconate or calcium chloride 10% to reverse ECG changes. To remove potassium from the body, use hemodialysis or peritoneal dialysis.

In digitalized patients too rapid lowering of serum potassium can cause digitalis toxicity.

STORAGE:

Store below 30˚C.

Keep out of reach of children

Shelf-life: 5 years

PRESENTATION

10 ml per plastic ampoule, 50 ampoules per carton box.

MADE IN GREECE BY:

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