INSTRUCTION
on the drug medical use
KALIUM CHLORIDE
solution for infusion 4 %

COMMERCIAL TITLE: Kalium Chloride
INTERNATIONAL NONPROPRIETARY NAME: Potassium chloride
DOSAGE FORM: Solution for infusion 4 %
COMPOSITION: *Active ingredient*: potassium chloride – 40 g/L, *inactive ingredient:* water for injection.
DESCRIPTION: Clear, colorless solution.
PHARMACOTHERAPEUTICAL GROUP – Potassium preparations
CODE ATC: B05XA01
PHARMACOLOGICAL EFFECT
Pharmacodynamics
Potassium is the major ion of body cells, plays an important role in the regulation of various body functions. It is essential for maintenance of acid-base balance, isotonicity and electric membrane potential of cell.
It is necessary for the conduction of nerve impulses and muscular contraction. The drug improves muscular contraction in muscular dystrophy and myasthenia.
Potassium chloride is used as a source of potassium ions for prevent and recovery potassium deficiency in body.
Pharmacokinetics
Potassium chloride is vell and quickly absorbed through the gastrointestinal tract; mainly excreted by the kidneys by secretion in the distal tubule, where also is exchange sodium- potassium ions.
The ability of the kidneys to maintain potassium is insignificant, its urinary excretion is maintained even in significant decrease of potassium level in the body.
Tubular secretion of potassium is influenced by chloride ion concentration, hydrogen ion exchange, acid-base balance, and adrenal hormones.
A small amount of potassium excreted in faeces, and saliva, then with bile and pancreatic juice.
INDICATIONS
Prevention and treatment of hypokalemia, caused by various reasons (use saluretics, increased potassium excretion by the kidneys, etc.); prevention of hypokalemia in patients with arrhythmias or patients taking digitalis preparations; intoxication with digitalis drugs.
DOSAGE AND ADMINISTRATION
The drug is used only in diluted form.
Adults, children and elderly intravenously by infusion (20 - 30 drops per minute) to 1,5 g in 500 ml of sodium chloride isotonic solution or 5 % glucose solution.
The dose is dependent on the content of potassium in the blood serum.
Potassium deficiency is calculated by the following formula:
Potassium (mmol) = body weight (kg) x 0.2 x 2 x 4.5
1 ml of drug solution contains 0.52 mmol of potassium.
4,5 - normal level of potassium in serum (in mmoles).
Maximal daily dose is not exceeded 2-3 mmol potassium in kg of body weight.
The drug must be administrated with infusion pump, if needed to use high dose and quickly administration.
CONTRAINDICATIONS
Hypersensitivity to the components of the drug product, erosive and ulcerative diseases of the gastrointestinal tract, concomitant therapy with potassium-sparing diuretics, metabolic disorders (acidosis, hypovolemia with hyponatremia), hyperkalemia, hyperchloremia, renal dysfunction (with oliguria, anuria, azotemia), Addison's disease, acute dehydration, heat cramps, age up to 18 years (safety and effectiveness have not been established).
SIDE EFFECTS
Nausea, vomiting, diarrhea, flatulence, abdominal pain, ulceration of the mucous membrane of the gastrointestinal tract, gastrointestinal bleeding, perforation and intestinal obstruction; lowering blood pressure, slowing of atrioventricular conduction, up to the complete AV blockade; allergic reactions.
High doses of the drug can cause hyperkalemia, especially in patients with renal failure.
Symptoms of hyperkalemia: paresthesia of the extremities, muscle weakness, paralysis, arrhythmias, heart block, cardiac arrest, mental confusion.
Local reactions: at concentration more than 30 mmol / L phlebitis and pain on the site of intravenous administration.
OVERDOSAGE
Overdose symptoms: paresthesia of the extremities (first feature), weakness, mental confusion, heaviness of legs, peripheral paralysis, pallor and coldness of the skin, pressure decrease, arrhythmia, cardiovascular collapse, and heart block.

Extremely high concentration of potassium in the plasma (8-11 mmol/L) may be the cause of death due to cardiac depression, arrhythmias or cardiac arrest.
If potassium concentration in serum is above 6,5 mmol/L or in the development of arrhythmias require immediate intravenous injection of 10-20 ml of 10% calcium gluconate solution for 1-5 minutes, with mandatory ECG monitoring.
Plasma concentrations of potassium can be reduced by intravenous infusion 300-500 ml of 10-25% glucose solution with insulin (10 units of insulin per 20 g glucose) for one hour or infusion sodium bicarbonate solution.

CAUTIONS

A concentrated solution! Apply with diluted in 0,9% sodium chloride or 5% glucose solutions.

The drug should be administered intravenously with caution, because of the high risk of hyperkalemia, especially in patients with renal failure.
Use with caution in patients with I-II degree AV block.
The safety and effectiveness of potassium chloride in the pediatric population have not been established.
A diet high in sodium increases the excretion of potassium from the body.
It should be borne in mind that hyperkalemia, leading to death, can develop quickly and be asymptomatic.
Acute hyponatremia can lead to acute hyponatremic encephalopathy (cerebral edema) characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with cerebral edema are at particular risk of severe, irreversible and life-threatening brain damage.
Children, women of reproductive age, and patients with reduced cerebral compliance (eg, meningitis, intracranial bleeding, brain contusion, and cerebral edema) are at particular risk of severe and life-threatening cerebral edema caused by acute hyponatremia.
Potassium salts should be administered with extreme caution to patients with heart disease or conditions predisposing to hyperkalemia, such as renal or adrenal insufficiency, acute dehydration, or extensive tissue destruction, as occurs in severe burns.
The potassium level in the blood serum and the ECG should regularly be monitored in the treatment period, especially in patients with renal failure, cardiovascular diseases as well as in patients receiving digitalis medications.
Initial potassium replacement therapy should not involve glucose infusions, because glucose may cause a further decrease potassium concentration in plasma.

Pregnancy and breast-feeding

Use the drug during pregnancy and breast-feeding is possible only in case of acute need if expected benefit exceeds potential risk.

Effects on ability to drive and use machines

Given the possible side effects, care must be taken when driving and performing work that requires precise coordination of movements.

DRUG INTERACTIONS

Beta-blockers increased both the maximum serum potassium concentration and the time required for it to return to baseline in patients who received an urgent intravenous loading dose of potassium.
Non-steroidal anti-inflammatory drugs increase the risk of hyperkalemia, due to the development of secondary hyperaldosteronism after inhibition of prostaglandin synthesis in the kidneys.
Heparin reduces the synthesis of aldosterone, which can lead to the development of hyperkalemia, especially in the presence of renal failure or other conditions that impair the excretion of potassium from the body.
The administration of potassium preparations is not recommended in patients with severe and complete heart block, concomitantly using cardiac glycosides. In the case of using potassium preparations to correct hypokalemia, careful monitoring of the patient's condition is required.
Concomitant use with insulin, sodium bicarbonate reduces serum potassium.
At simultaneous application with potassium-sparing diuretics (spironolactone, triamterene, amiloride), NSAIDs, angiotensin converting enzyme inhibitors, angiotensin II receptor antagonists, cyclosporine increases risk of hyperkalemia, which may be accompanied by convulsions and arrhythmias.

STORAGE CONDITIONS

Store at temperature from 10 to 25 °C in the protected from light place and out of reach of children.

SHELF LIFE

2 years. Do not use after expiry date indicated on the packing.

RELEASE FORM

Per 200 ml in plastic PVC bags.

DELIVERY TERMS

Prescription medicine.

MANUFACTURER

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