

USER INFORMATION
READ CAREFULLY

INFUSOL® K⁺ 0.15 D5
POTASSIUM CHLORIDE 0.15% w/v and DEXTROSE 5% w/v
INTRAVENOUS INFUSION BP

Composition:

Potassium Chloride BP 1.5 g/L
Dextrose Anhydrous BP 50.0 g/L

Electrolytes:	mmol/L	mEq/L	=	10mmol/500mL
Potassium Ion (K ⁺)	20	20		
Chloride Ion (Cl ⁻)	20	20		
Caloric Value: Approx. 837 kJ/L (200kcal/L)				
Osmolarity :	318 mOsm/L			

Product Description:

Potassium Chloride 0.15% and Dextrose 5% solution is a colourless or faintly straw-coloured intravenous (IV) solution.

Pharmacodynamic:

The pharmacodynamic properties of this solution are those of its components (potassium, chloride and glucose). Potassium is predominantly an intracellular cation, primarily found in muscle; only about 2% is present in the extracellular fluid. It is essential for numerous metabolic and physiological processes including nerve conduction, muscle contraction, and acid-base regulation. Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Glucose is the principal source of energy in cellular metabolism.

Pharmacokinetics:

The pharmacokinetic properties of Potassium Chloride 0.15% and Dextrose 5% are those of its components (potassium, chloride and glucose). Intravenous administration of this solution provides an immediate supply of electrolytes and glucose to blood. Factors influencing potassium transfer between intracellular and extracellular fluid such as acid-base disturbances can distort the relationship between plasma concentrations and total body stores. Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules in exchange for sodium or hydrogen ions. The capacity of the kidneys to conserve potassium is poor and some urinary excretion of potassium continues even when there is severe depletion. Some potassium is excreted in the faeces and small amounts may also be excreted in sweat. The two main metabolic pathways of glucose are gluconeogenesis (energy storage) and glycogenolysis (energy release). Glucose metabolism is regulated by insulin.

Indication:

Prevention and treatment of potassium depletion in cases where supply of energy is required.

Recommended Dosage:

The dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient and concomitant therapy.

The maximum recommended dose of potassium is 2 to 3 mmol/kg/24h

Route of administration: Intravenous (IV)

Rate of Infusion:

Max 10 mmol/h of K⁺ when serum K⁺ > 2.5 mmol/L

Max 40 mmol/h of K⁺ when serum K⁺ < 2 mmol/L

Monitoring:

Adequate urine flow must be ensured and careful monitoring of plasma-potassium and other electrolyte concentrations is essential. High dosage or high speed infusion must be performed under ECG control.

Contraindications:

- Hyperkalaemia,
- Severe renal impairment with oliguria, anuria, or azotaemia,
- Hyperchloraemia,
- Acute ischaemic stroke,
- Head trauma (first 24 hours).

Warnings and Precautions:

Potassium should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalaemia such as renal or adrenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns. Regular monitoring of clinical status, serum electrolytes and ECG is advisable in patients receiving potassium therapy, particularly those with cardiac or renal impairment. In diabetic patients, the amount of infused glucose has to be taken into account and insulin requirements may be modified. During long term parenteral treatment, a convenient nutritive supply must be given to the patient.

Interactions with Other Medicaments:

Solutions containing potassium should be used with caution in patients receiving drugs that increase serum potassium concentrations (potassium-sparing diuretics, ACE inhibitors, cyclosporine, and drugs that contain potassium such as potassium salts of penicillin). Glucose should not be administered through the same infusion equipment as whole blood as haemolysis and clumping can occur.

Statement on usage during pregnancy and lactation:

There is no data reported in the literature on special warnings or precautions regarding the use of Potassium Chloride 0.15% and Dextrose 5% solution in case of pregnancy or lactation. It may be used during pregnancy and lactation under the supervision of the prescribing physician.

Adverse Effects/Undesirable Effects:

Adverse reactions may be associated with the technique of administration, including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

Overdose and Treatment:

Excessive administration of potassium may lead to the development of hyperkalaemia, especially in patients with renal impairment. Symptoms include paresthesia of the extremities, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion.

One of the important indicators of potassium toxicity is ECG changes including tall, peaked T-waves, depression of S-T segment, disappearance of the P-wave, prolongation of the Q-T interval, and widening and slurring of the QRS complex. Treatment of hyperkalaemia involves the administration of calcium, insulin or sodium bicarbonate, and exchange resins or dialysis.

Excessive administration of chloride salts may cause a loss of bicarbonate with an acidifying effect. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant symptomatic and supportive measures should be provided as necessary.

Incompatibilities:

The compatibility of any additives to this solution should be checked before use. The additives should be verified for solubility and/or stability in water at the pH of this solution (4.5 - 7.0) before adding. When a compatible medication is added to this formulation, the solution must be administered immediately, unless dilution has taken place in controlled and validated aseptic conditions.

As a guidance, the solution are incompatible with the following medications (non-exhaustive listing):

- Amphotericin B
- Dobutamine.

Additives known to be incompatible should not be used.

Caution:

Single dose container. Discard all unused contents. Do not use if leakage is detected.
If any visible solid particles, growth or turbidity appears during storage, the product should not be used.

Shelf Life:

5 years from manufacturing date in proposed storage condition. Do not use after expiry.

Storage condition:

Do not store above 30°C.

Dosage form and packaging available:

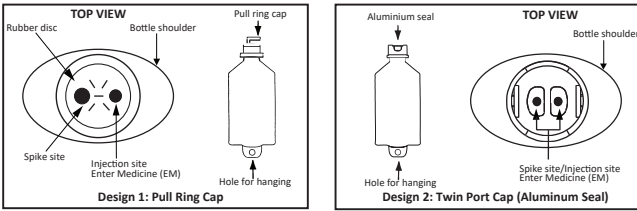
500mL x 20 LDPE plastic bottle per carton

Manufacturer / Product Registration Holder:**AIN MEDICARE SDN.BHD.**

Lot 4933, 4934 & PT2464, Jalan 6/44, Kaw. Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan, MALAYSIA.









HANDLING INSTRUCTION

AIN MEDICARE INTRAVENOUS INFUSION FLUID IN LOW DENSITY POLYETHYLENE (LDPE) BOTTLE
The bottle is made from injectable grade polyethylene.

PARTS OF THE PLASTIC BOTTLE

Top view after pull ring cap is removed. Please refer whichever applicable design.

INSTRUCTION FOR THE USAGE OF IV ADMINISTRATION SET & ADDITION OF DRUG

 Design 1	<p>1. Before use check for any solid particle, growth, turbidity or leakage. Discard the product if particle, growth, turbidity or leakage is found.</p>	 Design 2
 Design 1	<p>2. Design 1: Pull the cap's ring until completely removed. Design 2: Pull the aluminum seal until completely removed by centre line.</p>	 Design 2
 Design 1	<p>3. Additives may be injected through injection site (Refer to Design 1 or 2 whichever applicable) on the rubber. Mix the solution thoroughly.</p>	 Design 2
 Design 1	<p>4. Hold bottle down firmly and insert a spike of administration set into the spike site for Design 1 or for Design 2, pull the other aluminium seal until completely removed before inserting a spike of administration set. <i>(Spike site is meant for spiking of the administration set and is only for single use)</i></p>	 Design 2

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