

1. NAME OF THE MEDICINAL PRODUCT

Sterile Potassium Chloride Concentrate BP, 15% w/v, 1.5g in 10ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10ml contains 15% w/v (1.5g) Potassium Chloride BP.

3. PHARMACEUTICAL FORM

Clear, colourless, sterile, aqueous solution for injection, intended for parenteral administration to human beings.

4. Clinical Particulars

4.1. Therapeutic Indications

For use in patients requiring supplemental potassium therapy.

4.2. Posology and Method of Administration

Route of administration: Intravenous, after dilution.

Before administering Sterile Potassium Chloride Concentrate:

- 1.) This solution must be diluted with not less than 50 times its volume of sodium chloride solution or other suitable diluent.
- 2.) The solution should be carefully mixed with the infusion fluid.

During administration:

- 1.) The diluted injection should be administered by slow intravenous infusion at a maximal rate of 20mmol of potassium per hour.
- 2.) The ECG should be monitored continuously.

The goal of potassium replacement therapy is to elevate the plasma concentration of the ion to within the normal range.

Dose per hour: The maximal rate of intravenous infusion is 20mmol/hour.

Dose per day: Since the normal dietary intake of potassium is 50 to 100mmol daily, it is rare that a larger amount is required during potassium replacement therapy.

4.3. Contra-Indications

- 1.) Sterile Potassium Chloride Concentrate should never be used undiluted.
- 2.) Hyperkalaemia.

4.4. Special Warnings and Special Precautions for Use

The diluted solution should always be given slowly as high blood concentrations of potassium may cause serious cardiac toxicity.

Particular care is required when administering potassium to patients with renal or adrenal insufficiency, cardiac disease or extensive tissue destruction as may occur with severe burns.

In cases of renal insufficiency due to severe dehydration, excretory function should be

restored by correction of the fluid deficit in order to ensure adequate urinary excretion of potassium before its parenteral administration. Where renal insufficiency is accompanied by either inadequate urinary excretion of potassium or defective cellular uptake of potassium, administration of standard doses of potassium could result in life-threatening hyperkalaemia.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

Concomitant use of other drugs containing potassium or agents having the potential for hyperkalaemia, such as potassium-sparing diuretics, may lead to accumulation of potassium.

4.6. Pregnancy and Lactation

Potassium chloride should be used during pregnancy or lactation only if considered essential by the physician.

4.7. Effects on Ability to Drive and Use Machines

Nil.

4.8. Undesirable Effects

Excessive intake of potassium may cause hyperkalaemia, with paraesthesia, muscle weakness, paralysis, hypotension, cardiac arrhythmias and cardiac arrest.

4.9. Overdose

All drugs containing potassium should be withdrawn and potassium-sparing diuretics discontinued. Infusions of glucose alone or with insulin, or sodium bicarbonate solution may be used to reduce serum potassium concentrations. Intravenous administration of calcium gluconate may be used to treat cardiac toxicity. Mild hyperkalaemia may be treated with sodium polystyrene sulphonate, a cation-exchange resin administered by mouth or as an enema. If the above measures fail, haemodialysis or peritoneal dialysis may be required.

5. Pharmacological Properties

5.1. Pharmacodynamic Properties

Active ion transport by the sodium-potassium ATP ASE carrier maintains a high gradient of potassium across the plasma membrane. Intracellular concentrations of potassium are about 150 mEq per litre while the plasma concentration is in the range of 3.5 to 5 mEq per litre, although there is a modest variation from one cell type to another.

Potassium plays a vital physiological role in maintenance of normal electrical excitability of nerve and muscle. It is also important in the genesis and correction of imbalances of acidbase metabolism.

In acute hypokalaemia, parenteral administration of potassium chloride promptly corrects the deficit in plasma potassium concentration and restores normal physiological function to potassium-dependent systems.

5.2. Pharmacokinetic Properties

Potassium is an essential dietary constituent and is readily absorbed from the gastrointestinal tract. Accumulation of potassium by cells occurs via an energy-dependent mechanism that extrudes sodium. Active ion transport systems maintain a high gradient of potassium across the plasma membrane, resulting in plasma concentrations of about 3.5 to 5 mEq per litre and intracellular concentrations of approximately 150 mEq per litre.

Potassium is excreted mainly by the kidneys. It is freely filtered at the glomerulus and is mainly absorbed in the proximal tubules, so that by the time the tubular fluid reaches the late distal tubules, it contains less than 10% of the amount of potassium in the original glomerular filtrate. Normally, considerable amounts of potassium are secreted into the distal tubules and secretory transport is extremely important for the control of plasma potassium concentration.

As a consequence of the large volume of distribution and the rapid response of the kidney, intracellular and extracellular concentrations of potassium are normally maintained within relatively narrow limits. However, when potassium is administered as a drug, the factors that govern the rate and extent of its distribution are of critical importance. Although administration of potassium will not significantly increase the total body content of the ion, it may easily raise the extracellular concentration excessively. Because it is the extracellular concentration of potassium that determines life-threatening toxicity, awareness of the transient concentration achieved in plasma should govern the use of potassium therapy.

5.3. Pre-Clinical Safety Data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. Pharmaceutical Particulars

6.1. List of Excipients

Water for Injections BP.

6.2. Incompatibilities

Incompatibilities have been reported with dobutamine hydrochloride, amphotericin, amikacin sulphate and fixed oil emulsions

6.3. Shelf Life

5 years (60 months).

6.4. Special Precautions for Storage

Keep in outer carton
Do not store above 25°C.

6.5. Nature and Content of Container

10ml, clear Open point cut (OPC) glass ampoules, glass type 1 Ph.Eur. packed in cardboard cartons to contain 10 x10ml ampoules.

6.6. Instructions for Use, Handling and Disposal

Warning: Must be diluted before use.

Dilute before use with not less than 50 times its volume of Sodium Chloride Injection or another suitable diluent. Discard if cloudy or deposit present.

Use as directed by the physician.

If only part used, discard the remaining solution.

Keep out of reach of children.

ADMINISTRATION DATA

7. MARKETING AUTHORISATION HOLDER

Antigen International Ltd.,
Roscrea,
Co. Tipperary,
Ireland.

8. MARKETING AUTHORISATION NUMBER

PL 2848/5917R.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

1/12/86.

10. DATE OF (PARTIAL) REVISION OF THE TEXT

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