SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride Concentrate 15%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

15% of Potassium Chloride in 10ml

3 PHARMACEUTICAL FORM

Sterile Injection

4.1 Therapeutic indications

Potassium Chloride Concentrate 15% is used as a source of the potassium cation for the treatment or prevention of potassium depletion in patients for whom dietary measures or oral medication are inadequate. Potassium salts may also be used cautiously in those taking digoxin where potassium depletion may cause arrhythmias. Potassium Chloride Concentrate 15% must be administered by slow IV, as a dilute solution.

4.2 Posology and method of administration

Adults (including elderly) and Children:

Potassium Chloride Concentrate 15% must be diluted by adding to a large volume intravenous fluid before use. For example, 10mls diluted with not less than 500mls 0.9% Sodium Chloride Intravenous Infusion BP, or other suitable diluent, and mixed well.

Dosage depends on the serum ionogram value and the acid-base state. A potassium deficiency is calculated according to the formula:

MMOL Potassium = KG BW x 0.2 x 2 x (4.5 – actual serum potassium (MMOL)).

(The extracellular volume is calculated from the body weight in KG x 0.2).

It is recommended not to exceed 2-3 MMOL potassium per kg body weight in 24 hours.

4.3 Contraindications

Hyperkalaemia, Hyperchloraemia, impaired renal function with oliguria, anuria or azotaemia, Addison’s disease, acute dehydration and heat cramps.

4.4 Special warnings and precautions for use

Potassium Chloride Concentrate 15% must not be injected undiluted.

Plasma potassium concentration must be measured at regular intervals to avoid the development of hyperkalaemia, especially in patients with renal impairment.

ECG monitoring facilities should be available.

Initial potassium replacement therapy should not involve glucose infusions, because glucose may cause a further decrease in the plasma potassium concentration.

Potassium supplements should be administered with caution in patients with cardiac disease and in patients who are receiving potassium sparing diuretics or other medications which may increase plasma potassium levels.

4.5 Interaction with other medicinal products and other forms of interaction

Potassium sparing diuretics:
Potassium supplements should not be administered with potassium- sparing diuretics (such as amiloride, spironolactone and triamterene), particularly in patients with impaired renal function. Any patients on this combination require close monitoring in order to diagnose a potential hyperkalaemic condition as soon as possible.

Angiotensin-converting enzyme inhibitors and angiotensin II receptor antagonists:
Patients taking ACE-inhibitors or angiotensin II receptor antagonists, especially those with impaired renal function, should be closely monitored, as the potassium sparing effect in combination with potassium infusion may result in hyperkalaemia.

Ciclosporin:
Concurrent use of ciclosporin may increase the risk of hyperkalaemia.

Glucose Infusion:
Concomitant use of glucose infusions in hypokalaemic patients may cause a further decrease in plasma potassium concentrations.

4.6 Pregnancy and lactation

Potassium Chloride Concentrate 15% may be used during pregnancy and lactation under the supervision of the prescribing physician.

4.7 Effects on ability to drive and use machines

Not known

4.2 Undesirable effects

Pain at the injection site and phlebitis may occur during IV administration of solutions containing 30 MMOL potassium or more per litre.

Hyperkalaemia is the most common and serious hazard of potassium therapy.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report

any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Clinical signs and symptoms of potassium overdosage include:
paraesthesia of the extremities, listlessness, mental confusion, weakness or heaviness of the legs, flaccid paralysis, cold skin, grey pallor, peripheral vascular collapse, fall in blood pressure, cardiac arrhythmias and heart block. Extremely high plasma potassium concentrations (8-11mmol/litre) may cause death from cardiac depression, arrhythmias or arrest.

Cardiac Arrhythmias or a serum concentration above 6.5mmol/litre require immediate attention and may be treated by intravenous injection over 1-5 minutes of 10-20ml of 10% Calcium Gluconate Injection BP with E.C.G monitoring. Serum concentrations may be reduced by infusion of 300-500mls per hour of 10%-25% glucose solutions containing up to 10 units of insulin for each 20g of Glucose, or by the infusion of Sodium Bicarbonate Solution.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Potassium is the major cation of intracellular fluid and is essential for maintenance of acid-base balance, isotonicity and the electrodynamic characteristics of the cell. Potassium chloride is used as a source of the potassium cation for treatment or prevention of potassium depletion in patients in whom dietary measures are inadequate. Potassium chloride may also be used cautiously to abolish arrhythmias or cardiac glycoside toxicity precipitated by a loss of potassium.

5.2 Pharmacokinetic properties

Potassium chloride is generally readily absorbed from the gastro-intestinal tract. Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules which are also the site of sodium-potassium exchange. The capacity of the kidneys to conserve potassium is poor and urinary excretion of potassium continues even when there is severe depletion. Tubular secretion of potassium is influenced by several factors, including chloride ion concentration, hydrogen ion exchange, acid-base equilibrium and adrenal hormones. Some potassium is excreted in the faeces and small amounts may also be excreted in saliva, sweat, bile and pancreatic juice.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid Ph. Eur.

Water for Injections Ph. Eur.

6.2 Incompatibilities

The compatibility of the large volume IV fluid intended for dilution should be checked before use.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Protect from light and store at less than 25ºC

6.5 Nature and contents of container

10ml clear glass ampoules, hermetically sealed under flame at the gauging point

The ampoules are packed in cartons to contain 10 ampoules

6.6 Instructions for use, handling and disposal

Use as directed by a physician

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PL 01502/0007R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/06/1986 / 22/05/2002

10 DATE OF REVISION OF THE TEXT

26/06/2020