SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 15% w/v Concentrate for Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3 PHARMACEUTICAL FORM

Concentrate for Solution for Infusion

Clear, colorless, sterile, aqueous solution for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For use in patients requiring supplemental potassium therapy.

4.2. Posology and Method of Administration

Posology

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.

Method 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.

Deleted: ¶

4.3. Contra-Indications

1.) Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
2.) Sterile Potassium Chloride Concentrate should never be used undiluted.
3.) Hyperkalaemia (plasma-potassium concentration above 5 mmol/litre).
4.) Hyperchloraemia,
5.) Impaired renal function with oliguria, anuria or azotaemia
6.) Addison's disease,
7.) Acute dehydration
8.) Heat cramps.

4.4 Special warnings and precautions for use

Administration – see also section 4.2

• Only use with specialist advice

• ECG should be used throughout and monitored continuously

• High concentrations of potassium cause serious cardiotoxicity, so the concentration of the solution should not exceed 3g (40mmol)/L and the diluted solution given slowly (maximal rate 20mmol/L)

• Initially do not use with glucose infusions – glucose may further decrease potassium levels

Other concurrent treatment – also see section 4.5

• Extreme caution in patients on potassium sparing diuretics and other drugs that may increase potassium

• Glucose infusion – see above Administration

Monitoring

• Continuous ECG monitoring – see above Administration

• Regular potassium levels especially in patients with renal impairment (see section 4.3)

Underlying conditions – see also section 4.3

• Dehydration must be corrected to ensure adequate urinary output (and potassium excretion)

• Where renal excretion of potassium or cellular uptake deficient – life threatening hyperkalaemia can occur with standard doses

• Extreme caution with extensive tissue destruction (eg burns)

• Extreme caution in cardiac disease

4.5 Interaction with other medicinal products and other forms of interaction

Increased risk of severe hyperkalaemia with the following

• ACE-inhibitors
• Aliskerin
• Angiotensin-II receptor anatagonists
• Potassium sparing diuretics such as: amiloride, spironolactone and triamterene
and aldosterone antagonists
• Ciclosporin
• Tacrolimus (not topical formulations)

Particularly close monitoring required with these (see section 4.4) and any other
medicines or conditions that may increase potassium levels

Further reductions in potassium occurs with glucose infusions – see also section 4.4

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

Nil.

4.8 Undesirable effects

System Organ Class	Frequency	Adverse events
Metabolism and nutrition disorders	Not known	Hyperkalaemia[1]
Nervous system disorders	Not known	Paraesthesia[1], paralysis[1]
Cardiac disorders	Not known	Cardiac arrhythmias[1], cardiac arrest[1]
Vascular disorders	Not known	Phlebitis[2], hypotension[1]
Musculoskeletal and connective tissue disorders	Not known	Muscle weakness[1]
General disorders and administration site conditions	Not known	Pain[2]

[1]Excessive intake of potassium.

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

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 viavia Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine

4.9 Overdose

Symptoms

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, due to which patients may deteriorate rapidly.
Extremely high plasma potassium concentrations (8-11 mmol/litre) may cause death from cardiac depression, arrhythmias or arrest.
All drugs containing potassium should be withdrawn and potassium-sparing diuretics discontinued.

Treatment

Serum concentrations may be reduced by infusion of 300 – 500 mls per hour of 10% - 25% glucose solutions containing up to 10 units of insulin for each 20 g of glucose, or by the infusion of sodium bicarbonate solution.

Cardiac arrhythmias or a serum concentration above 6.5 mmol/litre, require immediate attention and may be treated by intravenous injection over 1 – 5 minutes of 10 – 20 ml of 10% Calcium Gluconate Injection B.P. with E.C.G. monitoring. 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.

Monitoring

- Measure urea, electrolytes and creatinine
- Monitor potassium levels regularly (2 to 3 hourly if raised)
- Continuous 12 lead ECG
- Observe asymptomatic patients for at least 6 hours

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Electrolyte solutions; ATC Code: B05XA01

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 acid-base 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

Absorption

Potassium is an essential dietary constituent and is readily absorbed from the gastro-intestinal 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.

Distribution

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.

Elimination

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 tubuler 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.

5.3 Preclinical 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 contents of container

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

6.6 Special precautions for 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.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals Limited,
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0598

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1/12/86.

10 DATE OF REVISION OF THE TEXT

05/01/2024