

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.4mmol/mL Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

20mmol of potassium chloride in 50mL; 40mmol of potassium chloride in 100mL

Concentration: 30 mg/ml.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion.

A clear colourless solution pH 5-7

Nominal osmolarity: 800 mOsm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Potassium Chloride 0.4mmol/ml Solution for Infusion 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 or in critical care settings in which patients are often fluid restricted and regular monitoring of serum potassium levels and ECG are regularly monitored.

It can be used for the treatment of severe hypokalaemia or diabetic ketoacidosis

Potassium salts may also be used cautiously in those taking digoxin where potassium depletion may cause arrhythmias.

Potassium Chloride Solution for Infusion must be administered by slow IV.

4.2 Posology and method of administration

This product is only for use in clinical care situations.

Posology

Potassium Chloride 0.4mmol/ml Solution for infusion is a ready to use infusion bag.

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

$\text{MMOL Potassium} = \text{KG BW} \times 0.2 \times 2 \times (4.5 - \text{actual serum potassium (MMOL)})$.

(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.

Adults (including the elderly):

Up to 6g (80 mmol) daily

Paediatric population:

Up to 3mmol per kg per day. Children over 25 kg refer to the adult dose. Infusions should be administered slowly over at least 2-3 hours.

Method of Administration

Slow intravenous infusion, infuse at a rate not exceeding 20 mmol potassium per hour using an infusion pump. To be used only via a central venous route.

In the treatment of severe hypokalaemia or diabetic ketoacidosis, the higher concentration and a higher infusion rate may be required. In this case the infusion should be into a high blood flow vein and continuous ECG monitoring is advisable.

4.3 Contraindications

Potassium Chloride is contraindicated in patients with:

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

4.4 Special warnings and precautions for use

This product must be given by slow intravenous infusion, under ECG control, ensuring adequate urine flow and with careful monitoring of electrolytes.

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

Potassium salts should be administered with considerable care to patients with renal and adrenal insufficiency, intestinal stricture, history of peptic ulcer, cardiac disease, acute dehydration, heat cramps, extensive tissue destruction as occurs with severe

burns, or to patients receiving potassium sparing diuretics or other medications which may increase plasma potassium levels.

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

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 aldosterone, 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, aliskiren 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.

Tacrolimus (not topical formulations) or ciclosporin:

Concurrent use of these immunosuppressive agents may increase the risk of hyperkalaemia.

Depolarising muscle relaxants, such as suxamethonium could increase the potassium- permeability of muscles, thereby leading to increases in serum potassium levels. There is also an increased risk of hyperkalaemia during long-term treatment with heparin, as it is a potent inhibitor of aldosterone production.

The response to intravenous potassium chloride is significantly decreased by concomitant treatment with furosemide, amphotericin B or potassium chloride in parenteral nutrition solutions. The response is significantly increased by enalapril, ethacrynic acid or haemodialysis.

Blood transfusions can contain significant serum potassium levels. If exchange resins or sodium cycles are administered with potassium supplements, serum potassium levels are reduced by sodium replacement of the potassium. Hyperkalaemia can be very dangerous in digitalised patients and careful monitoring of serum potassium levels is very important.

Hyperkalaemia may also result from concurrent use of thiazide diuretics,

tacrolimus,
β-Adrenoceptor blockers, non-steroidal anti-inflammatory drugs and drugs that contain potassium, such as the potassium salts of penicillin. Potassium can enhance the antiarrhythmic effect of quinidine.

Concurrent use of adrenocorticoids, glucocorticoids and mineralocorticoids may all decrease the effects of potassium supplements.

Glucose Infusion:

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

4.6 Fertility, Pregnancy and lactation

There is no, or inadequate, evidence of safety of the drug in human pregnancy or breast feeding, but it has been in wide use for many years without apparent ill consequence.

Potassium Chloride Solution for Infusion may be used during pregnancy and lactation under the supervision of the prescribing physician if considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not known

4.8 Undesirable effects

The following convention has been used for the classification of undesirable effects in terms of frequency: very common ($\geq 1/10$), common ($\geq 1/100$ to <

1/10), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data)

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
Gastrointestinal disorders	Not known	Nausea and vomiting ³ , oesophageal or small bowel ulceration

¹Excessive intake of potassium.

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

³Severe symptoms may indicate obstruction.

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 Website:

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

4.9 Overdose

Symptoms

Clinical signs and symptoms of potassium overdose 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

In the event of hyperkalaemia, discontinue all potassium containing medications and foods. If the condition is serious then intravenous glucose and insulin may be necessary to facilitate the transfer of potassium into the cells. Serum concentrations may be reduced by infusion of 300 – 500 ml 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.

The administration of calcium gluconate (though not to digitalised patients) may be needed to antagonise cardiotoxic effects. 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 sulfonate, a cation-exchange resin administered by mouth or as an enema. If the above measures fail, haemodialysis or peritoneal dialysis may be required.

If hyperkalaemia is very severe, techniques such as haemodialysis, peritoneal dialysis or the use of ion exchange resins may be necessary to rapidly lower the potassium level.

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 PHARMACOLOGICAL PROPERTIES

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 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.

5.3 Preclinical safety data

There are no other preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

Potassium Hydroxide (for pH adjustment)

6.2 Incompatibilities

None.

6.3 Shelf life

Unopened

20mmol in 50ml 9 months

40mmol in 100ml 12 months

For single use only, once opened use immediately

6.4 Special precautions for storage

Store the unopened bags in their overwrap. Protect from light and store at less than 25°C, do not freeze.

Store in a separate location away from other IV infusion bags.

Do not use if the overwrap or infusion bag is damaged or if the solution is cloudy or has particles in.

For single use only, discard any unused solution.

6.5 Nature and contents of container

Ready to use sterile solution supplied in a polyolefin/styrene or PVC infusion bag which is sealed in an overwrap.

Infusion bags filled with 50ml or 100ml. Each fill weight supplied in cartons of 20 infusion bags.

6.6 Special precautions for disposal

No special instructions.

For single use only, discard any unused solution.

7 MARKETING AUTHORISATION HOLDER

Ennogen IP Ltd,
Unit G4,
Riverside Industrial
Estate, Riverside Way,
Dartford,
DA1 5BS,
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 55612/0049

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

06/02/2025

10 DATE OF REVISION OF THE TEXT

26/02/2025