PROFESSIONAL INFORMATION

SCHEDULING STATUS

S3

1 NAME OF THE MEDICINE

POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS

Concentrate for solution for infusion.

2 QUALITATIVE AND QUANTITIVE COMPOSITION

Each 100 mL contains 15 g potassium chloride, i.e., 1,5 g of potassium chloride (15 % *m/v*) per 10 mL Flexivial.

Ionic content:

Cl^- 2 000 mmol/L

K^+ 2 000 mmol/L

Theoretical osmolarity: 4 000 mOsm/L

pH-value: 4,5 – 7,0

Sugar-free.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion.

Clear polyethylene ampoules containing a colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Potassium deficiency in patients for whom dietary measures or oral medicine are inadequate.

4.2 Posology and method of administration

Posology

Paediatric population

The safety and efficacy of potassium chloride (as in POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS) for paediatric patients has not been fully established.

Normal dose for adults:

Administer intravenously only after dilution in a suitable solution, up to a maximum concentration of 3 g/L of potassium chloride (or 40 mmol of potassium). For therapy of severe hypokalaemia or diabetic ketoacidosis higher concentrations may be necessary; in this case, the infusion should be into a high blood flow vein and continuous ECG monitoring is advisable.

1 g of potassium chloride corresponds to 13,4 mmol or 524 mg of potassium. Dose is dependent on results of serum electrolyte levels and acid-base-state. The potassium deficit is to be calculated via the following formula:

Potassium deficit (mmol) = kg body weight x 0,2 x 2 x (4,5 mmol/L – serum potassium) (The extracellular volume calculates from body weight in kg x 0,2.)

Normal daily intake is approximately 0,8 to 2 mmol of potassium per kilogram of body weight. The infusion rate should not be fast, a rate of 10 mmol/h is normally considered safe. As a general rule, the rate should never be higher than 20 mmol/h.

The maximum dose for adults should not exceed 150 mmol per day.

Patients with renal impairment

In patients with renal impairment the dose should be reduced.

Method of administration

Intravenous infusion after dilution.

The administration via an infusion pump is recommended, especially for solutions with higher concentrations.

For instructions on dilution of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS before administration, see section 6.6.

4.3 Contraindications

- Hypersensitivity to potassium chloride, or to any of the excipients of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS listed in section 6.1.
- Hyperkalaemia.

4.4 Special warnings and precautions for use

POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS MAY ONLY BE INFUSED AND SHOULD NEVER BE INJECTED DIRECTLY INTO A VEIN. THE SOLUTION MUST NOT BE INJECTED UNLESS DILUTED.

When injected intravenously, an excess of potassium ions produces depression of the heart and may cause cardiac arrest. Poisoning may occur from the intravenous injection of even small doses of potassium ions when excretion is delayed, as in the presence of renal insufficiency.

Direct injection of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS concentrate without appropriate dilution may cause instant death.

The administration should be slow (usually 10 mmol/h, not exceeding 20 mmol/h; see section 4.2).

Since adequate urine flow must be ensured, urine flow should be monitored.

Care should be taken in patients with uncompensated cardiac insufficiency, in patients under treatment with digitalis and in patients with severe or complete heart block.

Serum electrolyte levels and acid-base status of the patient should be monitored, and the dose should be adjusted to the needs of the patient. During treatment, plasma potassium

concentration must be measured at regular intervals to avoid the development of hyperkalaemia, especially in patients with renal impairment and other conditions often related to hyperkalaemia. ECG monitoring facilities should be available, and patients frequently monitored.

Care should be taken in conditions frequently associated with hyperkalaemia like adrenal insufficiency (Morbus Addison), decreased renal function (renal insufficiency), post-operative oliguria, shock with haemolytic reactions and/or dehydration, metabolic acidosis, patients treated with potassium-sparing diuretics, hyperchloraemia, Gamstorp episodic adynamy, sickle cell anaemia.

Attention should be paid to intravenous administration since extravasation can cause necrotic tissue damages.

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

Closely monitor patients with cardiac diseases, acute dehydration, heat cramps, extensive tissue destruction as occurs with severe burns, and elderly patients since renal function may be impaired or other conditions predisposing to hyperkalaemia may be present.

4.5 Interaction with other medicines and other forms of interaction

Combinations not recommended (except in cases of severe hypokalaemia):

- **Potassium-sparing diuretics** (single or combined) such as: amiloride, spironolactone, triamterene, potassium canrenoate, eplerenone; risk of potentially lethal hyperkalaemia, particularly in patients with renal impairment (addition of hyperkalaemic effects).
- **Angiotensin converting enzyme inhibitors (ACE), angiotensin II receptor antagonists, non-steroidal anti-inflammatory drugs (NSAIDs), ciclosporin, tacrolimus, suxamethonium**: potentially lethal hyperkalaemia, particularly in patients with renal insufficiency (addition of hyperkalaemic effects).

- **Blood products, penicillin potassium salts:** potential risk of hyperkalaemia due to the amount of potassium present in these products.

Combinations possible with special precautions of use:

- **Quinidine**: potassium can increase the anti-arrhythmic effects of quinidine.
- **Thiazides, adrenocorticoids, glucocorticoids, mineralocorticoids**: Effects of the potassium supplement may be decreased.
- **Digoxin**: hyperkalaemia can be dangerous in digitalized patients,
- **Exchange resins:** the serum levels of potassium are reduced by sodium replacement of the potassium.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

No information available

Pregnancy

There are no or limited amount of data from the use of potassium chloride in pregnant women. The use of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS concentrate for solution for infusion may be considered during pregnancy if clinically needed.

Breastfeeding

Potassium chloride is excreted in human milk to such an extent that effects on the breastfed newborn/infants are likely.

A risk to the newborns/infants cannot be excluded.

A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS concentrate for solution for infusion considering the benefit of breastfeeding for the child and the benefit of therapy for the woman.

Fertility

No information available.

4.7 Effects on ability to drive and use machines.

Potassium Chloride Fresenius 15 % “Flexivial” should not affect the ability to drive; no data is available.

4.8 Undesirable effects

Excessive intake of potassium may cause hyperkalaemia which may cause neuromuscular and cardiac disorders especially dysrhythmias, and even cardiac arrest may occur.

POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS should be given slowly as high blood concentrations may affect cardiac function.

Further undesirable effects, frequency unknown:

Metabolism and nutrition disorders:

- acidosis,

- hyperchloraemia.

Vascular disorders:

- venous thrombosis.

General disorders and administration site conditions:

- nausea,

- pain on injection,

- necrosis in case of extravasation,

- phlebitis in case of too high local concentrations.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers

are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

4.9 Overdose

Overdose causes hyperkalaemia which can produce ECG abnormalities, bradycardia, ventricular fibrillation, other dysrhythmias up to cardiac arrest, confusion, tiredness, diarrhoea, dysphagia, paraesthesia of the extremities, respiratory difficulty, skeletal muscles paralysis and death.

When any of these appear, immediately discontinue the treatment and avoid any potassium containing food and potassium-sparing diuretics.

In cases of severe hyperkalaemia (over 8 mmol K+ /L of plasma) administer IV dextrose (10 to 20 %) with 10 units of insulin for each 50 g of glucose. Use sodium bicarbonate via IV to correct acidosis.

Monitor continuously via ECG. If P-wave is absent, administer calcium gluconate 10 % (10 - 20 mL via IV).

In order to remove potassium from the body oral sulphonated sodium polystyrene or retention enemas can be used. Haemodialysis or peritoneal dialysis can also be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 24 - Mineral substitutes, electrolytes

Pharmacotherapeutic group: Electrolyte solutions, ATC code: B05XA01

Potassium is important in electrolyte metabolism because of the specific physiological effects of the ion, related primarily to the electrical excitability of cells; the relationship between acid-base disturbances and potassium depletion and the general effects of imbalance on cellular metabolism.

Paediatric population

The safety and efficacy of potassium chloride for paediatric patients has not been fully established.

5.2 Pharmacokinetic properties

When administered intravenously, the chloride and potassium ions enter directly into the blood stream and there, as it happens in the mechanism of action, elimination kinetics follows physiologic routes of the body, and it is eliminated in faeces (10 %), urine, sweat, teardrops. It is mainly excreted in urine (90 %).

About 10 - 50 mmol potassium are excreted renally per day, also in potassium depleted patients.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

Hydrochloric acid

6.2 Incompatibilities

POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS must not be mixed with other medicines except those mentioned in section 6.6.

Potassium chloride has been reported to be physically incompatible with the following active substances:

- amikacin
- amphotericin B
- dobutamine
- fat emulsion
- mannitol solutions 20 % - 25 %
- sodium penicillin G

6.3 Shelf life

Unopened: 2 years

Once opened: dilute and use immediately.

6.4 Special precautions for storage

Store at or below 25 °C.

For storage conditions after dilution of the medicine, see section 6.3.

6.5 Nature and contents of container

Clear 10 mL polyethylene ampoules (Flexivial)

Pack sizes of 20 or 50.

6.6 Special precautions for disposal and other handling

POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS is a sterile solution containing potassium chloride for IV infusion. It must be diluted before use by not less than 50-times its

volume with isotonic solution Sodium chloride 0,9 % *m/v* intravenous infusion or another suitable solution for infusion.

Compatibility of potassium chloride with any other infusion solution should be established prior to dilution.

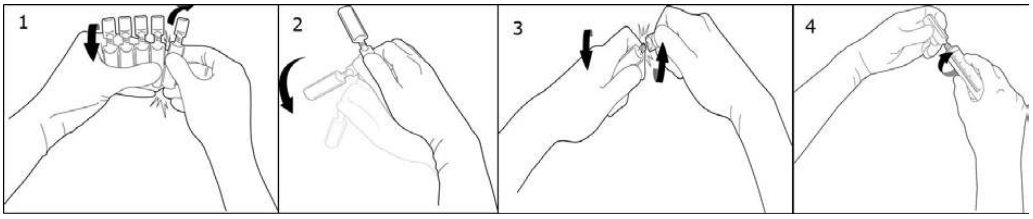
In order to avoid a bad homogenisation of the diluted solution, the concentrated solution of potassium chloride should not be added to a bottle/bag of infusion in hanging position. Once the concentrated solution has been added to the bottle/bag of infusion, the product must be mixed well before use, so shake the bottle/bag carefully with 3 - 5 slow movements in order to get a good product homogenisation. Then, hang the bottle/bag and start the infusion process.

For single use only. Always use diluted.

Once the ampoule is opened, its spout is perfectly adapted to the Luer syringe and Luer-Lock; therefore, no needle is needed.

Handling instructions

To break off a single ampoule, twist one ampoule against the remaining ampoules of the pack without touching the head and neck of the ampoules (1). Shake the ampoule with one single movement as shown below in order to remove the liquid kept in the cap (2). To open the ampoule, twist the ampoule body and the ampoule head in opposite directions until the neck breaks off (3). Connect the ampoule to the Luer syringe or Luer-lock syringe as shown in figure (4).



Therefore, no needle is needed to extract the solution. Extract the liquid.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Fresenius Kabi South Africa (Pty) Ltd

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8 REGISTRATION NUMBER

L/24/286

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 August 1979

10 DATE OF REVISION OF THE TEXT

18 November 2024