SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 15% w/v Sterile Concentrate BP.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 2mmol/ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion (sterile concentrate).

A clear colourless solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

The prevention and treatment of potassium deficiency when oral replacement therapy is not feasible.

4.2. Posology and Method of Administration

Method of administration:

Slow intravenous infusion.

Dilute with a suitable infusion fluid and mix well before use to produce a potassium concentration of 20 mmol per litre and not more than 40 mmol per litre. Infuse at a rate not exceeding 20 mmol potassium per hour. 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.

Adults and the elderly:

Up to 6 g (80 mmol) daily after dilution to a concentration of 20 mmol/litre and no greater than 40 mmol/litre.

Infants and children:
Up to 3 mmol per kg per day after dilution to a concentration of 20 mmol/litre.
For children weighing 25kg or over, refer to the adult dosage.

4.3. Contraindications

Potassium chloride is contraindicated in patients with hyperkalaemia.

4.4. Special Warning and Precautions for Use

Potassium chloride concentrate must be diluted with sodium chloride solution for injection (0.9% w/v) or other suitable diluent, thoroughly mixed and given by slow intravenous infusion under ECG control, ensuring adequate urine flow and with careful monitoring of electrolytes.

Concentrated potassium solutions are for intravenous admixtures only. Do not use undiluted. Direct injection may be instantaneously fatal.

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

Repeated measurements of plasma-potassium concentration are necessary to determine whether further infusions are required and to avoid the development of hyperkalaemia.

Patients with mild to moderate renal impairment and adrenal insufficiency should be closely monitored. Considerable care should also be taken with patients having cardiac disease, acute dehydration, heat cramps, extensive tissue destruction eg severe burns.

Care should be taken with elderly patients since renal function may be impaired.

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

Concurrent use with ACE inhibitors may result in hyperkalaemia.

There is an increased risk of hyperkalaemia with use of angiotensin-II receptor antagonists, cyclosporin, potassium-sparing diuretics, tacrolimus and potassium-containing salt substitutes.

In patients receiving digoxin, hypokalaemia may result in digoxin toxicity. Caution is therefore advised if discontinuing a potassium preparation in patients maintained on digoxin.

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.

Potassium can enhance the antiarrhythmic effect of quinidine.

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

4.6. Pregnancy and Lactation

There are no adequate data on the use of potassium chloride in pregnant women. Caution should therefore be exercised when prescribing to pregnant women.

Potassium salts are likely to be excreted in milk. Caution should therefore be exercised when prescribing to women who are breast-feeding.

4.7. Effects on Ability to Drive and Use Machines

None stated.

4.8. Undesirable Effects

Hyperkalaemia: Adverse reactions involve the possibility of potassium intoxication. Signs and symptoms include paresthesias of extremities, flaccid paralysis, muscle or respiratory paralysis, areflexia, weakness, listlessness, mental confusion, weakness

and heaviness of legs, hypotension, cardiac arrhythmia, heart block, ECG abnormalities.

Cardiovascular: Rapid infusion or injection can be toxic to the heart. Cardiac arrhythmias can occur and even cardiac arrest.

Reactions due to technique of administration: Febrile response, infection at injection site, venous thrombosis, phlebitis extending from the injection site and extravasation.

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:
For UK: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.
For IE: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

4.9. Overdose

If excretory mechanisms are impaired or if potassium is administered too rapidly, potentially fatal hyperkalaemia can result.

Signs: Signs of hyperkalaemia include cardiac arrhythmias, chest pain, muscle weakness and paralysis.

Treatment: In the event of hyperkalaemia, all potassium-containing medications and foods should be discontinued immediately. If the condition is serious, the first priority is to ensure stability of the cardiac rhythm. Continuous ECG monitoring is essential. Administration of calcium gluconate (but not to patients on digitalis) may be needed to reduce cardiotoxic effects. Intravenous glucose and insulin may be necessary to facilitate the transfer of potassium into cells. Severe and unresponsive hyperkalaemia can be effectively treated with haemodialysis, peritoneal dialysis or use of ion exchange resins.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Eletrolyte solution
ATC Code B05X A01.

Potassium is the predominant cation within cells. It is involved in numerous cellular metabolic processes and is necessary for the conduction of nerve impulses in such tissues as the heart, brain and skeletal muscle.

In hypokalaemia, prolongation of the QT interval and depression of the ST segment may be seen whereas hyperkalaemia results in increased height of T-waves, lengthened PR interval, and even asystole or ventricular fibrillation.

5.2 Pharmacokinetic Properties

Potassium is quickly transferred to the intracellular fluid by an active transport system which maintains high levels within cells. Extracellular fluid contains 4-5 mmol per litre while intracellular fluid contains 150 mmol per litre.
Potassium is mainly excreted by the kidneys, although about 10% is excreted by the colonic mucosa.

5.3 Preclinical Safety Data

There is no additional information relevant to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Water for Injections

6.2. Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in Section 6.6.

6.3. Shelf Life

Unopened: 5 years.

From a microbiological point of view, the product should be diluted and used immediately after opening. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4. Special Precautions for Storage

Unopened product: This medicinal product does not require any special storage conditions. Opened product: For storage conditions of the opened, reconstituted or diluted medicinal product, see section 6.3.

6.5. Nature and Contents of Container

Polypropylene ampoules, of 5, 10 or 20 ml, packed into cartons of 20 ampoules.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Do not use unless the solution is clear and practically free from particles.
Discard after single use.
Discard any unused portion.

Potassium chloride concentrate must be diluted before use by not less than 50 times its volume with sodium chloride 0.9% w/v intravenous infusion (0.9% w/v), dextrose 5% w/v intravenous solution to a maximum concentration of 40 mmol potassium per litre.

The solution must be mixed well before use.

7. MARKETING AUTHORISATION HOLDER

Noridem Enterprises Limited (Trading as Fannin)
Evagorou & Makariou,
Mitsi Building 3, Office 115
10 65 Nicosia, Cyprus

8. MARKETING AUTHORISATION NUMBER

PL 24598/0003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/08/2009

10. DATE OF REVISION OF THE TEXT

10/10/2016