SmPC

Country :	Lebanon
Date of approval :	13.05.2010
Procedure:	National

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

POTASSIUM CHLORIDE PROAMP® 0.0746 g/ml, concentrate for solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Potassium chloride…….0.0746 g
for 1 ml
An ampoule of 20ml contains 1.492 g of potassium chloride

Ionic formula:
Chlorides: 1.001 mmol/l
Potassium: 1.001 mmol/l

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Concentrate for solution for infusion.
Clear and colorless solution
Osmolarity: 2012 mOsm/l
pH between 5.0 and 6.5

4. CLINICAL PARTICULARS

4.1. Therapeutic indications
Potassium chloride PROAMP 0.0746 g/ml is a concentrate for solution for infusion used:
- in the treatment of hypokaliaemia
- to correct hydroelectrolytic disorders,
- as a potassium supply during total parenteral nutrition.

4.2. Posology and method of administration
Administration only by intravenous route after dilution

Usual adult and adolescent dose:
Administration only by intravenous route after dilution in a suitable solution, up to a maximum concentration of 4 g/l of potassium chloride (or 50 mmol/l of potassium).
1 g of potassium chloride corresponds to 13.4 mmol or 524 mg of potassium.
The usual daily intake is approximately 0.8 to 2 mmol of potassium per kilo of body weight.
The infusion rate should not be rapid; a rate of 10 mmol/h is usually considered to be safe. As a general rule, the rate should never exceed 15 mmol/h.

Pediatric dose:
Safety and effectiveness of potassium chloride in pediatric patients have not been fully established. However, administration by intravenous route after dilution in a suitable solution of a maximum concentration of 3 mmol of potassium per kilogrammes of body weight, or 40 mmol/m² of body surface per day is recommended.

4.3. Contraindications
The administration of Potassium chloride 0.0746 g/ml PROAMP is contra-indicated in case of hyperchloremia, hyperkaliaemia or any situation which could provoke hyperkaliaemia, in particular: renal failure, Addison's syndrome, uncontrolled diabetes or decompensated metabolic acidosis.

4.4. Special warnings and precautions for use
Special warnings
HYPERTONIC SOLUTION TO BE DILUTED BEFORE USE.
Hyperkaliaemia appearing during administration justifies the immediate stop of the treatment.

Precautions for use
Administration of potassium salts by parenteral route must be monitored by continuous ECG reading, with careful monitoring of electrolytes and especially potassium.

Method of administration:
- injection by IV route only,
- slow infusion (less than 15 mmol/hour),
- the concentration of the solution for infusion must not exceed 4 g/l of potassium chloride (or 50 mmol/l),
- administer under aseptic conditions.
- Before use, check that the container is undamaged and that the solution is clear.

4.5 Interaction with other medicinal products and other forms of interaction
1 – Unrecommended combinations (except in case of hypokaliaemia)

+ **Potassium-sparing diuretics** (alone or in combination) **as:** amiloride, spironolatone, triamterene, potassium canrenoate, eplerenone; risk of potentially lethal hyperkaliaemia, particularly in patients with renal failure (addition of hyperkaliemic effects).

+ Converting enzyme inhibitors (IEC), angiotensin II receptor antagonists, nonsteroidal anti-inflammatory drugs, ciclosporin and tacrolimus : potentially lethal hyperkaliaemia, particularly in patients with renal failure (addition of hyperkaliemic effects).

+ Blood products, potassium salts of penicillin: risk of potentially hyperkaliaemia due to the amount of potassium present in these products.

2 – Combinations possible with special precautions for use

+ **Quinidine**: potassium can enhance the anti-arrhythmic effects of quinidine.
+ **Thiazides, adrenocorticosteroids, glucocorticoids, mineralocorticoids:** potential decrease of effects of potassium supplement.
+ **Digoxine**: hyperkalaemia can be very dangerous in digitalised patients
+ **Exchange resins and administration of sodium**: serum potassium levels are reduced by sodium replacement of the potassium.

4.6. Pregnancy and lactation
Pregnancy
In clinical use, no malformative or foetotoxic effects have been observed to date.
However, the monitoring of pregnancies exposed to the administration of potassium by IV route is insufficient to exclude any risk.
Consequently, this solution should only be administered during pregnancy if absolutely necessary.

Lactation
In the absence of data on a possible passage into breast milk, it is preferable to avoid breast-feeding during treatment.

4.7. Effects on ability to drive and use machines
Not applicable.

4.8. Undesirable effects
Side effects of Potassium chloride PROAMP 0.0746 g/ml may be linked to the administration technique.
General disorders and administration site conditions
Unknown frequency
- pain at the injection site,
- necrosis in case of extravasation,
- phlebitis in case of too high concentration.

4.9. Overdose
Symptoms: Overdose may have dire consequences possibly resulting in the following symptoms :
- mental confusion, paralysis, paraesthesia of the extremities, areflexia, listlessness, weakness and heaviness of legs, muscle weakness progressing to paralysis and respiratory arrest,
- hypotension and death by cardiac arrest, usually preceded by electrical disturbances of the heart which appear on the electrocardiogram as full and peaking T waves, loss of P waves, then a widening of QRS complexes, ventricular tachycardia and ventricular fibrillation.

Emergency situation: Stop immediately the administration of potassium chloride and carry out infusion of either a bicarbonate solution (in case of significant metabolic acidosis), or a concentrated dextrose solution containing regular insulin.

In case of renal insufficiency, dialysis may have to be performed before stopping this infusion so as to avoid rebound hyperkalaemia.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

PLASMA SUBSITUTES AND SOLUTION FOR INFUSION
ATC code: B05XA01

Potassium chloride is a concentrate solution, which has to be diluted before use (osmolarity = 2012 mOsm/l).
Pharmacological properties of potassium chloride solution are those of potassium and chloride ions.

Potassium ion:
1 g of potassium chloride is equivalent to 524 mg of potassium ion (K+), corresponding to 13.4 mEq or mmol potassium ion (K+) or chloride ion (Cl-).
Potassium is the principal cation of the intracellular hydric sector. The normal adult serum concentration is 3.5 to 5.0 mmol/l, with 4.5 mmol/l often being used for a reference point.
The excretion of potassium by urinary route depends on mineralocorticoïds (aldosteron).
In healthy persons, extra-renal loss is weak.
Potassium level influences nerve impulse transmission and muscular concentrations.

Chloride ion:
It participates to the correction of metabolic alkalosis, usually combined with hypokaliaemia.

5.2. Pharmacokinetic properties
Potassium chloride is principally excreted by urinary route. The excretion is strongly decreased in case of renal failure and can provoke hyperkaliaemia.

5.3. Preclinical safety data
Preclinical safety data are not relevant considering that potassium is a physiological component of the human body.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Water for injections.

6.2. Incompatibilities
Check the compatibility of any medicinal products combined with the container.
Potassium chloride should not be added to mannitol, blood or blood products, or amino acids or lipid-containing solutions because it may precipitate these substances from solution or cause lysis of infused red blood cells.

6.3. Shelf life
3 years.

6.4. Special precautions for storage
Store below 25°C.

6.5. Nature and contents of container
20 ml in (polypropylene) ampoules, box of 10, 20, 50 or 100
Not all pack sizes may be marketed.

6.6. Special precautions for disposal (and other handling)
No special requirement.