POTASSIUM Chloride LAVOISIER 7,46% (0,0746g/ml) - 10% (0,10g/ml) - 15% (0,15g/ml)- 20% (0,20g/ml), solution for infusion

NAME OF THE MEDICINAL PRODUCT

POTASSIUM CHLORIDE LAVOISIER 7**,**46% (0,0746g/ml) - 10% (0,10g/ml) - 15% (0,15g/ml) - 20% (0,20g/ml), solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

DOSAGE	**7,46% (0,0746g/ml)**	**10% (0,10g/ml)**	**15% (0,15g/ml)**	**20% (0,20g/ml)**
POTASSIUM CHLORIDE for 1ml	0,0746 g	0,10 g	0,15 g	0,20 g
Potassium	1000 mmol/l or 1,0 mmol/ml	1340 mmol/l or 1,34 mmol/ml	2010 mmol/l or 2,01 mmol/ml	2680 mmol/l or 2,68 mmol/ml
Chloride	1000 mmol/l or 1,0 mmol/ml	1340 mmol/l or 1,34 mmol/ml	2010 mmol/l or 2,01 mmol/ml	2680 mmol/l or 2,68 mmol/ml

One 10 ml ampoule of potassium chloride 7,46% (0,0746g/ml) contains 0,746 g of potassium chloride.

One 20 ml ampoule of potassium chloride 7,46% (0,0746g/ml) contains 1,492 g of potassium chloride.

One 10 ml ampoule of potassium chloride 10% (0,10g/ml) contains 1,0 g of potassium chloride.

One 20 ml ampoule of potassium chloride 10% (0,10g/ml) contains 2,0 g of potassium chloride.

One 10 ml ampoule of potassium chloride 15% (0,15g/ml) contains 1,5 g of potassium chloride.

One 20 ml ampoule of potassium chloride 15% (0,15g/ml) contains 3,0 g of potassium chloride.

One 10 ml ampoule of potassium chloride 20% (0,20g/ml) contains 2,0 g of potassium chloride.

One 20 ml ampoule of potassium chloride 20% (0,20g/ml) contains 4,0 g of potassium chloride.

For the list of excipients, see section *List of Excipients.*

PHARMACEUTICAL FORM

Solution for infusion.

DOSAGE	**7,46% (0,0746g/ml)**	**10% (0,10g/ml)**	**15% (0,15g/ml)**	**20% (0,20g/ml)**
Osmolarity	2000 mOsm/l	2680 mOsm/l	4020 mOsm/l	5360 mOsm/l

pH between 4,5 and 7,0

CLINICAL PARTICULARS

Therapeutic indications

- Potassium supplement to meet the patient's daily needs in parenteral nutrition.
- Treatment of hypokalaemia and adjustment of potassium depletion, in case of severe disorders or when intake by enteral route cannot be achieved or is inadequate.

NB: IV administration of potassium salt leads to a rapid potassium gradient which can cause hyperkalaemia and heart failure (see section *Posology and administration*).

Posology and administration

SLOW INTRAVENOUS ADMINISTRATION ONLY AFTER DILUTION, BY INFUSION

Usual posology in adults

Usual daily intakes are of the order of 0,8 to 2 mmol of potassium ions per kilogram of body weight. 1g of potassium chloride corresponds to 13,4 mmol or 524 mg of potassium.

Usual posology in children

The safety and efficacy of potassium chloride have not been fully established in children. However, when the administration of potassium chloride is required, it is recommended to carry intravenous administration after dilution in an infusion solution. The maximum daily intake of potassium is 3 mmol of potassium per kg of body weight per day, or 40 mmol / m² body surface area per day.

Method of administration

Slow administration after dilution in an infusion solution, strictly by intravenous infusion. No direct intravenous injection. The administration of KCl must be performed under clinical and laboratory monitoring and, if necessary, under cardiovascular monitoring.

For a gradual correction of hypokalaemia in adults, compensation or parenteral hydration, dilute until a maximum concentration of 4 g / l of potassium chloride (approximately 50 mmol of potassium per liter) and infuse slowly over a period of 12 or 24 hours. The intravenous infusion rate should be controlled using a volumetric pump or a manual flow control to prevent too rapid infusion. In adults, an infusion rate corresponding to 10 mmol / h is usually considered as safe. In general, this infusion rate must not exceed 15 mmol / h.

When a rapid correction of hypokalaemia in adults is essential, the concentration of the solution after dilution and the infusion rate should be adjusted on a case by case basis and under reinforced monitoring in an intensive care unit. In this context, the use of an electric syringe pump may be considered if necessary.

Contra-indications

The administration of this medicine is contra-indicated in case of hyperkalaemia or any situation which may cause hyperkalaemia (acute kidney failure, acute adrenal deficiency, decompensated metabolic acidosis).

Special warnings and precautions for use

HYPERTONIC SOLUTION TO BE DILUTED BEFORE USE
CAUTION: A RAPID ADMINISTRATION OF KCl CAN RESULT IN CARDIAC ARREST

Special warnings

- Hyperkalaemia occurring while KCl is administered justifies the discontinuation of the treatment.

- In case of oligoanuric renal failure, the administration of KCl exposes to a particular important risk of hyperkalaemia.

- In the treatment of diabetic ketoacidosis, administration of potassium chloride may be necessary in combination with insulin to compensate for the potassium deficit generated by the ketotic decompensation and unmasked by insulin therapy.

Precautions for use

- Parenteral administration of potassium salts should be monitored by repeated monitoring of plasma electrolytes levels and if necessary a cardiovascular monitoring;

- Check the compatibility before mixing with other solutions;

- Taking this medicine is not recommended in combination with potassium-sparing diuretics, angiotensin converting enzyme inhibitors, angiotensin II receptor antagaonists, cyclosporin and tacrolimus (see section *Interactions with other drugs and other forms of interactions*).

Method of administration

- Administration after dilution strictly by intravenous infusion.
- Slow administration (in adults, less than 15 mmol / hour)
- The concentration of the solution to be administered must not exceed 4 g / l of potassium chloride (approximately 50 mmol / l of potassium).

Interactions with other drugs and other forms of interactions

+ Medicines causing hyperkalaemia

Some medicines or therapeutic classes may favor the occurrence of hyperkalaemia : salts of potassium, potassium-sparing diuretics, angiotensin converting enzyme inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory drugs, heparin (low molecular weight or unfractionated), immunosuppressants such as cyclosporin or tacrolimus, trimethoprim.

The combination of these drugs increases the risk of hyperkalaemia. This risk is particularly important with potassium-sparing diuretics, especially when they are combined with each other or with potassium salts, while the combination of an ACE inhibitor and an NSAID, for example, present less risk if all recommended precautions have been well implemented.

To know the risks and constraints levels specific to medicines causing hyperkalaemia, it should refer to the interactions of each substance.

However, some substances, such as trimethoprim, are not subject to specific interactions in relation to this risk. Nevertheless, they may act as contributing factors when they are associated with other drugs already mentioned in that section.

Contra-indicated associations

+ Potassium-sparing diuretics (alone or in combination) such as: amiloride, spironolactone, triamterene, potassium canrenoate, eplerenone : risk of potentially lethal hyperkalaemia particularly in patients with renal failure (addition of potassium-sparing effects) .

+ Angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor antagonists : addition of the potassium-sparing effects with risk of potentially lethal hyperkalaemia. This association should be avoided except in case of prior hypokalaemia.

+ **Cyclosporin, Tacrolimus** : potential lethal hyperkalaemia particularly in patients with renal failure (addition of potassium-sparing effects). This association should be avoided except in case of prior hypokalaemia.

Pregnancy and lactation

Pregnancy

Clinically, no teratogenic or foetotoxic effect has appeared to date. However, the monitoring of pregnancies exposed to the administration of potassium intravenously is insufficient to exclude any risk.

Therefore, this solution will be administered during pregnancy only if necessary.

Breast-feeding

In the absence of data on a possible passage into breast milk, it is best to avoid breasfeeding during the treatment.

Undesirable Effects

General disorders at administration site.

Not known frequency (can not be estimated from the available data).

- Pain at injection site
- Necrosis if case of extravasation
- Phlebitis at infusion site (especially in case of too high concentration).

Overdose

Symptoms

An overdose can have tragic consequences with the possible following symptoms:

- Paralysis, paresthesia in the limbs, areflexia, apathy, weakness and heaviness of the legs, muscle weakness progressing to paralysis and respiratory arrest.

- Hypotension and death by cardiac arrest, usually preceded by electrical disturbances in the heart appearing on the electrocardiogram with wide deep T waves, accompanied by absence of P waves and an expansion of the complex QRS, ventricular tachycardia and ventricular fibrillation. An intensive care physician should be sought urgently for advice.

Emergency procedure

Hyperkalaemia occurring while KCl is administered justifies the discontinuation of the treatment.

In case of threatening hyperkalaemia resulting in clinical or electric signs, the infusion should be stopped and calcium chloride should be administered immediately, followed by an infusion of bicarbonate serum, or a solution containing concentrated glucose serum and insulin. In the absence of clinical signs, oral or rectal administration of Kayexalate may be considered. In case of renal failure, dialysis should be considered.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic class : POTASSIUM SUPPLEMENT, ATC Code B05XA01.

- POTASSIUM ION : Potassium supplementation

In terms of laboratory tests, an hypokalaemia lower than 3,6 mmol/l indicates a potassium deficiency.

This deficiency can originate from :

- **the digestive tract** : diarrhoea, vomiting, stimulating laxatives.
- **the renal system**: by increased excretion in the urine in case of congenital tubular disease or during therapy by salidiuretics, corticoids or (IV) amphotericin B, by excessive alkaline or liquorice derivatives uptake.
- **the endocrine system** : primary hyperaldosteronism (that involves etiologic treatment).

Symptomatic potassium deficiency may produce some of the followings symptoms: muscular fatigability, pseudoparalysis, cramps and ECG modifications (repolarisation disorders, ventricular hyperexcitability).

- CHLORIDE ION: correction of metabolic alkalosis often associated with hypokalaemia.

Pharmacokinetic properties

Excretion, mainly urinary, is reduced in patients with renal failure with possibility of hyperkalaemia.

Preclinical safety data

No particular data, potassium is a physiological component of plasma.

PHARMACEUTICAL PARTICULARS

List of excipients

Water for injections.

Incompatibilities

In the absence of compatibility studies, this medicine should not be mixed with other drugs.

Shelf life

Glass ampoule before opening : 5 years
Polypropylene ampoule before opening: 3 years
After opening, the product should be used immediately.

Nature and contents of container

10 ml and 20 ml in ampoules bottles (type I glass) and in polypropylene ampoules; pack of 10, 50 or 100.

MARKETING AUTHORIZATION HOLDER

Laboratoires Chaix et du Marais
7 Rue Labie
75017 PARIS

PACKAGING AND PRODUCT LICENSE NUMBER

Pharmacy Packaging:

Ampoules bottles (glass)

KCl 7.46 % (0,0746g/ml) :
PL 3400936300033 : 10 ml - 10 units pack - Not reimbursed by French Health Care Security

KCl 10 % (0,10g/ml):
PL 3400936300323 : 10 ml - 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions.
PL 3400936300491 : 20 ml - 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions.

KCl 15 % (0,15g/ml) :
PL 3400936300552 : 10 ml - 10 units pack - Not reimbursed by French Health Care Security

KCl 20 % (0,20g/ml) :
PL 3400936340244 : 10 ml - 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions.
PL 3400936340305 : 20 ml - 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions.

Ampoules (polypropylene)

KCl 10 % (0,10g/ml) :
PL 3400939533735: 10 ml – 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions

Hospital Packaging :

Ampoules bottles (glass)

KCl 7.46 % (0,0746g/ml)
PL 3400956533336 : 10 ml - 100 units pack - Approved for Institutions.

KCl 10 % (0,10g/ml):
PL 3400956533626 : 10 ml - 100 units pack - Approved for Institutions.
PL 3400936300491 : 20 ml - 10 units pack - Approved for Institutions.

KCl 15 % (0,15g/ml)
PL 3400956533855: 10 ml - 100 units pack - Approved for Institutions.

KCl 20 % (0,20g/ml) :
PL 3400956534166 : 10 ml - 100 units pack - Approved for Institutions.
PL 3400956534227: 20 ml - 50 units pack - Approved for Institutions.

Ampoules (polypropylene)

KCl 10 % (0,10g/ml):
PL 3400957545482 : 10 ml- 100 units pack - Approval for Institutions
PL 3400957545543 : 20 ml- 50 units pack - Approval for Institutions

DATE OF REVISION

May 2014

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