POTASSIUM Chloride 7.46% - 10% - 15% - 20% LAVOISIER, injectable solution for infusion

POTASSIUM CHLORIDE 7.46 % LAVOISIER, injectable solution for infusion

POTASSIUM CHLORIDE 10% - 15% - 20% LAVOISIER, injectable solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

SPECIALTY DOSE	**7.46%**	**10%**	**15%**	**20%**
POTASSIUM CHLORIDE.....	7.46 g	10.0 g	15.0 g	20.0 g
Water for injectable preparations s.q.	100 ml	100 ml	100 ml	100 ml
Potassium (mmol/l)	1000	1340	2010	2680
Chloride (mmol/l)	1000	1340	2010	2680
Solution Osmolarity (mOsmol/l)	2000	2680	4020	5360

PHARMACEUTICAL FORM
Solution for injection

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 high potassium gradient which can cause hyperkalaemia and heart failure (see Posology and administration).

POSOLOGY AND ADMINISTRATION
- Administered as a very slow intravenous injection under medical supervision or as intravenous infusion after dilution in a glucose solution.

Parenteral nutrition: Must be adapted to patient's needs. The usual daily food intake is about 65 mmol of potassium (i.e. 5 g of potassium chloride).

Hypokaliemia: Posology varies dependent upon the imbalance of patient's potassium levels (electrolytes evaluation).
In case of serious hypokalaemia (< 3.6 mmol/l), initiate treatment with a daily dose equivalent to 4 g of potassium chloride (52 mmol of potassium) over 24 hours under medical and biological supervision as a slow intravenous infusion after dilution with a glucose solution.

CONTRA-INDICATIONS
- Hyperkaliemia or any situation which may cause hyperkaliemia particularly: kidney failure, Addison's syndrome , untreated diabetes except under strict control of potassium levels.
- Contra-indicated in combination with potassium-sparing diuretics
- Interactions with conversion enzyme inhibitors are not recommended (see Interactions).

WARNINGS AND PRECAUTIONS FOR USE

Warnings
If hyperkalaemia occurs while KCl is administered, treatment should be discontinued. In case of severe hyperkalaemia or in response to clinical or electric symptoms, initiate a perfusion, either with bicarbonate solution, or concentrated glucose solution containing 10 IU of insulin for 100 g of glucose. In case of renal failure, purification through dialysis should sometimes be performed prior to discontinuing perfusion because of the risk of rebound hyperkalaemia.

Special warnings and precautions for use
- To be used with great care in elderly patients.
- Urinary excretion mainly which decreases in case of renal failure and may induce hyperkalaemia
- Check potassium levels prior and during treatment particularly in any situation which can produce hyperkalaemia.
- Strict intravenous injection must be performed gradually. Rate of perfusion should not usually exceed 15 mmol/hour. Solution concentration should not exceed 4 g/l of potassium chloride (i.e. 50 potassium mmol/l).
- Administering potassium salts by parenteral route requires continuous electrocardiographic monitoring when given at a fast rate and in any case in repeated doses of plasmatic electrolytes.

INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

Contra-indicated associations:

Potassium-sparing diuretics: amiloride, potassium canrenoate, spironolactone, triamterene (monotherapy or combination therapy): risk of potentially lethal hyperkalaemia particularly in patients with renal failure (addition of the effects of potassium-sparing diuretics) which is a contra-indication except if hypokalaemia is present.

Not recommended associations:

Conversion enzyme inhibitors: risk of potentially lethal hyperkalaemia particularly in case of renal failure (addition of the effects of potassium-sparing diuretics). Potassium salts should not be administered in combination with a conversion enzyme inhibitor except in case of hypokalaemia.

PREGNANCY AND LACTATION
Not applicable.

ADVERSE REACTION
- Pain may be experienced at the site of injection.
- Risk of venous thrombosis in case of injection with highly concentrated solution.
- Risk of necroses in case of paravenous injection.

OVERDOSAGE
- Overdose may have life-threatening episodes going into heart failure. Cardiac electric abnormalities displayed on ECG reveal wide deep T-waves, a flattening of P wave, a lengthening of PR interval then broadening of QRS complex, usually preceding heart failure.

CLINICAL PHARMACOLOGY

Pharmacodynamics

POTASSIUM SUPPLEMENT
In terms of laboratory tests, an hypokalaemia lower than 3.6 mmol/l indicates potassium deficiency.

This deficiency can affect:

- **the digestive tract** : diarrhoea, vomiting, stimulating laxatives.
- **the renal system**: 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 consumption.
- **the endocrine system** : primary hyperaldosteronism (that involves etiologic treatment).

Symptomatic potassium deficiency may produce some of the followings symptoms: muscular fatigability, pseudoparalysis, cramping and ECG modification, repolarisation disorders and ventricular hyperexcitability.

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

Pharmacokinetics

Urinary excretion mainly.

PHARMACEUTICAL DATA

Shelf life

Glass ampoule: 5 years
Polypropylene ampoule: 3 years

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.

PACKAGING AND PRODUCT LICENSE NUMBER

Pharmacy Packaging:

Ampoules (glass)

KCl 7.46 % :
PL 363 000-3: 10 ml - 10 units pack - Not reimbursed by French Health Care Security

KCl 10 %:
PL 363 003-2: 10 ml - 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions.
PL 363 004-9: 20 ml - 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions.

KCl 15 %:
PL 363 005-5: 10 ml - 10 units pack - Not reimbursed by French Health Care Security

KCl 20 %:
PL 363 402-4: 10 ml - 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions.
PL 363 403-0: 20 ml - 10 units pack - Not reimbursed by French Health Care Security - Approved for Institutions.

Ampoules (polypropylene)

KCl 10 % :
PL 395 337-3 : 10 ml - 10 units pack - Not reimbursed by French Health Care Security- Approval for Institutions requested
PL 395 339-6 : 20 ml - 10 units pack - Not reimbursed by French Health Care Security- Approval for Institutions requested

Hospital Packaging : Ampoules bottles (glass)

KCl 7.46 %:
PL 565 333-3: 10 ml - 100 units pack - Approved for Institutions.

KCl 10 %:
PL 565 336-2: 10 ml - 100 units pack - Approved for Institutions.
PL 565 337-9: 20 ml - 50 units pack - Approved for Institutions.

KCl 15 %:
PL 565 338-5: 10 ml - 100 units pack - Approved for Institutions.

KCl 20 %:
PL 565 341-6: 10 ml - 100 units pack - Approved for Institutions.
PL 565 342-2: 20 ml - 50 units pack - Approved for Institutions.

Ampoules (polypropylene)

KCl 10 % :
PL 575 454-8 : 10 ml- 100 units pack - Approval for Institutions requested
PL 575 455-4 : 20 ml- 50 units pack - Approval for Institutions requested

HOW SUPPLIED

Not applicable

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