Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 15% w/v Concentrate for Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of solution contains 1.5 g of Potassium Chloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion
Clear, colourless sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use in patient**s** requiring supplemental potassium therapy.

4.2 Posology and method of administration

Posology
The goal of potassium replacement therapy is to elevate the plasma concentration of the ion to within the normal range.

Dose per hour: The maximal rate of intravenous infusion is 20mmol/hour.

Dose per day: Since the normal dietary intake of potassium is 50 to 100 mmol daily, it is rare that a larger amount is required during potassium replacement therapy.

Method of administration
For intravenous administration, after dilution.
Before administering Potassium Chloride 15% w/v Concentrate for Solution for Infusion:
1. This solution must be diluted with not less than 50 times its volume of sodium chloride solution or other suitable diluent.
2. The solution should be carefully mixed with the infusion fluid.

During administration:
1. The diluted injection should be administered by slow intravenous infusion at a maximal rate of 20 mmol of potassium per hour.
2. The ECG should be monitored continuously.

4.3 Contraindications

1. Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1
2. Potassium Chloride Concentrate (15%) should never be used undiluted.
3. Hyperkalaemia.

4.4 Special warnings and precautions for use

The diluted solution should always be given slowly as high blood concentrations of potassium may cause serious cardiac toxicity. Particular care is required when administering potassium to patients with renal or adrenal insufficiency, cardiac disease or extensive tissue destruction as may occur with severe burns. In cases of renal insufficiency due to severe dehydration, excretory function should be restored by correction of the fluid deficit in order to ensure adequate urinary excretion of potassium before its parenteral administration. Where renal insufficiency is accompanied by either inadequate urinary excretion of potassium or defective cellular uptake of potassium, administration of standard doses of potassium could result in life-threatening Hyperkalaemia.

4.5 Interaction with other medicinal products and other forms of interactions

Concomitant use of other drugs containing potassium or agents having the potential for hyperkalaemia, such as triamterene, spironolactone or other potassium-sparing diuretics, may lead to severe hyperkalaemia.

4.6 Fertility, pregnancy and lactation

There is no detailed experience of the use of this product during pregnancy and lactation. Potassium Chloride should only be used during pregnancy or lactation if considered essential.
Fertility
No data available

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

System Organ Class	Frequency	Adverse events
Metabolism and nutrition disorders	Not known	Hyperkalaemia[1]
Vascular disorders	Not known	Phlebitis[2],
General disorders and administration site conditions	Not known	Pain[2]

[1]Excessive intake of potassium may cause hyperkalaemia, the symptoms of which are described under Overdose below.
[2]Pain or phlebitis may occur at the site of administration.

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
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

Symptoms
Overdosage may cause hyperkalaemia, with paraesthesia, muscle weakness, paralysis, hypotension, cardiac arrhythmias and cardiac arrest.
Treatment
All drugs containing potassium should be withdrawn and potassium-sparing diuretics discontinued. Infusions of glucose alone or with insulin or sodium bicarbonate solution may be used to reduce serum potassium concentrations. Intravenous administration of calcium gluconate may be used to treat cardiac toxicity. Mild hyperkalaemia may be treated with sodium polystyrene sulphonate, a cation-exchange resin administered by mouth or as an enema. If the above measures fail, haemodialysis or peritoneal dialysis may be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Electrolyte solutions; ATC Code: B05XA01
Potassium plays a vital physiological role in maintenance of normal electrical excitability of nerve and muscle. The normal plasma concentration of potassium is in the range of 3.5 to 5 mEq per litre, and intracellular concentrations are about 150 mEq per litre.
In acute hypokalaemia, parenteral administration of potassium chloride promptly corrects the deficit in plasma potassium concentration and restores normal physiological function to potassium-dependent systems.

5.2 Pharmacokinetic properties

Absorption
Potassium is an essential dietary constituent and is readily absorbed from the gastro-intestinal tract. Accumulation of potassium by cells occurs via an energy-dependent mechanism that extrudes sodium.
Distribution
As a consequence of the large volume of distribution and the rapid response of the kidney, intracellular and extracellular concentrations of potassium are normally maintained within relatively narrow limits.
Although administration of potassium will not significantly increase the total body content of the ion, it may easily raise the extracellular concentration excessively.
Because it is the extracellular concentration of potassium that determines life-threatening toxicity, awareness of the transient concentration achieved in plasma should govern the use of potassium therapy.
Elimination
Potassium is excreted mainly by the kidneys. It is freely filtered at the glomerulus and is mainly absorbed in the proximal tubules. Normally, considerable amounts of potassium are secreted into the distal tubules.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Incompatibilities have been reported with dobutamine hydrochloride, amphotericin, amikacin sulphate and fixed oil emulsions.
In the absence of compatibility studies 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.
Dilute immediately after opening. Use the diluted product immediately.

6.4 Special precautions for storage

As packaged for sale:
Do not store above 25^{o}C.
Keep the ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

10 ml, clear glass one-point-cut (OPC) ampoules, glass type I Ph. Eur. borosilicate glass packed in cardboard cartons to contain 10 x 10 ml ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Dilute before use with not less than 50 times its volume of sodium chloride injection or another suitable diluent.
For single use only. Discard any remaining contents.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals (Ireland) Ltd
4045 Kingswood Road
Citywest Business Park
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA0073/106/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 November 1988

Date of last renewal: 18 November 2008

10 DATE OF REVISION OF THE TEXT

August 2020