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

1 ml of solution contains	
Potassium Chloride	150 mg

1 dosage unit of solution contains	
Potassium Chloride	
• per 10 ml ampoule	1.50 g

Electrolyte concentrations	[mmol/ml]
Potassium	2
Chloride	2

Excipients
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion
Clear solution, free from visible particles. pH in the range 5.0- 7.0.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- Treatment of potassium deficiency, in particular if accompanied by hypochloraemic alkalosis.
- Supplementation of potassium as a part of parenteral nutrition.

4.2 Posology and method of administration

Posology
The dosage should be adjusted according to the actual serum electrolyte concentrations and the acid base status and the individual requirements of the patient. Potassium concentrates for infusion must be diluted with a compatible i.v. solution prior to administration.

Adults and elderly patients:

Treatment of moderate, asymptomatic potassium deficiency:

The amount required for correction of moderate potassium deficiency and in maintenance may be calculated according to the following formula:

mmol K^+required = (BW*[kg] × 0.2)** × 2 × (serum-K^+target*** – serum-K^+actual [mmol/l])

*BW = body weight
**Term represents the extracellular fluid volume
***K^+target should be 4.5 mmol/ per litre

Maximum infusion rate:
Up to 10 mmol potassium per hour (corresponding to 0.15 mmol potassium/kg body weight per hour).

Treatment of severe symptomatic potassium deficiency (serum potassium level below 2.5 mmol/ per litre):
Maximum daily dose:
Up to 2 – 3 mmol/kg body weight/day

Maximum infusion rate:
Up to 20 mmol potassium per hour (corresponding to 0.3 mmol potassium/kg body weight per hour).

If serum potassium levels are below 2 mmol/ per litre and continuous ECG monitoring is ensured,the infusion rate may be as high as 40 mmol per hour.

Potassium supplementation as part of parenteral nutrition:
The daily requirements of potassium are 1- 1.5 mmol/ kg body weight.

The administration rate should not exceed 10 mmol potassium per hour (corresponding to 0.15 mmol potassium/ kg body weight per hour).

Paediatric population

Treatment of potassium deficiency
In children, the solution must be diluted to a concentration of 20-40 mmol of KCl/ per litre before administration.

Maximum daily dose:
The maximum daily dose depends on the severity of potassium deficiency and overall condition of the individual patient. The maximum daily dose might therefore exceed the amount of potassium given as part of parenteral nutrition (see section "Potassium supplementation as part of parenteral nutrition" below).

Maximum infusion rate:
Symptomatic hypokalemia can be corrected at a maximal rate of 1 mmol/kg body weight per hour with a maximum rate of 20 mmol/h.

Potassium supplementation as part of parenteral nutrition:

Recommended maximum daily dose for potassium supplementation as part of parenteral nutrition (in mmol/kg body weight)

Period	Term neonates	Preterm neonates	
		<1500 g	>1500 g
1st postnatal week	0 – 2.0		
1st month of life prior to stable growth	1.0 – 3.0	1.0 – 2.0	1.0 – 3.0
1st month of life with stable growth	1.5 – 3.0	2.0 – 5.0	

Children and infants after the first month of life must not receive more than 3 mmol per kg body weight per day.

Other special patient groups
Changes in acid-base balance affect plasma concentrations. The demand of potassium is increased in compensation of ketoacidosis in diabetic patients and when glucose/insulin is given.

Method of administration

Intravenous use (see section 4.4).

Only to be administered by infusion after dilution in suitable infusion solutions.

The potassium concentration in the infusion solution should normally not exceed 40 mmol/ per litre.

If serum potassium levels in adults are below 2 mmol/ per litre the potassium concentration in the infusion solution may be as high as 80 mmol/ per litre.

For instructions on dilution of the medicinal product before administration, see section 4.4 and 6.6.

As a matter of principle, infusion pumps should be used for the infusion of potassium in the setting of correction therapy.

4.3 Contraindications

Potassium Chloride 15% w/v must not be administered in case of.
- hyperkalaemia.
- hyperchloraemia.

4.4 Special warnings and precautions for use

Potassium Chloride 15% w/v should only be administered with caution in the presence of:

- Cardiac diseaseDisorders associated with potassium retention such as impaired renal function, Addison's disease, sickle cell anaemia. Treatment of patients with severe renal impairment and patients on dialysis must be consulted with nephrologist.
- Concurrent treatment with potassium-saving diuretics, Angiotensin II receptor antagonists, ACE inhibitors or potentially nephrotoxic medicinal products (nonsteroidal anti-inflammatories etc.), see also section 4.5.
- shock
- Extensive tissue destruction (e.g. burn injuries)
- hyperkalaemic familial periodic paralysis

Sudden discontinuation of potassium administration may be followed by marked hypokalaemia, which may lead to increased toxicity of cardiac glycosides taken concomitantly.

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

ECG monitoring should be available.
There are typical changes in the ECG when the potassium balance is disturbed (hypo- or hyperkalaemia). However, there is no linear relationship between the ECG changes and the concentration of potassium in the blood.

Refeeding syndrome
Refeeding severely undernourished patients may result in the refeeding syndrome. Refeeding syndrome consists of hypophosphatemia which is often accompanied by hypokalaemia, hypomagnesaemia, fluid retention and hyperglycaemia. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Clinical monitoring should include checks of the serum electrolyte levels and the acid-base balance.

It must be made absolutely sure that the solution is administered intravenously, because paravenous administration may cause tissue necrosis.
Elderly patients:
Elderly patients, who are more likely to suffer from cardiac insufficiency and renal impairment, should be closely monitored during treatment, and the dosage should be carefully adjusted.

4.5 Interaction with other medicinal products and other forms of interactions

• **Cardiac glycosides**
An increase in the extracellular potassium concentration reduces the effect of cardiac glycosides, a decrease leads to an intensification of the arrythmogenic effect of cardiac glycosides.

• **Medicinal products reducing potassium excretion**
These include:
- potassium saving diuretics (e.g. triamterene, amiloride, spironolactone)
- Angiotensin II receptor antagonists
- ACE inhibitors
- tacrolimus
- ciclosporin
- non-steroidal anti-inflammatory drugs
- peripheral analgesics
- heparin

Severe hyperkalaemia adversely affecting heart rhythm can result when these drugs are administered concurrently with potassium chloride.

•**Medicinal products increasing potassium excretion**
ACTH, corticosteroids and loop diuretics can increase the renal elimination of potassium.

• **Suxamethonium**
Severe hyperkalaemia, with adverse effect on the heart rhythm, can also occur when suxamethonuium and potassium are administered concurrently.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of Potassium Chloride Concentrates in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

On the basis of known physiological effects of potassium, no adverse effects on the unborn are expected of a normalisation of an abnormal serum potassium concentration. Too high or too low potassium levels can however be detrimental to maternal and foetal cardiac function.
The product should be used only when clearly needed and after carefully weighing out expected benefits against possible risks.

Lactation
Potassium Chloride is excreted in human milk. However, from a normalisation of potassium in the blood no adverse effect is expected on the potassium level in breast milk. Potassium chloride concentrate for infusion - if used according to the directions given - may therefore be used during lactation.

Fertility
No data available

4.7 Effects on ability to drive and use machines

Potassium Chloride 15% w/v has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are listed according to their frequencies as follows:

Very common: (≥ 1/10)
Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1,000 to < 1/100)
Rare: (≥ 1/10,000 to < 1/1,000)
Very rare: (< 1/10,000)
Not known (Frequency cannot be estimated from the available data)

Metabolism and nutrition disorders
Not known: Acidosis, hyperchloraemia

Cardiac disorders
Not known: Too rapid infusion may provoke cardiac arrhythmia.

Gastrointestinal disorders
Not known: Nausea

General disorders and administration site conditions
Not known: Local reactions at the site of administration, including local pain, vein irritation, thrombophlebitis 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 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

Symptoms

Overdose may cause hyperkalaemia, in particular in the presence of acidosis or kidney insufficiency.

The symptoms of hyperkalaemia are primarily cardiovascular disorders. They may include bradycardia, AV blockade, ventricular fibrillation and cardiac arrest. In the ECG there are high, sharp, symmetrical T-waves and, at very high potassium levels, broadening of the QRS complex. The vascular effects are hypotension and centralisation.

The neuromuscular symptoms include fatigue, weakness, states of confusion, heaviness of limbs, muscle twitching, paraesthesia, and ascending paralysis.

Plasma potassium concentrations of 6.5 mmol/l or more are dangerous, over 8 mmol/l often lethal.

Treatment

The first measure is immediate stop of infusion.

Further corrective measures include slow intravenous administration of 10 % calcium gluconate, infusion of glucose together with insulin, increase of diuresis, oral or rectal administration of cation exchangers, correction of acidosis, if necessary.

In severe cases haemodialysis may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: IV solution additives - electrolytes
ATC code: B05X A01

Mechanism of action
Potassium is the most important cation of the intracellular space, approx. 98 per cent of the organism's total potassium is located there.

Potassium is involved in electrochemical processes of cells and in carbohydrate and protein metabolism.

Potassium deficiency may be caused by increased renal excretion, increased gastro-intestinal losses, e.g. by vomiting or diarrhoea, or through fistulae, by increased intracellular uptake, e.g. during therapy of acidosis or therapy with glucose and insulin, or by insufficient potassium intake

Hypokalaemia is accompanied by muscle weakness, atony of gastro-intestinal smooth muscles (constipation up to paralytic ileus), loss of capability of kidneys to concentrate urine, ECG alterations and cardiac arrhythmia.

5.2 Pharmacokinetic properties

Absorption
As the medicinal product is administered intravenously, its bio-availability is 100 per cent.

Distribution
The distribution of potassium follows the normal physiological pathways of potassium metabolism.

The plasma potassium concentration is closely related to the acid-base balance. Alkalosis is often accompanied by hypokalaemia and acidosis by hyperkalaemia. Normal plasma potassium concentrations in acidosis indicate potassium deficiency.

The intracellular potassium concentration is approx. 140-150 mmol/l. The normal potassium serum concentration is between 3.5 and 5 mmol/l.

Elimination
Potassium is mainly excreted into the urine (about 90 per cent) and about 10 per cent are excreted via the gastrointestinal tract.

5.3 Preclinical safety data

Non-clinical data are insufficient. If electrolytes are kept within physiological range, toxic effects are not expected.

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: 3 years.

After first opening the container:
To be added to diluent immediately after opening the container. See also section 6.6.

Shelf life after dilution according to directions:

Chemical and physical in-use stability of dilutions in 0.9% w/v Sodium Chloride, 5% w/v Glucose and 10% w/v Glucose has been demonstrated for 24 hours at room temperature (15-25°C).

From a microbiological point of view, the product should be used immediately. 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 reconstitution/dilution (etc) has taken place in controlled and validated aseptic condition.

6.4 Special precautions for storage

Do not store above 25°C.

For storage conditions after dilution of the medicinal product, see section 6.3

6.5 Nature and contents of container

Supplied in round or oval polyethylene ampoules (Mini-Plasco®) containing 10ml of solution, in packs of 20 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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Single-dose container.Discard unused contents.
Only to be used if solution is clear and the container and its closure does not show visible signs of damage.

Must be diluted before use with not less than 500ml of suitable diluent and mixed well. The following infusion solutions can be used as diluents: 0.9% w/v sodium chloride, 5% w/v glucose, 10% w/v glucose, compound sodium lactate solution.

Potassium Chloride 15% w/v Concentrate for Solution should only be added immediately before setting up the infusion and strictly aseptic technique should be observed. The infusion bottle should then be gently shaken.

7 MARKETING AUTHORISATION HOLDER

B. Braun Medical Limited
3 Naas Road Industrial Park
Dublin 12
Ireland

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 November 1991

Date of last renewal: 26 November 2006

10 DATE OF REVISION OF THE TEXT

May 2018