SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 14.9 %

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL of concentrate contains 0.149 g potassium chloride
corresponding to 2 mmol K^+ and 2 mmol Cl^-

1 ampoule (= 10 mL ampoule) contains 1.49 g potassium chloride
corresponding to 20 mmol K^+ and 20 mmol Cl^-

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion
Clear, colourless solution

Theoretical osmolarity	3 995 mOsm/L
pH	4.5-7.5

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

States of potassium deficiency when oral replacement is not feasible.

4.2 Posology and method of administration

Posology

Individualize dosage. Guide dosage and rate of infusion by ECG and serum electrolyte determinations. The potassium deficit is calculated according to the following formula:
mmol potassium = kg body weight x 0.2 x 2 x [4.5 – current
serum potassium (mmol/l)]. (Body weight x 0.2 represents the extracellular fluid volume.)

Maximum daily dose
Not more than 2–3 mmol/kg body weight/day.

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

Children
IV infusion up to 3 mEq/kg/day. Adjust volume of administered fluids to body size.

Method of administration
Intravenously use. Use only diluted as an additive to infusion solutions. The potassium concentration in the infusion solution must not exceed 40 mmol/l. Suitable vehicle solutions are e.g. 5% or 10% glucose solutions, isotonic sodium chloride solution, Compound Sodium Lactate solution, or complete electrolyte solutions.
Do not infuse rapidly. Adjust rate of administration according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended.

In addition to ECG effects, vein irritation may result when a potassium concentration greater than 40 mEq/l is infused.
Concentrated potassium solutions are for IV admixtures only; do not use undiluted. Direct injection may be instantaneously fatal.
In critical states, potassium chloride may be administered in saline (unless saline is contraindicated) since dextrose may lower serum potassium levels by producing an intracellular shift.
Concentrated Sterile Solution containing 14.9% Potassium Chloride 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.
As a matter of principle, infusion pumps should be used for the infusion of potassium in the setting of correction therapy.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Potassium Chloride 14.9% must not be administered in the event of:
- hyperkalaemia
- hyperchloraemia

4.4 Special warnings and precautions for use

Potassium Chloride 14.9% should only be administered with caution in the presence of:
- cardiac disorders
- disorders associated with potassium retention, such as impaired renal function, Addison's disease, sickle cell anaemia. When treating patients with severe renal impairment and patients on dialysis, a nephrologist must be consulted
- concomitant treatment with potassium-sparing diuretics, angiotensin II receptor antagonists, ACE inhibitors or potentially nephrotoxic medicinal products (non-steroidal anti-inflammatory drugs, etc.), see also section 4.5
- shock
- extensive tissue damage (e.g. burns)
- familial hyperkalaemic 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
In the event of abnormal changes in the potassium level (hypokalaemia or hyperkalaemia), typical changes are found in the ECG. However, there is no linear relationship between ECG changes and the blood potassium concentration.

Refeeding syndrome
Refeeding severely undernourished patients may result in the refeeding syndrome. This manifests as hypophosphataemia, 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 serum electrolyte levels and acid-base balance.

Special attention should be paid to strictly intravenous administration, as paravenous administration can lead to 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 interaction

Cardiac glycosides

An increase in the extracellular potassium concentration decreases the effect of cardiac glycosides and a decrease intensifies the arrhythmogenic effect of cardiac glycosides.

Medicinal products that reduce potassium elimination

These include:
– potassium-sparing 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 medicinal products are administered concomitantly with potassium chloride.

Medicinal products that increase potassium elimination

ACTH, corticosteroids and loop diuretics may increase the renal elimination of potassium.

Suxamethonium

Severe hyperkalaemia adversely affecting heart rhythm can also occur when suxamethonium and potassium are administered concomitantly.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or a limited amount of data from the use of Potassium Chloride 14.9% 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 child are expected from 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 medicinal product should be used only when clearly needed and after carefully weighing out the expected benefits against the possible risks.

Breastfeeding

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. If used as intended, Potassium Chloride 14.9% may therefore be used during breastfeeding.

Fertility

No data are available.

4.7 Effects on ability to drive and use machines

Potassium Chloride 14.9% 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	(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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (https://sideeffects.health.gov.il).

4.9 Overdose

Symptoms

Overdose may result in hyperkalaemia, particularly in the presence of acidosis or renal failure.

Symptoms of hyperkalaemia are mainly cardiovascular disorders. These may include bradycardia, AV block, ventricular fibrillation and cardiac arrest. In the ECG, tall, sharp and symmetric T-waves, and, if potassium levels are very high, widening QRS complexes can be seen. The vascular effects are hypotension and centralisation.

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

Plasma potassium concentrations of 6.5 mmol/L and above are threatening and concentrations above 8 mmol/L are 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 in diuresis, oral or rectal administration of cation exchangers, and correction of acidosis, if necessary.

In cases of massive overdose, haemodialysis may be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: IV solution additives, electrolyte solutions
ATC code: B05X A01

Mechanism of action

Potassium is the most important cation of the intracellular space, approx. 98% of the body's potassium

content is intracellular.

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

Potassium deficiency may occur as a result of increased renal excretion, increased gastrointestinal losses (e.g. due to vomiting, diarrhoea or fistulae), increased intracellular potassium uptake (e.g. during acidosis treatment or glucose-insulin therapy) or inadequate potassium intake.

Hypokalaemia is associated with muscular weakness, atony of the gastrointestinal smooth muscles (constipation or even paralytic ileus), reduced renal concentrating ability, ECG changes and cardiac arrhythmia.

5.2 Pharmacokinetic properties

Absorption

As the medicinal product is administered intravenously, its bioavailability is 100%.

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 frequently associated with hypokalaemia and acidosis with hyperkalaemia. In the case of existing acidosis, normal plasma potassium concentrations indicate a potassium deficiency.

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

Elimination

Potassium is mainly excreted via the urine (about 90%) and about 10% 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 Injection

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened

The expiry date of the product is indicated on the packaging materials.

After first opening the container

Not applicable. See also section 6.6.

After dilution

From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user. Under normal circumstances, dilutions should not be stored for longer than 24 hours at 2°C–8°C, unless dilution has taken place in controlled and validated aseptic conditions.

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

Low-density polyethylene (LDPE) ampoules, contents: 10mL,
20 mL,available in packs of 20 × 10 mL, 20 x 20 mL.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

Dilution
Suitable vehicle solutions are, for example, a 5% or 10% glucose solution, isotonic saline solution, Ringer's lactate solution or balanced electrolyte solutions.
Potassium Chloride 14.9% may only be added immediately before setting up the infusion, thereby observing a strictly aseptic technique. The infusion container should then be shaken gently.

The containers are intended for single use only. Discard any unused contents.

Only use if the solution is clear, colourless and practically free from visible particles and the container and seal are intact.

7. MANUFACTURER

B. Braun Melsungen AG

Carl-Braun-Straße 1
D-34212
Melsungen
Germany

8. REGISTRATION HOLDER

Lapidot Medical Import and Marketing Ltd.
8 Hashita Street, Industrial Park Caesarea 38900, ISRAEL

9. MARKETING AUTHORISATION NUMBER

117-63-29912-00

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