SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.15% w/v and Glucose 5% w/v Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1000ml of solution for infusion contains:

Potassium chloride	1.50 g
Glucose (as glucose monohydrate)	50.00 g (55.00 g)

Electrolyte concentrations:

Potassium	20 mmol/l
Chloride	20 mmol/l

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Clear, colourless up to faintly straw-coloured aqueous solution

Energy	835 kJ/l □ 200 kcal/l
Theoretical osmolarity	318 mOsm/l
pH	3.5-6.5

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Supply of potassium to correct or prevent potassium deficiency and supply of glucose to cover basic energy requirements.

4.2 Posology and method of administration

Posology

The dosage is dependent on age, weight and clinical condition of the patient, especially those with renal or cardiac insufficiency. Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially in patients

with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. Potassium Chloride 0.15 % w/v and Glucose 5% w/v Solution for Infusion may become hypotonic after administration due to glucose metabolisation in the body (see sections 4.4, 4.5 and 4.8).

Dosage and rate of infusion should be determined by ECG and serum electrolyte monitoring. Adequate urine flow must be ensured.

Adults:

The following recommendations are general guidelines on potassium.

Potassium

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

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

*Term represents the extracellular fluid volume

** should be 4.5 mmol/l

The maximum recommended dose of potassium is 2 – 3 mmol/kgBW/24 h.

Fluid

Generally, not more than 40 ml fluid/kg BW/d should be supplied. In cases where more potassium is needed, other strengths should be considered as well.

Maximum infusion rate

Up to 5 ml/kg body weight per hour, corresponding to 0.25 g glucose/kg body weight per hour and 0.1-0.2 mmol/kg/ body weight per hour potassium (for 0.15% w/v and 0.3% w/v, respectively).

Paediatric population:

The volume and rate of infusion will depend upon the requirements of the individual patient. Reduced volumes and rates of infusion may be required. Generally a substitution rate of 0.5 mmol/kg potassium BW per hour should not be exceeded. Continuous ECG monitoring should be applied during infusion.

Maximum daily dose

The maximum recommended dose of potassium is 3 mmol/kg BW per 24 hours. In any case the limits for daily fluid intake must not be exceeded.

Elderly

Basically the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age. See section 4.4.

Duration of use

This medicinal product may be administered as long as there is an indication for energy, potassium and fluid administration.

Method of administration

Intravenous use.

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

4.3 Contraindications

- Hyperkalaemia
- Severe renal impairment with oliguria and anuria
- Severe hyperchloraemia
- Head trauma (first 24 hours)
- Hyperhydration
- Hyperglycaemia

4.4 Special warnings and precautions for use

Special warnings

Solutions containing potassium should be administered slowly and only after renal function has been established and proved adequate. In patients with renal impairment, its use must be carefully controlled by frequent determinations of plasma potassium concentrations and periodic ECGs. The infusion must be discontinued if signs of renal insufficiency develop during infusion.

Potassium supplements should be administered with caution in patients with cardiac disease particularly in digitalised patients (see section 4.5).

Care must be exercised in the administration of large volume infusion of hypotonic fluids to patients with congested states or pulmonary oedema.

Solutions with low electrolyte content, especially sodium, should also be administered with care in patients with hyponatraemia.

Care should be taken to avoid a rapid marked decrease of the serum sodium level as this may be associated with the risk of osmotic central nervous damage.

Adequate sodium supplementation should be assured depending on the volume of Potassium Chloride 1.5 mg/ml (0.15 % w/v) and Glucose 50 mg/ml (5% w/v) Solution for Infusion to prevent hyponatraemia.

Potassium Chloride 0.15% w/v and Glucose 5% w/v Solution for Infusion is an isotonic solution. In the body, however, the solution can become physiologically hypotonic due to rapid glucose metabolisation (see section 4.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolise

glucose, intravenous administration of these solutions can cause electrolyte

disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia:

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, bums, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with

brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Caution should be exercised when the solution is administered to patients with diabetes, and in patients with impaired glucose tolerance for any other reason (see also section 4.5). Blood glucose monitoring will be required.

Due to the risk of developing a severe lactic acidosis and/or a Wernicke encephalopathy a preexisting thiamin (Vitamin B1) deficiency must be corrected before infusion of glucose containing solutions.

Solutions containing glucose should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment because of the possibility of pseudoagglutination.

Administration of glucose solutions is not recommended after acute ischaemic strokes as hyperglycaemia was reported to worsen ischaemic brain damage and impair recovery.

Caution should be exercised in patients with disorders that are frequently associated with hyperkalaemia e.g. Addison's disease or sickle cell anaemia.

Paediatric population

Solutions with low salt, especially sodium, should only be administered with special caution to children and close monitoring of electrolyte and fluid balance should be performed.

Intravenous fluid therapy should be closely monitored in the paediatric population as they may have impaired ability to regulate fluids and electrolytes. The infusion of hypotonic fluids together with the non-osmotic secretion of ADH (for example in pain, anxiety, the post-operative state, nausea, vomiting) may result in hyponatraemia.

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, in order to avoid cardio circulatory and renal complications resulting from fluid overload.

Precautions for use

Clinical supervision should include ECGs, regular checks of fluid balance, serum electrolytes and monitoring of blood glucose.

4.5 Interaction with other medicinal products and other forms of interaction

- **Digoxin, cardiac glycosides**

In patients under treatment with cardiac glycosides care should be taken to keep the potassium concentration constant.
In case of **hyperkalaemia** - the effect of cardiac glycosides may be weakened, and in case of hypokalaemia it may result in cardiac glycoside toxicity. Potassium administration must be very carefully discontinued in these patients.
Interactions might occur in the concurrent administration of other antiarrytmics.

- **Drugs with the potential to induce hyperkalaemia**

Care should be taken in the concurrent use of drugs containing potassium and drugs with the potential to induce hyperkalaemia, such as:
– potassium-sparing diuretics e.g. spironolactone, triamterene
– ACE inhibitors
– AT1- receptor antagonists
– non-steroidal anti-inflammatory agents
– cyclosporine
– tacrolimus
– suxamethonium

The concomitant administration of potassium-containing solutions and these drugs may lead to severe hyperkalaemia, which may in turn lead to cardiac arrhythmia.

- **Drugs leading to a decrease of the serum potassium level**

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

- **Medicinal products leading to an increased vasopressin effect**

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i. v. fluids (see sections 4.2, 4.4 and 4.8)

Drugs stimulating vasopressin release, e.g.:
Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine , ifosfamide, antipsychotics, narcotics

Drugs potentiating vasopressin action, e.g.:
Chlorpropamide, NSAIDs, cyclophosphamide

Vasopressin analogues, e.g.:
Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

Other clinically relevant pharmacological drug interactions are not known.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of Potassium Chloride 0.15% w/v and Glucose 5% w/v Solution for Infusion in pregnant women.
Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). However, as all components of Potassium Chloride 0.15 % w/v and Glucose 5% w/v Solution for Infusion are naturally present in the body and their biochemical properties are well known, no toxic effects in relation to pregnancy are to be expected.

Potassium Chloride 0.15 % w/v and Glucose 5% w/v Solution for Infusion can be used during pregnancy if clinically needed.

However, Potassium Chloride 0.15 % w/v and Glucose 5% w/v Solution for Infusion should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

Breast-feeding
There are no or limited amount of data from the use of potassium chloride and glucose in lactating women.

However, as all components of this medicinal product are naturally present in the body and their biochemical properties are well known, no toxic effects in relation to lactation are to be expected.

Potassium Chloride 0.15 % w/v and Glucose 5% w/v Solution for Infusion can be used during breastfeeding if clinically needed.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Potassium Chloride 0.15 % w/v and Glucose 5% w/v Solution for Infusion has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

General

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).

General disorders and administration site conditions

Not known: Local reactions at the infusion site, including local pain, venous irritation and occasionally thrombophlebitis may occur.

Metabolism and nutrition disorders

Not known: Hospital Acquired Hyponatraemia

Neurological disorders:

Not known: Hyponatraemic encephalopathy

Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

In case of overdose hyperkalaemia, hyponatraemia, hyperhydration, hyperglycaemia, potassium intoxication, oedema, metabolic and electrolyte disorders can result

The symptoms of hyperkalaemia are primarily cardiovascular disorders and include hypotension, cardiac arrhythmia, heart block, ECG abnormalities with development of biphasic curves and cardiac arrest. Other symptoms include paresthesias of extremities, muscle or respiratory paralysis, areflexia, weakness and mental confusion.

Treatment

Immediate interruption of the infusion, ECG monitoring, if necessary enhancement of urine flow and thus fluid and electrolyte excretion, administration of sodium bicarbonate and insulin. If insulin is given to increase cellular uptake of potassium, glucose should be given to avoid hypoglycaemia. In patients with persistent ECG abnormalities e.g. calcium gluconate may be administered to antagonize the cardiotoxic effects of potassium. Haemodialysis or peritoneal dialysis may be required in patients with renal insufficiency.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Solutions affecting the electrolyte balance

ATC code: B05B B02

Potassium Chloride 0.15% w/v and Glucose 5% w/v Solution for Infusion contains glucose and the electrolytes potassium and chloride in water for injections.

Mechanism of action

Potassium is the major cation of intracellular fluid and is essential for maintenance of acid-base balance, isotonicity, and electrodynamic characteristics of the cell. The electrolyte is an important activator in many enzymatic reactions and is essential to a number of physiologic processes including transmission of nerve impulses, contraction of cardiac, smooth, and skeletal muscles, gastric secretion, renal function, tissue synthesis, carbohydrate utilisation and protein synthesis. Chloride, the major extracellular anion and closely follows the physiologic disposition of sodium and also potassium. Together with sodium and bicarbonate, chloride plays an important role in the regulation of acid-base balance and changes in the acid-base balance of the body are reflected by changes in serum chloride concentration.

Glucose is the main carbohydrate in the body and is essential to some organs. In the body glucose itself and derivates of glucose metabolism are used for energy supply, modification of proteins and lipids, formation of mucopolysaccharides and lactose, as components of nucleic acids, and conjugates for the excretion of various substances.

Pharmacodynamic effects

In postoperative, posttraumatic and other clinical instances severe fluid and electrolyte losses and catabolic situations are frequently observed and the above named physiologic functions are impaired. In these patients the application of the components contained in Potassium Chloride 0.15% and Glucose 5% w/v Solution for Infusion are indicated to restore electrolyte levels, supply energy and thus prevent further damage to the body.

5.2 Pharmacokinetic properties

Absorption
Since the ingredients of Potassium Chloride 0.15% w/v and Glucose 5% w/v Solution for Infusion are infused intravenously their bioavailability is 100%.

Distribution
Infused potassium is actively transported into the cells, where its concentration is up to 40 times that outside the cell. Plasma potassium concentrations generally range from 3.5-5 mmol/l. Chloride mainly distributes in the extracellular space. Plasma chloride concentration is normally regulated at a concentration of 95-107 mmol/l.

Fasting values of plasma glucose levels vary only between 3.9 and 5.6 mmol/l (70-100 mg/dl).

Biotransformation

Plasma glucose levels are most closely regulated mainly by the liver together with various hormones and skeletal muscle. Normally glucose is completely oxidised to CO_2 and water, but this metabolic pathway is limited. Excess glucose is stored as glycogen or converted to fat. Glucose clearance, oxidation, and recycling are affected in severe trauma and other clinical situations such as diabetes. In these situations, the solution must be administered carefully in order to avoid hyperglycaemia.

Elimination

The kidneys are the main route of excretion for *potassium* and *chloride* but small amounts are lost via the skin and intestinal tract. The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidney's (water). Especially surgery results in increased urinary excretion of potassium while water and sodium is retained. For supplementation it is essential to take into consideration that the homeostasis of the single electrolytes is influenced each other and their regulation is thus interdependent to some degree.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development. All components of Potassium Chloride 0.15 % w/v and Glucose 5% w/v Solution for Infusion are naturally present in the body and their biochemical properties are well known. Therefore, toxic effects are not to be expected.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

- *unopened*
3 years

-after first opening the container

Not applicable. Please see section 6.6.

- *after addition of additives*

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Unopened: Do not store above 25 °C.

For storage conditions of the medicinal product after addition of an additive, see section 6.3.

6.5 Nature and contents of container

Bottles of colourless low-density polyethylene, contents: 500 ml and 1000 ml available in packs of 10.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Use only if the solution is clear, colourless up to faintly straw-coloured and if the container is undamaged. The solution should be free of visible particles. The solution should not be administered if the container or its closure shows visible signs of damage.

The containers are for single use only. Discard container and any remaining contents. Do no re-connect partially used container.

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

The equipment must be primed with the solution in order to prevent air entering the system.

The infusion should be stopped immediately if adverse reactions occur.

7 MARKETING AUTHORISATION HOLDER

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Carl-Braun-Str. 1
34212 Melsungen
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8. MARKETING AUTHORISATION NUMBER

PL 03551/0078

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