

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.3%w/v Glucose 5%w/v Solution for Infusion

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Component

Potassium chloride

Glucose monohydrate

Per 500ml	Per 1000ml
1.5g	3.0g
K <sup>+</sup> 20 mmol	K <sup>+</sup> 40 mmol
Cl <sup>-</sup> 20 mmol	Cl <sup>-</sup> 40 mmol
equivalent to 25.0g anhydrous glucose 139 mmol	equivalent to 50.0g anhydrous glucose 278 mmol

Osmolality approx. 370 mOsm/kg H<sub>2</sub>O.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for infusion (Intravenous Infusion)

Colourless to faintly straw-coloured solution without visible particles in bags, individually overwrapped.

pH 3.5 - 6.5.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For prevention and treatment of potassium depletion and/or hypokalaemia in cases where supply of water and carbohydrates is required due to restriction of intake of fluids and electrolytes by normal routes.

### 4.2 Posology and method of administration

For intravenous infusion under medical supervision.

Single use only.

The pathophysiological response to dehydration, to electrolyte loss and to potassium chloride and glucose infusion will vary with the age of the patient being treated and this should be taken into account during rehydration therapy.

The volume of solution needed to replenish deficits varies with hydration state, age, body weight, complementary treatment and clinical and biochemical status.

Doses may be expressed in terms of mEq or mmol of potassium, mass of potassium or mass of potassium salt:

1 g KCl = 525 mg of K<sup>+</sup> or 13.4 mEq or 13.4 mmol of K<sup>+</sup> and Cl<sup>-</sup>

1 mmol K<sup>+</sup> = 39.1 mg K<sup>+</sup>

### Posology

#### **Adults:**

500ml to 3000ml/24h

#### **Paediatric population:**

0 – 10kg body weight: 100ml/kg/24h

10 – 20kg body weight: 1000ml + (50ml/kg over 10kg)/24h

> 20kg body weight: 1500ml + (20ml/kg over 20kg)/24h

The infusion rate should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore the maximum dose ranges from 5mg/kg/min for adults to 10-18 mg/kg/min for babies and children depending on age and total body mass.

### ***Posology for prevention and treatment of potassium depletion***

Typical doses of potassium for the prevention of hypokalaemia and treatment of mild potassium deficiency may be up to 50mmoles per day. The recommended maximal dose of potassium is 2-3mmol/kg/24h.

When used for the treatment of hypokalaemia, the recommended dosage is 20 mmoles of potassium over 2 to 3 hours (i.e. 7-10 mmol/h) under ECG control.

Patients with renal impairment should receive lower doses.

## **Method of Administration**

### ***Route of administration***

The administration is performed by intravenous route using sterile and non-pyrogenic equipment. Intravenous potassium should be administered in a large peripheral or central vein to diminish the risk of causing sclerosis. If infused through a central vein, to avoid localised hyperkalaemia the catheter must not be in the atrium or ventricle.

### ***Rate of administration***

The rate of administration of potassium containing solutions should not exceed 15 to 20 mmoles/h to avoid dangerous hyperkalaemia. Rapid infusion may be harmful. Infusion rates greater than 500ml over three hours should be controlled by infusion pump.

### ***Monitoring***

Adequate urine flow must be ensured and careful monitoring of plasma-potassium and other electrolyte concentrations is essential. Higher dosage or high speed infusion must be performed under ECG control. Repeated 500ml doses must be monitored by repeated plasma potassium levels.

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 0.3%w/v Glucose 5%w/v Solution for Infusion may become extremely hypotonic after administration due to glucose metabolism in the body (see sections 4.4, 4.5 and 4.8).

## **4.3 Contraindications**

Severe impairment of renal function or hyperkalaemia such as is associated with adrenal insufficiency. Hyperchloraemia, uncompensated cardiac failure, uncompensated diabetes, other known glucose intolerances (such as metabolic stress situations, thionine (Vit B1) deficiency), hyperosmolar coma, hyperglycaemia, hyperlactatemia. Conditions of water excess.

Administration of glucose-containing solutions may lead to hyperglycaemia. Infusion of solutions containing glucose are contraindicated after acute ischaemic strokes as hyperglycaemia has been implicated in increasing cerebral ischaemic brain damage and impairing recovery, and in the first 24 hours following head trauma.

## **4.4 Special warnings and precautions for use**

Potassium Chloride 0.3%w/v Glucose 5%w/v Solution for Infusion is a hypertonic solution, with an approximate osmolarity of 370mOsm/l.

The solution must be administered with caution to patients with conditions associated with high potassium levels, cardio-pulmonary disease, oedema, acute dehydration, acute acidosis and cell destruction as in tissue trauma, burns, haemolysis, rhabdomyolysis, renal dysfunction, digitalisation or hepatic insufficiency.

Use with caution in diabetic patients: blood and urine glucose levels must be monitored and insulin requirement may be modified.

Glucose infusions are incompatible with blood for transfusion as haemolysis or clumping can occur; do not administer through the same infusion equipment as blood or blood components for transfusion (either before, during or after their administration).

Fluid replacement therapy should be administered with caution to very young and elderly patients who have reduced capacity to compensate for fluctuations in fluid and electrolyte balance.

Administration should be carried out under regular and careful surveillance. Regular monitoring of clinical status, plasma potassium, blood and urinary glucose level, serum and/or urinary electrolytes, plasma creatinine levels, BUN level, acid-base balance and ECG is essential in patients receiving potassium therapy, particularly those with cardiac or renal impairment. Plasma electrolyte concentrations should be carefully monitored especially in patients with pre-existing imbalances or conditions predisposing to hyperkalaemia, such as renal or adrenal insufficiency.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure.

Adequate urine flow must be ensured and fluid balance should be monitored.

Administration of potassium chloride in glucose solutions may lower the level of serum potassium attained.

Blood glucose concentration should be closely monitored during intracranial hypertension episodes.

If hyperglycaemia occurs, the rate of infusion should be adjusted or insulin administered.

During long-term treatment, a convenient nutritive treatment supply must be given to the patient.

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism (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 metabolize glucose, intravenous administration of glucose 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, burns, 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.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

##### **Drugs 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.

Care should be taken in the concurrent use of drugs containing potassium, potassium-sparing diuretics such as spironolactone and triamterene, and drugs which have the potential for inducing hyperkalaemia, ACE inhibitors, angiotensin II receptor antagonists, tacrolimus and cyclosporine.

Check compatibility of medicinal products with the solution before admixture and administration.

#### **4.6 Fertility, pregnancy and lactation**

Administration of intravenous fluids to pregnant and lactating women requires special consideration of the consequences of possible unwanted effects in relation to the desired therapeutic objective.

It has been suggested that if used during labour the glucose load on the mother may lead to foetal hyperglycaemia, hyperinsulinaemia, and acidosis, with subsequent neonatal hypoglycaemia and jaundice. Others have found no evidence of such an effect.

Hyperkalaemic and hypokalaemic serum levels lead to impaired cardiac function of the maternal and foetal hearts. Therefore, maternal electrolyte levels must be controlled regularly. As long as the maternal electrolyte serum levels are kept within the physiological range, there are no potential concerns regarding administration of Potassium Chloride 0.3%w/v Glucose 5%w/v Solution for Infusion during pregnancy and lactation.

Potassium Chloride 0.3%w/v Glucose 5%w/v Solution for Infusion should be administered with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see sections 4.4, 4.5 and 4.8).

#### **4.7 Effects on ability to drive and use machines**

Not applicable.

#### **4.8 Undesirable effects**

Prolonged intravenous infusion may lead to venous irritation and thrombophlebitis at the infusion site.

Adverse reactions may be associated with the technique of administration and include febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

Metabolism and nutrition disorders: hospital acquired hyponatraemia\*(frequency not known)

Nervous system disorders: hyponatraemic encephalopathy \*(frequency not known)

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

Discontinue infusion if adverse reaction occurs.

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization 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 national reporting system:

##### **For United Kingdom**

##### **Yellow Card Scheme**

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

##### **For Ireland**

##### **HPRA Pharmacovigilance**

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

#### **4.9 Overdose**

Excessive or rapid administration of potassium-containing solutions may cause hyperkalaemia with hypotension, cardiac arrhythmias, heart block, ECG abnormalities and cardiac arrest, mental confusion, and neuromuscular dysfunction such as muscle weakness, paraesthesia of the extremities and paralysis.

ECG changes are important indicators of potassium toxicity, including tall, peaked T-waves, depression of S-T segment, disappearance of the P-wave, prolongation of the Q-T interval, and widening and slurring of the QRS complex.

Excessive administration of chloride salts may cause a loss of bicarbonate with an acidifying effect.

In the event of accidental over infusion, treatment should be discontinued.

Treatment depends on the individual clinical situation but involves administration of calcium to counteract the effects of hyperkalaemia on cardiac excitability, the use of agents such as insulin or sodium bicarbonate to promote cellular uptake of potassium, and enhanced potassium excretion with exchange resins or dialysis. Administration of excessive amounts of 5% glucose may result in hyperglycaemia. Treatment is symptomatic.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group (ATC code): "electrolytes with carbohydrates" (B05BB02).

Potassium Chloride 0.3%w/v Glucose 5%w/v Solution for Infusion is a hypertonic solution, with an approximate osmolarity of 370mOsmol/kg H<sub>2</sub>O.

The pharmacodynamic properties of this solution are those of its components (potassium, chloride and glucose). Potassium is predominantly an intracellular cation, primarily found in muscle; only about 2% is present in the extracellular fluid. It is essential for numerous metabolic and physiological processes including nerve conduction, muscle contraction, and acid-base regulation.

Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa.

Glucose is the principal source of energy in cellular metabolism.

### 5.2 Pharmacokinetic properties

The pharmacokinetic properties of this solution are those of its components (potassium, chloride and glucose). Intravenous administration of the solution provides an immediate supply of electrolytes and glucose to blood. Factors influencing potassium transfer between intracellular and extracellular fluid such as acid base disturbances can distort the relationship between plasma concentrations and total body stores. Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules in exchange for sodium or hydrogen ions. The capacity of the kidneys to conserve potassium is poor and some urinary excretion of potassium continues even when there is severe depletion.

Some potassium is excreted in the faeces and small amounts may also be excreted in sweat. The two main metabolic pathways of glucose are gluconeogenesis (energy storage) and glycogenolysis (energy release). Glucose metabolism is regulated by insulin.

### 5.3 Preclinical safety data

Preclinical safety data of Potassium Chloride 0.3%w/v Glucose 5%w/v Solution for Infusion in animals are not relevant since potassium chloride and glucose are physiological components of the body. Toxic effects are not to be expected if serum electrolytes are kept within physiological range.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Water for Injections in bulk.

### 6.2 Incompatibilities

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

### 6.3 Shelf life

2 years.

Use immediately on removal from overwrap.

### 6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Store in the original outer container (over-wrap) to prevent moisture loss to the air.

### 6.5 Nature and contents of container

Flexible COSINUS<sup>PVC</sup> bags containing 500ml or 1000ml solution, individually overwrapped in transparent polypropylene laminate.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal and other handling**

Do not use unless the solution is clear and the container undamaged.  
Discard any unused solution. For single use only.  
The space between the bag and the overwrap is not guaranteed sterile.

Before use, remove the bag from the plastic overwrapping. Remove the twist-off protector of the infusion site and connect by clamping to the administration set.

Addition of medicinal products: Confirm additive compatibility before addition through the injection port. Clean the injection site using antiseptic solution. Carefully introduce the sterile needle into the sterile chamber in the injection site, attach the needle to the container with the medicinal product, introduce the needle through the second membrane into the bag and inject the medicine. Carefully withdraw the needle. Mix thoroughly with the solution. Use immediately.

## **7 MARKETING AUTHORISATION HOLDER**

Carelide  
Rue Michel Raillard  
59420 Mouvaux  
France

## **8 MARKETING AUTHORISATION NUMBER**

PA22859/005/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 02 December 2005  
Date of last renewal: 07 May 2009

## **10 DATE OF REVISION OF THE TEXT**

October 2022