Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.3% w/v Sodium Chloride 0.9% w/v Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride
Sodium Chloride

3.00g	Potassium K^+	40 mmol/litre
9.00g	Sodium Na^+	150 mmol/litre
	Chloride Cl^-	190 mmol/litre

Osmolality approx. 360 mOsmol/kg water.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Sterile endotoxin-free solution, colourless to faintly straw coloured without visible particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For fluid replacement, and provision of potassium, sodium and chloride electrolytes in the prevention and treatment of hypokalaemia and potassium depletion.
Medium for intravenous administration of medicinal products known to be compatible.

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 and sodium chloride 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 age, body weight, complementary treatment and clinical and biochemical status. Rapid infusion may be harmful. The rate of administration should not exceed 30mmol of potassium per hour. Typically 500ml is infused slowly over 2 to 3 hours, but the dose and rate of administration are subject to clinical and laboratory assessment in each case. A recommended maximum dose is 2 – 3 mmol potassium per kg body weight in 24 hours.

Fluid balance, serum electrolytes and acid-base balance may need to be monitored before and during administration, with particular attention to serum sodium 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 hospital acquired hyponatraemia (see sections 4.4, 4.5 and 4.8).
Monitoring of serum sodium is particularly important for hypotonic fluids.
Potassium Chloride 0.3%w/v Sodium Chloride 0.9%w/v Solution for Infusion tonicity: slightly hypertonic.

The infusion rate and volume depend on the age, weight, clinical condition (e.g. burns, surgery, head-injury, infections), and concomitant therapy should be determined by the consulting physician experienced in paediatric intravenous fluid therapy (see sections 4.4. and 4.8).

4.3 Contraindications

Hyperkalaemia, hypervolaemia and hypernatraemia.

4.4 Special warnings and precautions for use

The solution must be administered with caution to patients with conditions associated with high potassium levels or with conditions of impaired sodium excretion, including renal or adrenocortical insufficiency, cardio-pulmonary disease, peripheral or pulmonary oedema, acute dehydration, acute acidosis, hypertension, cirrhosis of the liver, pre-eclampsia, and cell destruction as in tissue trauma, burns, haemolysis, rhabdomyolysis.

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.

Repeated measurements of plasma potassium, and serum and/or urinary electrolytes are necessary to monitor treatment and to ascertain whether further infusions are required and to avoid development of hyperkalaemia. Specialist advice and ECG monitoring are necessary in difficult cases. Adequate urine flow must be ensured.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia (see below).

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 (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral 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, cerebral contusion and brain oedema) 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 may 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 include:
Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors,
3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
• Drugs potentiating vasopressin action include:
Chlorpropamide, NSAIDs, cyclophosphamide
• Vasopressin analogues include:
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, and drugs which have the potential for inducing hyperkalaemia, such as spironolactone and triamterene, as well as drugs which promote sodium retention such as angiotensin converting enzyme (ACE) inhibitors.
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.

Potassium Chloride 0.3%w/v Sodium Chloride 0.9%w/v Solution for Infusion should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin (see sections 4.4, 4.5 and 4.8).

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

General disorders and administration site conditions:
Prolonged intravenous infusion may lead to venous irritation and thrombophlebitis at the infusion site. In the event of adverse reaction, stop infusion immediately.

- Hospital acquired hyponatraemia*
- Acute hyponatraemic encephalopathy*

*Hospital acquired hyponatraemia may cause irreversible brain injury and death, due to development of acute hyponatraemic encephalopathy, frequency unknown (see sections 4.2. 4.4, 4.5).

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

For Ireland
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

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 and paralysis. Excessive or rapid administriation of sodium chloride solution may lead to fluid and electrolyte imbalances such as metabolic acidosis, hypokalaemia, hypervolemic haemodilution, sodium accumulation and hypernatraemia with resultant dehydration of organs particularly the brain, and oedema, also hypertension, tachycardia, oedema and gastrointestinal effects.
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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group (ATC Code): 'electrolytes' (B05BB01)
Maco Pharma Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v Solution for infusion is a sterile endotoxin-free solution. Potassium is predominantly an intracellular cation found primarily in skeletal muscle and is essential for nerve conduction, muscle contraction and acid-base regulation. Sodium and chloride contribute to acid-base balance.

Sodium is the principal cation in extracellular fluid and is the main osmotic component in control of blood volume. The solution provides important ions in near physiological concentration and allows cellular rehydration and restoration of electrolyte balance. It also serves as an isotonic medium for admixture of medicinal substances for intravenous infusion.

5.2 Pharmacokinetic properties

Potassium is predominantly an intracellular cation found primarily in skeletal muscle with approximately 2% in extracellular fluid. Body content is regulated primarily by renal glomerular filtration and tubular secretion. Normal plasma concentration is 3.5 – 5.0 mmol/litre.
Sodium is principally distributed into extracellular fluid (44%), skeleton (47%) and intracellular fluid (8%). Half life is 11 – 13 days. Excretion is predominantly by renal filtration and reabsorption by the proximal tubule, with a small quantity excreted by faeces, sweat and saliva. The pharmacokinetics of chloride are linked to those of sodium.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber not already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections.

6.2 Incompatibilities

Confirm additive compatibility before use. The extent of incompatibility can vary with concentration of additive, the delay between addition of additive and infusion, conditions of storage after addition of additive, and duration of infusion.

6.3 Shelf life

2 years.
Use immediately on removal from overwrap.

6.4 Special precautions for storage

Do not store above 25^{o}C. Do not freeze. Store in the original outer container in order to protect from light.

6.5 Nature and contents of container

COSINUS^{PVC} flexible PVC 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use under medical supervision.
Do not use unless the solution is clear and the container undamaged.
Do not reconnect partially used bags.

Any unused solution should be disposed of in accordance with local requirements.
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

PA22859/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 December 2002
Date of last renewal: 11 November 2006

10 DATE OF REVISION OF THE TEXT

October 2022