SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion - BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 1.50 g/l

Sodium Chloride 9.00 g/l

Each ml contains 1.50 mg Potassium Chloride and 9.00 mg Sodium Chloride.

mmol/l:	K+:	20	Na+:	154	Cl-:	174

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Clear solution, free from visible particles.

Osmolarity: 348 mOsm/L (approx.)

pH: 4.5 – 7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Potassium Chloride 0.15 % w/v & Sodium Chloride 0.9% w/v Solution for Infusion is indicated for the prevention and treatment of potassium depletion and/or hypokalaemia, in sodium chloride and water-losing conditions.

4.2 Posology and method of administration

Posology

Adults, the Elderly, Adolescents and Children

Fluid balance, serum electrolytes and acid-base balance should 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.

Potasssium chloride 0.15% & Sodium Chloride 0.9% Solution for Infusion has a tonicity of 348 mOsm/l (approx.)

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).

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

- for sodium
  1 g NaCl = 394 mg of Na^+ or 17.1 mEq or 17.1 mmol of Na^+ and Cl^-
  1 mmol Na^+ = 23mg Na^+

- for potassium
  1 g KCl = 525 mg of K^+ or 13.4 mEq or 13.4 mmol of K^+ and Cl^-
  1 mmol K^+ = 39.1 mg K^+

Posology for prevention and treatment of potassium depletion

- For Adults, the Elderly and Adolescents:

  Typical dose of potassium for the prevention of hypokalaemia may be up to 50 mmoles daily and similar doses may be adequate in mild potassium deficiency.

  When used for 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.

  The maximum recommended administration rate should not exceed 15-20 mmol/h.

  Patient with renal impairment should receive lower doses.

- Use in Paediatric Population (28 days to 11 years):

  The maximal recommended dose of potassium is 2 to 3 mmol/kg bw/day.

Method 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 central vein, be sure the catheter is not in the atrium or ventricle to avoid localized hyperkalaemia.

The osmolarity of a final admixed infusion solution must be taken into account when peripheral administration is considered.

Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, clinically significant hyperosmolar solutions are recommended to be administered through a large central vein, for rapid dilution of the hyperosmolar solution.

Additional electrolyte supplementation may be indicated according to the clinical needs of the patient. When introducing additives to Potassium chloride 0.15% w/v & Sodium Chloride 0.9% w/v solution for infusion, the instructions for use of the medication to be added and other relevant literature must be consulted *(see also Special precautions for disposal and other handling, section 6.6).*

Risk of air embolism
Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Rate of administration
Solution containing potassium should be administered slowly. As administered intravenously, potassium should not be given faster than 15 to 20 mmoles/h to avoid a dangerous hyperkalaemia. Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurological complications) (see also Special Warnings and precautions for Use; section 4.4).

Monitoring

Adequate urine flow must be ensured and careful monitoring of plasma-potassium and other electrolyte concentrations is essential. High dosage or high speed infusion must be performed under ECG control.

4.3 Contraindications

The Potassium chloride 0.15% w/v & Sodium Chloride 0.9% w/v solution for infusion is contra-indicated in patients with:

- known hypersensitivity to the product
- documented hyperkalaemia, hyperchloraemia or hypernatraemia
- severe renal insufficiency (with oliguria/anuria)
- uncompensated cardiac failure
- Addision's disease

4.4 Special warnings and precautions for use

Potassium chloride 0.15% w/v & Sodium chloride 0.9% w/v solution for infusion is a hypertonic solution.

Hypersensitivity reactions:

- Hypersensitivity/infusion reactions, including anaphylaxis, have been reported with other products containing potassium chloride and sodium chloride.
- Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Risk of serum electrolytes and water imbalance

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition, intravenous administration of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for infusion can cause:

- electrolyte disturbances such as
  - Hypernatremia,
  - Hyponatremia (see use in patients at risk for sodium imbalance).
- acid–base imbalance.
- overhydration/hypervolemia and, for example, congested states, including central (e.g., pulmonary congestion) and peripheral edema.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations, and acid–base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

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.

Potassium salts should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalaemia such as renal or adrenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns. In patients under digitalis therapy, regular monitoring of the plasma potassium level is mandatory.

Sodium salts should be administered with caution to patients with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia, or other conditions associated with sodium retention (see also Section 4.5 – Interactions with other medicinal products and other forms of interaction).

Pediatric use
The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy, and should be determined by a physician experienced in pediatric intravenous fluid therapy.

Elderly use
When selecting the type of infusion solution and the volume/rate of infusion for an elderly patient, consider that elderly patients are generally more likely to have cardiac, renal, hepatic, and other diseases and/or concomitant drug therapy.

4.5 Interaction with other medicinal products and other forms of interaction

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Potassium Chloride 0.15% w/v & Sodium chloride 0.9% w/v Solution for infusion and this can result in decreased lithium levels.

Potassium Chloride 0.15% w/v & Sodium chloride 0.9% w/v Solution for infusion should be used with caution in patients treated concurrently or recently with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia, such as medicinal products that contains potassium, potassium sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants cyclosporine and tacrolimus.

Administration of potassium in patients treated with such agents is associated with an increased risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia.

Potassium Chloride 0.15% w/v & Sodium chloride 0.9% w/v Solution for infusion should be used with particular caution in patients on concomitant medications that may increase the risk of sodium and fluid retention, such as corticosteroids.

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, terlipressin

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

4.6 Fertility, Pregnancy and Lactation

There are no adequate data from the use of Potassium chloride 0.15% w/v & Sodium chloride 0.9% w/v solution for infusion in pregnant or lactating women.

Physician should carefully consider the potential risks and benefits for each specific patient before administering Potassium chloride 0.15% w/v & Sodium chloride 0.9% w/v solution for infusion.

Potassium chloride 0.15% w/v & Sodium chloride 0.9% w/v should be administered with special caution for pregnant women during labour, particularly as to serum-sodium if administered in combination with oxytocin (see section 4.4, 4.5 and 4.8).

4.7 Effects on ability to drive and use machines

There is no information on the effects of Potassium Chloride 0.15% w/v & Sodium chloride 0.9% w/v solution for infusion on the ability to operate automobile or other heavy machinery.

4.8 Undesirable effects

The following adverse reactions have been reported spontaneously during Post-Marketing use of the product. The frequencies cannot be estimated due to the nature of the data.

System Organ Class (SOC)	MedDRA Preferred Term
Infections and infestations	Injection site infection[(1)]
Metabolism and nutrition disorders	Hypervolemia[(1)] Hospital acquired hyponatraemia[(2)]
Nervous system disorders	Acute hyponatraemic encephalopathy[(2)]
General disorders and administration site conditions	Extravasation[(1)] Injection site irritation[(1)] Injection site pain[(1)] Injection site phlebitis[(1)] Injection site reaction[(1)] Injection site thrombosis[(1)] Pyrexia[(1)]

[(1)] Adverse reactions that may be associated to the technique of administration.
[(2)] 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).

Others adverse reactions reported with other potassium chloride and sodium chloride formulations include:
Hypersensitivity, hyperkalemia, acidosis hyperchloremic, cardiac arrest as a manifestation of rapid intravenous administration and/or of hyperkalemia.

In case of undesirable effect(s), the infusion must be discontinued.

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. Health care professionals are asked to report any suspected adverse reactions via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Excessive administration of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion can cause:

- hyperkalemia, manifestations of hyperkalemia may include:
    - disturbance in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation.
    - hypotension,
    - muscle weakness up to and including muscular and respiratory paralysis, paresthesia of extremities,
    - gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain)

Among the important indicators of potassium toxicity are ECG changes, 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.

Retention of excess sodium when there is a defective renal sodium excretion may result in pulmonary and peripheral oedema.

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

- See also section 4.3, 4.4 and 4.8

When assessing an overdose, any additives in the solution must be considered.

The effect of an overdose may require immediate medical attention and treatment.

Treatment of hyperkalaemia involves the administration of calcium, insulin or sodium bicarbonate, and exchange resins or dialysis.

Interventions include discontinuation of Potassium chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for infusion administration, dose reduction and other measures as indicated for the specific clinical constellation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolytes

ATC code: B05BB01

Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion is an hypertonic solution of electrolytes, with an approximate osmolarity of 348 mOsm/l.

The pharmacodynamic properties of the solution are those of the sodium, potassium and chloride ions in maintaining the fluid and electrolyte balance.

Potassium is essential for numerous metabolic and physiological processes including nerve conduction, muscle contraction, and acid-base regulation. A normal concentration of potassium in plasma is about 3.5 to 5.0 mmoles per liter. Potassium is predominantly an intracellular cation. The passage of potassium into the cells and retention against the concentration gradient requires active transport via the Na^+/K^+ ATPase enzyme.

Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion are those of the ions its composition includes (sodium, potassium and chloride).

Intravenous administration of the solution provides an immediate supply of electrolytes 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 of 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 feces and small amounts may also be excreted in sweat.

After injection of radiosodium (^{24}Na), the half-life is 11 to 13 days for 99% of the injected Na and one year for the remaining 1%. The distribution varies according to tissues: it is fast in muscles, liver, kidney, cartilage and skin; it is slow in erythrocytes and neurons; it is very slow in the bone. Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption. Small amounts of sodium are lost in the feces and sweat.

5.3 Preclinical safety data

Preclinical safety data of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion in animals are not relevant since electrolytes are physiological components of the body.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

Incompatibility of the medicinal product to be added to Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion in the Viaflo container must be assessed before addition.

The Instructions for Use of the medicinal product to be added must be consulted.

Before adding a medicinal product, verify it is soluble and/or stable in water at the pH of Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion (pH: 4.5 to 7.0).

Those additives known to be incompatible should not be used**.**

6.3 Shelf life

3 years

In-use shelf life (Additives)

Chemical and physical stability of any additive medicinal product at the pH of the Potassium Chloride 0.15% w/v and Sodium Chloride 0.9% w/v Solution for Infusion in the Viaflo container should be established prior to use.

From a microbiological point of view, the reconstituted 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 has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The bags known as Viaflo are composed of polyolefin /polyamide co-extruded plastic (PL 2442).

The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene.

The bag size is either 500 or 1000 ml.

Outer carton contents: - 20 bags of 500 ml
or - 10 or 12 bags of 1000ml.

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact.

Administer immediately following the insertion of infusion set.

Do not remove unit from overwrap until ready for use.

The inner bag maintains the sterility of the product.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Additives may be introduced before infusion or during infusion through the injection site.

When additive is used, verify isotonicity prior to parenteral administration.

After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use.

Thorough and careful aseptic mixing of any additive is mandatory.

Solutions containing additives should be used immediately.

Adding medicinal product or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

1. Opening

   a. Remove the Viaflo container from the overpouch just before use.

   b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be broken.

   c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

   Use sterile material for preparation and administration.

   a. Suspend container from eyelet support.
   b. Remove plastic protector from outlet port at bottom of container:
      - grip the small wing on the neck of the port with one hand,
      - grip the large wing on the cap with the other hand and twist,
      - the cap will pop off.
   c. Use an aseptic method to set up the infusion.
   d. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medicinal products

   Warning: Additives may be incompatible.

   To add medicinal products before administration

   a. Disinfect medication site.
   b. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
   c. Mix solution and medicinal product thoroughly. For high-density medicinal products such as potassium chloride, tap the ports gently while ports are upright and mix.

   Caution: Do not store bags containing added medicinal products.

   To add medicinal products during administration

   a. Close clamp on the set.
   b. Disinfect medication site.

c. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
d. Remove container from intravenous pole and/or turn to an upright position.
e. Evacuate both ports by tapping gently while the container is in an upright position.
f. Mix solution and medicinal product thoroughly.
g. Return container to in use position, re-open the clamp and continue administration.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PL 00116/0336

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10 DATE OF REVISION OF THE TEXT

30/04/2024