Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Normal saline 0.9% w/v intravenous infusion BP.

2. Qualitative and quantitative composition

Each mL of the solution contains 9mg of sodium chloride

For the full list of excipients: see section 6.1

3. Pharmaceutical form

Solution for infusion
Sterile, non-pyrogenic, and clear solution, free from visible particles

4. Clinical particulars

4.1 Therapeutic indications

Sodium Chloride 0.9% intravenous infusion is indicated for:

- Treatment of isotonic extracellular dehydration
- Treatment of sodium depletion
- Vehicle or diluent of compatible drugs for parenteral administration
- It is also of value in the treatment of poisoning, by aiding excretion.

4.2 Posology and method of administration

Posology

Adults, older people, and children:

Doses may be expressed in terms of mEq or mmol of sodium, mass of sodium, or mass of sodium salt (1 g NaCl = 394 mg, 17.1 mEq or 17.1 mmol of Na and Cl).

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 hyponatremia (see sections 4.4, 4.5 and 4.8). Monitoring of serum sodium is particularly important for hypotonic fluids.

Sodium Chloride 0.9% intravenous infusion has a tonicity of 308 mOsm/l (approx.)

The infusion rate and volume depend on age, weight, clinical condition (e.g., burns, surgery, head injury, infections), and concomitant therapy

should be determined by the consulting physician experienced in intravenous fluid therapy.

The recommended dosage for the treatment of isotonic extracellular dehydration and sodium depletion is:

- For adults: 500 ml to 3 litres/24h
- For babies and children: 20 to 100 ml per 24h and per kg of body weight, depending on the age and the total body mass.

The recommended dosage when used as a vehicle or diluent ranges from 50 to 250 ml per dose of medicinal product to be administered.

When Sodium Chloride 0.9 % is used as a diluent for injectable preparations of other drugs, the dosage and the infusion rate will also be dictated by the nature and the dose regimen of the prescribed drug.

Method of administration

The solution is for administration by intravenous infusion through a sterile and non-pyrogenic administration set, using aseptic technique. The equipment should be primed with the solution in order to prevent air from entering the system.

The product should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear, free from visible particles, and the seal is intact.

Do not remove the unit from the overwrap until ready for use. The inner bag maintains the sterility of the solution. Administer immediately following the insertion of the infusion set.

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.

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

For information on incompatibilities and preparation of the product (with additives), please see sections 6.2 and 6.6.

4.3 Contraindications

The solution is contraindicated in patients presenting with hypernatremia or hyperchloremia.
The contraindications related to the added medicinal product should be considered.

4.4 Special warnings and precautions for use

Fluid balance/renal function

Use in patients with (severe) renal impairment

Sodium Chloride 0.9% should be administered with caution to patients with or at risk of severe renal impairment. In such patients, administration of Sodium Chloride 0.9% may result in sodium retention. (See "Use in patients at risk for sodium retention, fluid overload and oedema" below; for additional considerations).

Risk of fluid and/or solute overload and electrolyte disturbances

Depending on the volume and rate of infusion, intravenous administration of Sodium Chloride 0.9% can cause:

- Fluid and/or solute overload resulting in overhydration/hypervolemia and, for example, congested states, including central and peripheral oedema.
- Clinically relevant electrolyte disturbances and acid-base imbalance.

In general, the risk of dilutional states (retention of water relative to sodium) is inversely proportional to the electrolyte concentrations of Sodium Chloride 0.9% and its additions. Conversely, the risk of solute overload causing congested states (retention of solute relative to water) is directly proportional to the electrolyte concentrations of Sodium Chloride 0.9% and its additions.

Special clinical monitoring is required at the beginning of any intravenous infusion. 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 patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatremia.

Hyponatremia

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 are at particular risk of acute hyponatremia upon infusion of hypotonic fluids.

Acute hyponatremia can lead to acute hyponatremic 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 hyponatremia.

Use in patients at risk for sodium retention, fluid overload, and oedema

Sodium Chloride 0.9% should be used with caution, if at all, in patients with or at risk for:

- Hypernatremia. Rapidly correcting hypernatremia once adaptation has occurred may lead to cerebral oedema, potentially resulting in seizures, permanent brain damage, or death.
- Hyperchloremia
- Metabolic acidosis, which may be worsened by prolonged use of this product, especially in patients with renal impairment. Hypervolemia, such as congestive heart failure and pulmonary oedema, may be precipitated, particularly in patients with cardiovascular disease.
- Iatrogenic hyperchloremic metabolic acidosis (e.g., during intravenous volume resuscitation)
- Conditions that may cause sodium retention, fluid overload, and oedema (central and peripheral), such as patients with:
    - ❖ Primary hyperaldosteronism
    - ❖ Secondary hyperaldosteronism, associated with, for example:
      - hypertension
      - congestive heart failure,
      - liver disease (including cirrhosis),
      - renal disease (including renal artery stenosis, nephrosclerosis) or preeclampsia.
      - Medications that may increase the risk of sodium and fluid retention, such as corticosteroids

Infusion reactions

Symptoms of unknown etiology, which can appear to be

hypersensitivity reactions, have been reported very rarely in association with the infusion of Sodium Chloride 0.9 %. These have been characterized as hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus. Stop the infusion immediately if signs or symptoms of these reactions develop. Appropriate therapeutic countermeasures should be instituted as clinically indicated.
Specific patient groups

The consulting physician should be experienced in this product's use and safety in these special populations that are especially sensitive to rapid changes in serum sodium levels.

Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurologic complications). See section "*Hyponatremia/ hypernatremia*" above.

Pediatric population

Plasma electrolyte concentrations should be closely monitored in the pediatric population, as this population may have an impaired ability to regulate fluids and electrolytes. Repeated infusions of sodium chloride should, therefore, only be given after the serum sodium level is determined.

Geriatric population

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

For information on the preparation of the product and additives, please see section 6.6.

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 IV 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.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during the administration of Sodium Chloride 0.9%. Administration of Sodium Chloride 0.9% may result in decreased lithium levels.

Corticoids/Steroids and carbenoxolone are associated with the retention of sodium and water (with oedema and hypertension). See Section 4.4 Special warnings and precautions for use.

4.6 Pregnancy and Lactation

There are no adequate data from the use of Sodium Chloride 0.9% in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride 0.9%.

Sodium Chloride 0.9% should be administered with special caution for pregnant women during labor, particularly as to serum-sodium if administered in combination with oxytocin.

Caution is advised with patients with pre-eclampsia.

When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation have to be considered separately.

4.7 Effects on the ability to drive and use machines

No studies have been conducted on the influence of Sodium Chloride 0.9% on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

The following adverse reactions have been reported in post-marketing experience. The frequency of the adverse drug reactions listed in this section cannot be estimated from the available data.

System Organ Class (SOC)	Adverse reactions (Preferred Term)	Frequency
Nervous system disorders	Tremor Acute hyponatremic encephalopathy*	Not known
Metabolism and nutrition disorders	Hospital-acquired hyponatremia*	Not known
Vascular disorders	Hypotension	Not known

Skin and subcutaneous tissue disorders	Urticaria Rash Pruritus	Not known
General disorders and administration site conditions:	Infusion site reactions, such as • Infusion site erythema, • Vein irritation, Injection site streaking, burning sensation, • Local pain or reaction, Infusion site urticaria • Infection at the site of injection, • Venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia • Pyrexia • Chills	Not known

*Hospital-acquired hyponatremia may cause irreversible brain injury and death, due to the development of acute hyponatremic encephalopathy, the frequency unknown.

Additives

When Sodium Chloride 0.9% is used as a diluent for injectable preparations of other drugs, the nature of the additives will determine the likelihood of any other undesirable effects.

If an adverse event occurs, the patient should be evaluated and appropriate countermeasures should be started; if needed, the infusion should be stopped. The remaining part of the solution should be kept for investigation if deemed necessary.

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 website: https://pv.pharmacyboardkenya.org/

4.9 Overdose

General adverse effects of sodium excess in the body include nausea, vomiting, diarrhea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma, and death.

An excessive volume of Sodium Chloride 0.9% may lead to hypernatremia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema, and death) and sodium overload (which can lead to central and/or peripheral oedema) and should be treated by an attending specialized physician.

Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.

When Sodium Chloride 0.9% is used as a diluent for injectable preparations of other drugs, the signs and symptoms of overinfusion will be related to the nature of the additives being used. In the event of accidental over infusion, treatment should be discontinued, and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: "Other IV Solution Additives"

Sodium Chloride 0.9% intravenous infusion is an isotonic solution, with an approximate osmolarity of 308 mOsm/L.

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

5.2 Pharmacokinetic properties

Sodium is predominantly excreted by the kidneys, but there is extensive renal reabsorption.

Small amounts of sodium are lost in the feces and sweat.

5.3 Preclinical safety data

The safety of sodium chloride in animals is not relevant, given its presence as a normal component in animal and human plasma.

6. Pharmaceutical Particulars

6.1 List of Excipients

Water For Injection.

6.2 Incompatibilities

As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition. In the absence of

compatibility studies, this solution must not be mixed with other medicinal products. Those additives known to be incompatible should not be used.

6.3 Shelf-Life

36 months

50ml and 100ml with Reconstitution Device, the shelf life is 9 months, provided the unit has not been opened.

Once opened, the in-use shelf life is typically shorter, with 50ml or smaller bags being stable for 15 days and 100ml or larger bags being stable for 30 days.

In-use shelf life: Additives**.**

Chemical and physical stability of any additive at the pH of Sodium Chloride 0.9% Intravenous Infusion in the Viaflo container should be established before use.

From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

50- and 100-ml bags: Do not store above 30°C.

250-, 500-, and 1000-ml bags: This medicinal product does not require any special storage conditions.

6.5 Nature and content of the container

Bag sizes: 50, 100, 250, 500, or 1000 mL

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

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

Before adding a drug, verify it is soluble and stable in water at the pH range of the Sodium Chloride 0.9% Intravenous Infusion solution. Additives may be introduced before infusion or during infusion through the injection site.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Sodium Chloride 0.9% Intravenous Infusion solution by checking for eventual color change and/or eventual precipitate, insoluble complexes, or crystal apparition. The Instructions for Use of the medication to be added must be consulted.

The solution for infusion should be visually inspected prior to use.

Use only if the solution is clear, without visible particles and if the container is undamaged.

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. 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.

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 from entering the system.

Additives may be introduced before infusion or during infusion through the re-sealable medication port. When an additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

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

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

Do not remove the unit from the overwrap until ready for use. The inner bag maintains the sterility of the product.

Instructions for use

The normal saline 0.9% intravenous infusion bag has an outlet port designed for an administration set with a short single connector. If an administration set with a combined air inlet/fluid path connector has to be used, ensure the air inlet tube is always clamped off.

Opening

- Remove the protective overpouch by tearing down from the notch and remove the container.
- Carefully straighten hanger and ports, if necessary.
- Check for minute leaks by squeezing the inner bag firmly. If leaks are found, discard the solution, as sterility may be impaired

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

Preparation for administration

Use sterile material for preparation and administration.

- Suspend the container from the base eyelet support.
- Use an aseptic technique to prepare the administration set.
- Remove the blue protector from the outlet port and insert the set connector well into the port.
- Prime set and regulate administration as required.
- If the administration set becomes blocked, do not pump contents back into the container, but replace the equipment.
- Discard any unused portion and equipment after use. Do not store or reconnect partly used containers.

Techniques for the injection of additive medications

The normal saline container has a second port with a self-sealing rubber medication port designed for the addition of medication using a syringe. This is the only port for adding medication. Warning: Additives may be incompatible.

To add medication before administration:

- Swab the medication port with the appropriate antibacterial fluid in line with current recommended practice and procedure.

- Using a syringe with a 20 – 22-gauge needle, puncture the re-sealable medication port and inject. Do not leave the syringe and needle in the port once the medication has been injected.

- Shake and squeeze the container so that the solution and medication are thoroughly mixed. For high-density medications

such as potassium chloride, squeeze both ports while upright and invert the container several times while shaking and squeezing to ensure thorough mixing.

Caution: Do not store bags containing added medications.

To add medication during administration

- Close the clamp on the set
- Disinfect the medication site.
- Using a syringe with a 20 – 22-gauge needle, puncture the resealable medication port and inject.
- Remove the container from the IV pole and/or turn to an upright position.
- Evacuate both ports by tapping gently while the container is in an upright position.
- Mix the solution and medication thoroughly.
- Return the container to in-use position, re-open the clamp, and continue administration.

Cautions

- Do not vent.
- Do not administer unless the solution is clear and container undamaged.
- Do not use in series connections as this could result in air embolism due to residual air being drawn from the primary container before administration of fluid from the secondary container is completed.
- Discontinue infusion if adverse reaction occurs.
- Rapid infusion may be harmful.
- It is recommended that the intravenous administration set be replaced at least once every 24 hours. Details of the use of the set can be recorded.

In-use shelf life

Chemical and physical stability of any additive medication at the pH of the Sodium chloride 0.9 Infusion in the container should be established prior to use.

From a microbiological point of view, the diluted 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.

Incompatibilities of additive medications

WARNING: Additives may be incompatible. The introduction of additives to any solution, regardless of the type of container, requires special attention to ensure that no incompatibilities result.

While some incompatibilities are readily observed, it is important to be aware that subtle physical, chemical, and pharmacological incompatibilities can occur. The medical literature, the additive package inserts, and other available sources of information should be reviewed for a more thorough understanding of possible incompatibility problems.

If, in the informed judgment of the physician, it is deemed advisable to introduce additives into this solution, aseptic technique must be employed.

It is recommended that medication is added only under Pharmaceutical supervision.

Do not add medication before hanger and ports have been straightened and the container inspected.

Do not store solutions with added medication. Before adding a drug, verify it is soluble and stable in water at the pH of the Sodium chloride 0.9 Infusion.

Those additives known to be incompatible should not be used.

7. Marketing Authorization Holder

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8. Marketing Authorization Number

CTD11680

9. Date of first authorization/renewal of the authorization

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10. Date of revision of the text

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