SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Tasaline 3% Solution for Injection / Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Sodium Chloride

Each 1 mL solution for infusion contains 30 mg Sodium Chloride, equivalent to 513 mmol/L of sodium ions and 513 mmol/L of chloride ions.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Sodium Chloride 3% intravenous infusion is indicated as a source of water and electrolytes.

4.2 Posology and Method of Administration

Posology

Sodium Chloride 3% intravenous infusion is hypertonic and should be administered into a large vein, at a rate not exceeding 100 mL per hour.

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).

Sodium Chloride 3% intravenous infusion is hypertonic, with an osmolarity of approximately 1027 mOsm/L.

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

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 to prevent air entering the system.

The product should be inspected visually for particulate matter and discolouration 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, to avoid air embolism due to possible residual air contained in the primary container. Pressurising 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.

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 hypernatraemia or hyperchloraemia.

4.4 Special Warnings and Precautions for Use

Fluid balance/renal function

Use in patients with (severe) renal impairment

Sodium Chloride 3% should be administered with caution to patients with, or at risk of, severe renal impairment. In such patients, administration of Sodium Chloride 3% 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 3% can cause:

- Fluid and/or solute overload resulting in overhydration/hypervolaemia 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 3% 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 3% 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.

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

Sodium Chloride 3% should be used with caution, if at all, in patients with, or at risk for:

- Hypernatraemia. Rapidly correcting hypernatraemia once adaptation has occurred may lead to cerebral oedema, potentially resulting in seizures, permanent brain damage, or death.
- Hyperchloraemia.
- Metabolic acidosis, which may be worsened by prolonged use of this product, especially in patients with renal impairment.
- Hypervolaemia, such as congestive heart failure and pulmonary oedema, may be precipitated, particularly in patients with cardiovascular disease.
- Iatrogenic hyperchloraemic 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 pre-eclampsia.
- Medications that may increase the risk of sodium and fluid retention, such as corticosteroids.

Infusion reactions

Symptoms of unknown aetiology which can appear to be hypersensitivity reactions have been reported very rarely in association with infusion of Sodium Chloride 3%. These have been characterised 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 special populations that are especially sensitive to rapid changes in serum sodium levels.

Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurologic complications). See "Fluid balance/renal function" above.

Paediatric population

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

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.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

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

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 Sodium Chloride 3%. Administration of Sodium Chloride 3% 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 Fertility, Pregnancy and Lactation

There are no adequate data from the use of Sodium Chloride 3% in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride 3%.

Sodium Chloride 3% should be administered with special caution to pregnant women during labour, particularly with regard to serum sodium, if administered in combination with oxytocin (see sections 4.4, 4.5 and 4.8).

Caution is advised in patients with pre-eclampsia (see section 4.4, Special warnings and precautions for use).

4.7 Effects on Ability to Drive and Use Machines

No studies have been conducted on the influence of Sodium Chloride 3% on the ability to drive or operate heavy machinery.

4.8 Undesirable Effects

Tabulated summary of adverse reactions

Adverse events are listed below by system organ class and frequency. The following adverse reactions have been reported in post-marketing experience.

Term	Frequency of Occurrence
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	Cannot be estimated from the available data

System Organ Class	Frequency	Undesirable Effects
Nervous system disorders	Not known	Tremor
Metabolism and nutrition disorders	Not known	Hyperchloraemia, hyperchloraemic metabolic acidosis
Vascular disorders	Not known	Hypotension
Skin and subcutaneous tissue disorders	Not known	Urticaria, rash, pruritus
General disorders and administration site conditions	Common	Infusion site reactions, such as thrombosis, phlebitis, irritation, infusion site erythema, injection site

System Organ Class	Frequency	Undesirable Effects
		streaking, burning sensation, infusion site urticaria

The following general adverse effects may occur due to excess sodium chloride in the body: nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lachrymation, sweating, fever, hypotension, tachycardia, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.

Infants may appear not to be severely dehydrated, but coma and convulsions may persist due to vascular injury. They may show respiratory distress with tachypnoea and flaring nostrils.

Intra-amniotic injection of hypertonic solutions of sodium chloride can lead to serious adverse effects such as disseminated intravascular coagulation, renal necrosis, cervical and uterine lesions, haemorrhage, pulmonary embolism, pneumonia, and death.

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

4.9 Overdose

Excessive administration of sodium chloride causes hypernatraemia, the most serious effect of which is dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage.

Normal serum sodium concentrations should be carefully restored at a rate not exceeding 10–15 mmol per day by intravenous administration of hypotonic saline solutions.

Dialysis may be necessary if there is significant renal impairment, the patient is moribund, or if the serum sodium concentration is greater than 200 mmol per litre. Serum electrolyte levels need to be monitored and any imbalance corrected.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Other I.V. solution additives

ATC code: B05XA03

Sodium Chloride 3% intravenous infusion is hypertonic, with an approximate osmolarity of 1027 mOsm/L.

The pharmacodynamic properties of the solution are those of the sodium and chloride ions in maintaining fluid and electrolyte balance. Ions such as sodium circulate across the cell membrane using various transport mechanisms, including the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, as well as in renal metabolism.

5.2 Pharmacokinetic Properties

The body contains 40–60 mmol of sodium per kg body weight, approximately 40% of which is found in the skeleton. The normal concentration range for extracellular fluid is 135–154 mmol per litre. The intracellular sodium concentration is about 5–10 mmol per litre.

Chloride ions constitute 0.1–1.0% of body content, contained in the extracellular fluid surrounding nerve cells and in gastric juices; 0.6% is found in the urine.

Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

5.3 Preclinical Safety Data

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Water for Injections, Hydrochloric Acid and Sodium Hydroxide (for pH adjustment).

6.2 Incompatibilities

Streptomycin sulfate is stated to be incompatible with sodium chloride.

The addition of sodium chloride to mannitol 20–25% may cause precipitation of the mannitol.

As with all parenteral solutions, compatibility of 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. Additives known to be incompatible should not be used.

See section 6.6 for further instructions on use of the product with additives.

6.3 Shelf Life

2 years.

6.4 Special Precautions for Storage

Do not store above 30°C.

6.5 Nature and Contents of Container

Ampoule: 10 mL

Bag sizes: 50 mL & 100 mL

The bags are composed of polyolefin/polyamide co-extruded plastic and are overwrapped with a protective tri-laminate pouch.

Not all pack sizes may be marketed.

6.6 Special Precautions for Disposal and Other Handling

Please see section 4.2 for information regarding the method of administration.

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

Opening

- Remove the bag from the over-pouch just before use.
- 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 eyelet support.
- Remove the plastic protector from the outlet port at the bottom of the container.
- Use an aseptic method to set up the infusion.
- Attach the administration set. Refer to the directions of the accompanying set for connection, priming of the set, and administration of the solution.

7. MARKETING AUTHORISATION HOLDER

Tasa Pharma Limited

Unit C1-C3, Kay Complex,

Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER(S)

H2022/CTD10670/24207

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

2023 September 26

10. DATE OF REVISION OF THE TEXT

2023 September 26