SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium Chloride Vioser Solution 0.9%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL solution contains:

Sodium chloride 0.9 g

Approximate osmolarity 308 mOsm/l

Electrolytes	mmol/l
Sodium	154
Chloride	154

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution
Clear and colourless solution free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Short - term intravascular volume substitution.
- Hypotonic dehydration or isotonic dehydration.
- Vehicle solution for supplementary medication.Fluid and electrolyte replacement, hypochloremic alkalosis and chloride losses.
- Externally for wound irrigation and moistening of wound tamponade dressings.

4.2 Posology and method of administration

Dosage

The dosage guideline for adults:

Average dose: 1000 ml per day.
Flow rate: Up to 180 drops/min, corresponding to 550 ml/h.
Maximum recommended dosage: 40 ml per KG body weight and per day, not more than 2000 ml per day.
Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determination.

Method of administration
I.V., S.C., I.M. – in use as dissolvent and carrier; External.

When administering a solution packed in a flexible container via a pressure infusion, all air must be removed from the container and infusion system prior to administering the infusion.

4.3 Contraindications

Sodium chloride 0.9 % may not be used in the event of

- hyperhydration
- severe hypernatraemia
- severe hyperchloraemia

4.4 Special warnings and precautions for use

Sodium chloride 0.9 % should be used with caution only in

- hypokalaemia
- hypernatraemia
- hyperchloraemia
- Conditions requiring a restricted intake of sodium, such as heart failure, generalised oedema, pulmonary oedema, hypertension, eclampsia and severe renal failure.

In order to prevent osmotic demyelination syndrome from developing, serum sodium concentrations should not exceed 9 mmol/L/day. As a general recommendation, a rate of correction of 4 to 6 mmol/L/day is considered appropriate in the majority of cases, depending on the patient's conditions and associated risk factors.

Clinical monitoring should include checks of the serum ionogram, water balance and the acid-base balance.

If the rapid infusion of 0.9 % NaCl is required, the cardiovascular and respiratory status should be monitored closely.

Please note: if this solution is being used as a carrier solution, the safety information on the additive provided by the respective manufacturer is to be taken into account.

Children and adolescents

Premature or newborn babies may develop excess sodium levels due to immature kidney function.

Therefore, repeated sodium chloride infusions should only be administered after serum sodium levels have been determined.

4.5 Interactions with other medicinal products and other forms of interaction

Medicinal products leading to sodium retention
The simultaneous use of sodium-retaining medicinal products (e.g. corticosteroids, non-steroidal anti-inflammatory drugs) can lead to oedema.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data from the use of Sodium chloride 0.9 % in pregnant women. Similarly, animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Given that the concentrations of sodium and chloride are similar to those found in the human body, no harmful effects are to be expected when the product is used correctly.

Sodium chloride 0.9 % may therefore be used as stated.

Caution must be exercised, however, in the event of eclampsia (see section 4.4).

Lactation
Sodium chloride is excreted in human milk. Given that the concentrations of sodium and chloride are similar to those found in the human body, no harmful effects are to be expected when the product is used correctly.

Sodium chloride 0.9 % may be used during lactation if required.

Fertility
No data are available.

4.7 Effects on ability to drive and use machines

Sodium chloride 0.9 % has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

None known if used correctly.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: http://sideeffects.health.gov.il and emailed to the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

4.9 Overdose

Symptoms

An overdose of Sodium chloride 0.9 % can lead to hypernatraemia, hyperchloraemia, hyperhydration, acute volume overload, oedema, serum hyperosmolality and hyperchloraemic acidosis.

In patients with chronic hyponatraemia, a rapid rise in the serum sodium concentration can lead to osmotic demyelination syndrome (see section 4.4).

The first signs of overdose may be thirst, confusion, sweating, headache, weakness, drowsiness or tachycardia. Hypertension or hypotension, respiratory failure or coma may occur in the event of severe hypernatraemia.

Management

Depending on the severity of the symptoms, immediate stopping of the infusion and administration of diuretics whilst constantly monitoring serum electrolytes, and correction of electrolyte and acid-base imbalances.

Dialysis may be required in the event of major overdosage or oliguria or anuria.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: solutions affecting electrolyte balance, electrolytes, ATC code: B05B B01

Mechanism of action
Sodium is the primary cation in the extracellular space and, together with various anions, regulates the size of the latter. Sodium is one of the major mediators of bioelectric processes within the body.

Chloride is the main osmotically active anion in the extracellular space.

A rise in the serum chloride concentration leads to increased renal bicarbonate excretion. An acidifying effect is therefore induced through the administration of chloride.

Pharmacodynamic properties
The sodium content and fluid metabolism in the body are closely connected. Each deviation in plasma sodium from the physiological concentration simultaneously affects the body's fluid status.

Independently of serum osmolality, a rise in the sodium content within the body also means a drop in free body water.

An 0.9 % solution of sodium chloride has the same osmolarity as plasma. Administration of this solution leads primarily to filling of the interstitial space, which represents roughly 2/3 of the whole extracellular space. Only 1/3 of the volume administered remains in the intravasal space. The haemodynamic effect of the solution is therefore only short-lasting.

5.2 Pharmacokinetic properties

Absorption

As the solution is administered as an intravenous infusion, the bioavailability of the solution is 100 %.

Distribution
The body's total sodium content is approximately 80 mmol/kg (5600 mmol), of which 300 mmol can be found in intracellular fluid in a concentration of 2 mmol/L and 2500 mmol of which are bound in bones. Approximately 2 mol can be found in extracellular fluid in a concentration of 135-145 mmol/L (3.1-3.3 g/L).

The total chloride content in the body is approximately 33 mmol/kg bodyweight. Serum chloride ranges from 98 to 108 mmol/L.

Biotransformation

Although sodium and chloride are absorbed, distributed and excreted, they are not metabolised in the strict sense.

The kidneys are the main regulators of sodium and fluid balance. Together with hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and with the hypothetical natriuretic hormone, they are chiefly responsible for keeping the volume of the extracellular space constant and for its fluid composition.

Chloride is exchanged for hydrogen carbonate in the tubule system and, in this way, is involved in the regulation of the acid-base balance.

Elimination

Sodium and chloride are excreted via sweat, urine and the gastrointestinal tract.

5.3 Preclinical safety data

No preclinical studies have been conducted with Sodium chloride 0.9 %.

Given that sodium and chloride ions are major elements of the human body, Sodium chloride 0.9 % is not expected to have any toxic effects when used correctly.

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 medicinal product must not be mixed with other medicinal products. Those additives known to be incompatible should not be used.

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

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

LDPE bottle:
100 ml, 250 ml, 500ml, 1000 ml

Not all pack sizes may be marketed.

6.6 Special precautions fordisposal

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

Administer immediately following the insertion of infusion set.

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

It is the responsibility of the physician to judge the incompatibility of an additive medication with Sodium Chloride Vioser Solution 0.9% by checking for eventual colour change and/or eventual precipitate, insoluble complexes or crystals apparition.

When 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.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used containers.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Instructions for use

• Check for minute leaks by squeezing container firmly. If leaks are found, discard solution, as sterility may be impaired.

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

• Each plastic bottle has a protective cap. The protective ring is removed just before use with a simple pull and the infusion device is adjusted in the special elastic slot. Administer immediately following the insertion of infusion set.

Preparation for administration

Use sterile material for preparation and administration.

• Suspend container from eyelet support.

• Remove plastic protector from outlet port at bottom of container.

• Use an aseptic method to set up the infusion.

• Attach administration set. Refer to directions of the accompanying set for connection,

priming of the set and administration of the solution.

Techniques for injection of additive medications

Warning: Additives may be incompatible (see section 6.2 "") .

To add medication before administration:

• Disinfect medication site.

• Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture

medication port and inject.

• Mix solution and medication thoroughly.

Caution: Do not store bags containing added medications.

7. MANUFACTURER

Vioser S.A. Parenteral Solutions Industry, Greece,
9th KM National Road Trikala-Larisa, Taxiarches Trikala,

42100, Greece.

8. MARKETING AUTHORISATION HOLDER
Eldan Electronic Instruments Co. Ltd., Israel.
Ha-Shiloah 6, POB 7641, Petach Tikva 4917001, Israel.

9. MARKETING AUTHORISATION NUMBER(S)
167-70-35947-00

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