SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Natriumklorid Evolan 500 mg, capsule, hard

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 500 mg of sodium chloride corresponding to 8.6 mmol sodium and 8.6 mmol chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsule.
Green capsule, size 1 (19.0 x 6.6 mm).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic chronic euvolaemic hyponatraemia when there is an insufficient efficacy of fluid restriction and/or treatment with diuretics (e.g. inappropriate ADH secretion, SIADH).

Hypovolaemic hyponatremia (e.g. ileostomy/jejunostomy).

4.2 Posology and method of administration

Posology

Adults:
The dosage is adapted individually and adjusted in accordance with treatment response, up to a maximum of 20 capsules per day, divided in several dosage occasions. Severe hyponatremia must be treated with intravenous fluids.

Method of Administration
The capsules should be swallowed whole with water.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Severe renal failure (with oliguria/anuria). Uncompensated heart failure. Generalized oedema. Decompensated liver cirrhosis. Pre-eclampsia.

4.4 Special warnings and precautions for use

The cause of hyponatraemia should always be determined before starting treatment with sodium chloride capsules. During treatment serum sodium levels must be checked regularly to avoid hypernatraemia. Considerable caution should be exercised in patients with heart failure, reduced renal and/or hepatic function, hypertension or in conditions with sodium retention and in patients treated with cortisone. Treatment of geriatric and post-operative patients should be carefully monitored.

4.5 Interaction with other medicinal products and other forms of interaction

In people with chronic renal failure, sodium chloride tends to impair the effect of antihypertensive medicinal products. Ingestion of large amounts of sodium can prevent the establishment or maintenance of lithium levels.

4.6 Fertility, pregnancy and lactation

No known risks at therapeutic doses.

4.7 Effects on ability to drive and use machines

Natriumklorid Evolan has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Gastrointestinal disorders
Frequency not known (cannot be estimated from the available data) Nausea, vomiting

Reporting of side effects
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. Healthcare professionals are asked to report any suspected adverse reaction via the national reporting system listed in Appendix V.

4.9 Overdose

Toxicity
Overdose of sodium chloride involves a risk, especially for children, but also adults can suffer from symptoms. An intake of 0.5 to 1 g of sodium chloride per kg body weight is toxic in most cases.

Excessive intake of sodium chloride can result in hypernatraemia. Symptoms of hypernatraemia include thirst, decreased salivation, lacrimation decreased, fever, swollen tongue, tachycardia, hypertension/hypotension, fluid retention with peripheral oedema, headache, dizziness, restlessness, irritability, weakness, abdominal cramps, vomiting and diarrhoea. In severe cases: pulmonary and cerebral oedema, seizures, coma and respiratory arrest.

Treatment:
Give water orally. In the event of a significant overdosage, serum sodium levels should be evaluated as soon as possible, especially in children. Treatment depends on the degree of hypernatraemia and symptoms. The use of sodium-free intravenous fluids and a loop diuretic, such as furosemide, under close monitoring of the electrolytes may be appropriate in severe cases of hypernatremia. Acute symptomatic hypernatraemia (< 24 hours) should be corrected quickly, while chronic hypernatraemia should be corrected slowly because of the risk of cerebral oedema.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other mineral supplements
ATC code: A12CA01

Sodium chloride works primarily by maintaining osmotic pressure in blood and tissues. Changes in the osmotic pressure affect the flow of liquids and diffusion of salts in cell tissues.

5.2 Pharmacokinetic properties

Sodium chloride is readily absorbed from the gastrointestinal tract and is present in all body fluids but specially in the extracellular fluid. The amount of sodium that is secreted (via sweating) is usually small. The osmotic balance is maintained by excretion of excess sodium in urine.

5.3 Preclinical safety data

There is no relevant preclinical data for evaluation of safety beyond those already considered in the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:
Magnesium stearate
Silica colloidal anhydrous

Capsule shell:
Gelatin
Chlorophyllin copper complex sodium (E141)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30 C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Aluminum/PVC/PE/PVDC blisters: 20, 40, 60, 80, 100, 105, 200, 300, 400, 500 and 1,000 capsules.
White plastic jar (HDPE) with a plastic screw cap (PP): 105 and 120 capsules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKET AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: [To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2025-01-20
[To be completed nationally]