SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Natriumklorid 500 mg, film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains 500 mg sodium chloride which corresponds to 8,6 mmol sodium and 8,6 mmol chloride respectively.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet
Round, white, biconvex tablets with 10 mm diameter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic chronic euvolemic hyponatremia when insufficient efficacy of fluid restriction and/or diuretic therapy (e.g. Syndrome of Inappropriate Antidiuretic hormone secretion, SIADH).

Hypovolemic hyponatraemia (e.g. ileostomy/jujenostomy).

4.2 Posology and method of administration

Posology

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

Method of administration

For oral use only. Should be swallowed whole.

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. General oedema. Decompensated liver cirrhosis. Preeclampsia.

4.4 Special warnings and precautions for use

The cause of hyponatremia should always be determined before treatment with sodium chloride tablets is initiated. During treatment, serum sodium levels should be monitored regularly to avoid hypernatremia. Great caution should be exercised in heart failure, reduced renal and/or liver function, hypertension or in

conditions with sodium retention and in patients treated with cortison. Treatment of geriatric and post-operative patients should be carefully monitored.

4.5 Interaction with other medicinal products and other forms of interaction

The effect of some antihypertensive drugs (especially vasodilators) may be reduced during excessive salt intake. The ingestion of large amounts of sodium can prevent the establishment or maintenance of adequate lithium levels.

4.6 Fertility, pregnancy and lactation

No known risks at therapeutic dosage.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

There is no modern clinical documentation regarding frequency of side-effects for this medicinal product.

Gastrointestinal disorders
Not known (cannot be estimated from the available data): Nausea, vomiting

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. Healthcare professionals are asked to report any suspected adverse reactions 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. Intake of 0,5 – 1 g sodium chloride per kg body weight is toxic in most cases.

Symptoms
Excessive intake of sodium chloride can result in hypernatraemia. Symptoms of hypernatraemia include thirst, reduced salivation, swollen tongue, tachycardia, hypertension/hypotension, fluid retention with peripheral oedema, headache, restlessness, irritability, dizziness, abdominal cramps, vomiting and diarrhoea. In severe cases lung- and brain oedema, cramps, coma and respiratory arrest.

Treatment
Give water orally. In case of significant overdose the serum sodium levels should be evaluated as soon as possible, especially in children. Treatment depends on degree of hypernatraemia and symptoms. Use of sodium free fluids and loop diuretics e.g. furosemide under careful monitoring of the electrolytes can be suitable in severe cases of hypernatraemia.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mineral supplements, ATC code: A12CA01

Mechanism of action

Sodium chloride mainly functions by maintaining the osmotic tension in blood and tissues. Changes in osmotic tension affect the flow of fluids and diffusion of salts in cell tissue.

5.2 Pharmacokinetic properties

Absorption
Sodium chloride is readily absorbed from the gastro-intestinal tract.

Distribution
Sodium chloride is present in all body fluids but specially in the extracellular fluid.

Elimination
The amount of sodium excreted (as sweat) is normally small. Osmotic pressure is maintained by excretion of surplus amounts in the urine.

5.3 Preclinical safety data

There are no preclinical data relevant for safety evaluation beyond those already considered in the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core: microcrystalline cellulose, talc
Filmcoating: hypromellose, macrogol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

No special storage conditions.

6.5 Nature and contents of container

Plastic jar (polyethene) with 30, 40, 50, 60, 70, 80, 90, 98 or 100 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Abcur AB,

Box 1452
251 14 Helsingborg

8. MARKETING AUTHORISATION NUMBER(S)

For SE: 49347

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be completed nationally>

10. DATE OF REVISION OF THE TEXT

2021-04-12