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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ardeaelytosol F 1/1 9 g/l infusion solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of infusion solution contains:

Natrii chloridum	9.0 g

Electrolyte content:

Na^+	154 mmol/l
Cl^-	154 mmol/l
Osmotic pressure:	676 kPa
pH:	4.5 – 7.0

For the full list of excipients, see the section 6.1.

3. PHARMACEUTICAL FORM

Infusion solution

Description of the product: clear, colorless solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Mild metabolic alkalosis

Hyponatraemia

Isotonic dehydration (in cases when the patient's kidneys are able to balance acidosis caused by Cl^- ions that are present in the solution in a higher amount than in extracellular fluid).

Vehiculum for administration of other medicaments

Lavage and rinsing of open wounds and cavities

4.2. Posology and method of administration

Intravenous drop infusion in the closed system. It is usually administered by the infusion set into peripheral vein. It can be administered also in central vein.

The dosage must be adjusted to the age, body weight and clinical condition of each individual patient.

When used for dilution or dissolving medicines, the amount of Ardeaelytosol F 1/1 is dependent on the medicine concentration required.

The maximum daily dose is 40 ml/kg of body weight.

4.3. Contraindications

Hypernatraemia, overhydration, oedemas, oliguria or anuria, cardiac failure

4.4. Special warnings and precautions for use

In serious cases, with extensive infusion therapy, the combination with colloid solutions and well-balanced supplementation of other ions are essential as well.

Fluid balance, serum electrolytes and acid base balance may need to be monitored before and during administration. Sodium serum levels should be monitored very carefully, especially 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 hyponatraemia (see sections 4.4, 4.5 and 4.8).

High volume infusions must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hyponatraemia (see below).

Hyponatraemia

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema).

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, cerebral contusion and cerebral oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Changes in natraemia during the correction of disorders (especially of chronic ones) should not exceed 10 mmol/l per day. When the changes are more rapid than given above, then cerebral oedema is threatening.

Increased precaution is necessary also in patients with metabolic acidosis.

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 an increased risk of hyponatraemia following inappropriately balanced treatment with i.v. solutions (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, vasopressin, terlipressin.

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

4.6. Fertility, pregnancy and lactation

The medicinal product of Ardeaelytosol F 1/1 should be administered with special caution in pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin (see sections 4.4, 4.5 and 4.8).

4.7. Effects on ability to drive and use machines

With regard to the character and indication of the product, Ardeaelytosol F 1/1 has no influence on ability to drive and use machines.

4.8. Undesirable effects

There is a possibility of general undesirable effects connected with an unsuitable management of the infusion therapy.

Frequency of undesirable effects, as given below, is defined according to the following convention:

Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000); not known (cannot be established from the available data).

Organ system class according to MedDRA database	Character of undesirable effect	Frequency of occurrence
Metabolism and nutrition disorders	Ion balance breakdown Hypernatraemia Hyperchloraemia Overhydration Hyperchloraemic metabolic acidosis Hyponatraemia*	Not known
Cardiac disorders	Oedemas Ascites Cardiac failure	Not known
Nervous system disorders	Acute hyponatraemic encephalopathy*	Not known

*Hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2, 4.4 and 4.5).

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 to the address:

Státní ústav pro kontrolu léčiv (State Institute for Drug Control)
Šrobárova 48
100 41 Praha 10

Website: www.sukl.cz/nahlasit-nezadouci-ucinek

4.9. Overdose

The overdose with the product of Ardeaelytosol F 1/1 is manifested by symptoms given in the section 4.8.

When the product of Ardeaelytosol F 1/1 is used as a dissolvent for other medicinal products administered via injections, the symptoms of overdose are related to the character of the additives used.

In case of overdose as well as in occurrence of undesirable effects, the primary therapy is the stop of infusion followed by adjustment of electrolyte levels and parameters of acid base balance under permanent monitoring of the patient's internal environment.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

- Pharmacotherapeutic group: infundabilium, ATC code: B05BB01 (Intravenous solutions – solutions affecting the electrolyte balance - electrolytes).

- Basic infusion solution containing sodium and chloride ions.
- It contains surplus of chloride ions in comparison with plasma resulting in acidification of internal environment.

5.2. Pharmacokinetic properties

a) General information – no active metabolites are generated. Na^+ and Cl^- ions are water-soluble, fat-insoluble.
b) Characterization of the active substances – it is a simple inorganic salt - Na^+ and Cl^- ions are natural for the body.
c) Characterization after the administration in patients – it is a product intended for intravenous use. It persists in the blood circulation only for a few tens of minutes after i.v. administration; it leaks into extravascular compartment easily.
d) Sodium and chloride ions are distributed in the body according to the concentration gradients in extracellular fluid. Free water is distributed according to the concentration gradient in all compartments.

   Ionic balance is dependent on the excretion of individual ions by kidneys and is particularly subordinated to mineralocorticoids regulation.

   Water homeostasis is regulated by antidiuretic hormone.

5.3. Preclinical safety data

The issue of safety of the preparation for the body is not relevant with regard to the composition and usage of the product as well as to the properties of the active substance. It is a product with a long-term usage ("well implemented therapeutic use") in which no preclinical studies had been performed with its introduction into the therapy.

6. PHARMACEUTIAL PARTICULARS

6.1. List of excipients

Aqua pro iniectione

6.2. Incompatibilities

No physical or chemical incompatibilities are known. Physical chemical properties of the added drug are necessary to be considered when the product is used as a vehiculum.

6.3. Shelf life

3 years provided that the package is intact.

The shelf life after the first opening:

Chemical and physical stability before the use after the opening was confirmed for 48 hours at 25°C.

From microbiological point of view, the product should be used immediately. If it is not used immediately, then the period and storage conditions of the product after the opening before the use are within the reliability of the user and in common case it should not be longer than 24 hours at 2-8 °C as far as the opening was not performed under the controlled and validated aseptic conditions.

6.4. Special precautions for storage

Protect from frost.

6.5. Nature and contents of container

Infusion glass bottle with a rubber stopper and a metallic closure, carton box.

Package size: 1x 80 ml, 1x 100 ml, 1x 250 ml, 1x 500 ml
20x 80 ml, 20x 100 ml, 10x 250 ml, 10x 500 ml

Not all package sizes may be marketed.

6.6. Special precautions for use, disposal and other handling

This medicinal product is dispensed entirely on the base of medical prescription.

Parenteral products should be checked up visually before the use. The product must not be administered if visible solid particles are present or the package is not intact.

The preparation is intended only for a single use.

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

7. MARKETING AUTHORISATION HOLDER

ARDEAPHARMA, a.s., Třeboňská 229, 373 63 Ševětín, Česká republika (Czech Republic)

8. MARKETING AUTHORISATION NUMBER(S)

76/224/95-C

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of the first authorization: 19th April 1995

Date of the last renewal of the authorization: 10th June 2015

10. DATE OF REVISION OF THE TEXT

13th April 2018