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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ardeaelytosol conc. natriumchlorid 5,85% concentrate for solution for infusion
Ardeaelytosol conc. natriumchlorid 10% concentrate for solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ardeaelytosol conc. natriumchlorid	**5.85%**	**10%**
Each 1000 ml of the concentrate for infusion solution contains:		
Natrii chloridum	58.5 g	100.0 g
Electrolyte content::		
Na^+ [mmol/l]	1000	1711
Cl^- [mmol/l]	1000	1711
Osmotic pressure [kPa]	4 841	7 510
pH	4.5-7.0	4.5-7.0

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

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion
Description of the product: clear, colorless solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Hyponatremia (only in case of deficient fluid volume and hyposmolality)
Metabolic alkalosis
Hypochloremia

4.2. Posology and method of administration

Dosage is individual according to the losses. It should be diluted with a carrying solution (e.g. Ardeanutrisol G 5) in a ratio of 1:6 (alternatively in a lower ratio). Dosage according to base excess: BE x 0.3 x kg = mmol Cl^- in case of correction of alkalosis. For Na^+ supplementation, the following is valid: (140 - update Na^+) x 0.2 kg = mmol Na^+ (= ml 5.85% NaCl). Speed of administration is approximately 2 mmol/kg/hour. Maximum speed of infusion then depends on the clinical condition of the patient.

Method of administration:
Intravenous drop infusion in the closed system. Natrium chloride concentrate is always applied diluted in a carrying solution.

4.3. Contraindications

Hypernatremia
Hyperchloremia
Metabolic acidosis

4.4. Special warnings and precautions for use

Natrium chloride concentrates should be applied very cautiously in cases of hypokalemia, in disorders in which an increased intake of sodium is associated with risks (cardiac failure, generalized edema, pulmonary edema, hypertension, corticoid therapy, metabolic acidosis).

During the application, the serum iontogram and fluid balance should be monitored, acid-base balance should be checked up.

4.5. Interaction with other medicinal products and other forms of interaction

During corticoid therapy, sodium and chloride retention may be increased.

4.6. Fertility, pregnancy and lactation

The use of the preparation during gravidity or lactation is not contraindicated. Particular attention should be paid in cases of eclampsy or preeclampsy.

4.7. Effects on ability to drive and use machines

With regard to the character of the product and its indication is not relevant.

4.8. Undesirable effects

No undesirable effects are given with the product of Ardeaelytosol conc. natriumchlorid 5.85% (10%). However, there is a general possibility of undesirable effects connected with an unsuitable management of the infusion therapy such as hyperhydration, hypernatremia, hyperchloremia, cardiac failure, edema, ion balance breakdown.

Organ system class according to MedDRA database	**Character of undesirable effect**	**Frequency of occurrence**
Blood and lymphatic system disorders	Ion balance breakdown	Accurate data are not available; it can be expected that they occur rarely with the frequency of occurrence >1/10,000 and < 1/1,000.
Cardiac disorders	Edema	Accurate data are not available; it can be expected that they occur rarely with the frequency of occurrence >1/10,000 and < 1/1,000.
	Cardiac failure	Accurate data are not available; it can be expected that they occur rarely with the frequency of occurrence >1/10,000 and < 1/1,000.
Renal and urinary disorders	Hyperhydration	Accurate data are not available; it can be expected that they occur rarely with the frequency of occurrence >1/10,000 and < 1/1,000.

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

In the event of overdose, the volume overload, hypernatremia or metabolic acidosis can occur. Then it is necessary to interrupt further administration of the product. Diuretics are applied and serum

electrolytes are continuously monitored and adjusted together with treatment of acid base balance disorders.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: infundabilium, ATC code: B05XA03 (Additives to intravenous solutions – electrolyte solutions – sodium chloride).

Concentrated infusion solution is used for supplementation of sodium and chloride losses.

Basic concentrated electrolyte infusion solution. After the administration, it has a moderate acidification effect.

5.2. Pharmacokinetic properties

97 % of sodium is included in the extracellular compartment and 3 % in the intracellular compartment.

The kidneys are the main regulators of sodium balance. The kidneys together with hormonal control mechanisms are primarily responsible for the constant volume and distribution of fluids in the extracellular compartment. Chloride is changed in the tubular system for bicarbonate and this way chloride is involved in acid base balance regulation.

Infusion of sodium chloride results in a higher excretion of bicarbonate. That is the reason why the sodium chloride solutions have moderate acidification properties.

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.

6. PHARMACEUTIAL PARTICULARS

6.1. List of excipients

Water for injection

6.2. Incompatibilities

The product is compatible with the most of commonly used medicinal products.

No physical or chemical incompatibilities are known except of those with solutions with oxidants content or solutions showing a different pH value.

6.3. Shelf life

3 years provided that the package is intact.

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/dilution 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 200 ml
20x 80 ml, 10x 200 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.

The product must not be used undiluted! The preparation is not intended for direct infusion. It is administered intravenously diluted with a higher amount of the carrying solution.

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 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)

Ardeaelytosol conc. natriumchlorid 5,85%: 76/922/95-A/C

Ardeaelytosol conc. natriumchlorid 10%: 76/922/95-B/C

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of the first authorisation: 22nd November 1995

Date of the last renewal of the authorization: 8th February 2017

10. DATE OF REVISION OF THE TEXT

2nd July 2020