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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ardeaelytosol conc. natriumhydrogenfosfát 8,7%

Concentrate for infusion solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml of concentrate for infusion solution contains:

Natrii hydrogenophosphas dodecahydricus	71.6 g
Natrii dihydrogenophosphas dihydricus	15.6 g

Electrolyte content:

Na^+	500 mmol/l
HPO_4^{2-}	200 mmol/l
$H_2PO_4^-$	100 mmol/l
Osmotic pressure:	1 452 kPa
pH	6.0-8.0

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

3. PHARMACEUTICAL FORM

Concentrate for infusion solution

Description of the product: clear, colourless solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Hypophosphatemia of various causes.
Supplementation of phosphate ions in complex parenteral nutrition.

4.2. Posology and method of administration

In case of hypophosphatemia, the posology is individual according to the losses; the daily dose is up to 80 mmol/24 hours and about 0.4-0.8 mmol/kg/24 hours in children.

5-20 mmol per 4 200 kJ to be administered for prophylaxis of hypophosphatemia in parenteral nutrition, with products of calcium administered concurrently in amount of 2.3-4.5 mmol (not to mix in the same solution!).

Speed of administration: Phosphate supply is always to be administered slowly being added into a carrying solution via continuous infusion, over 24 hours preferably.

Method of administration:
Intravenous drop infusion in the closed system. The product is always applied diluted in a carrying solution.

4.3. Contraindications

Hyperphosphatemia, hypernatremia, oliguria, anuria, renal insufficiency (phosphate retention).

4.4. Special warnings and precautions for use

During the product administration, frequent and regular phosphates and calcium serum levels monitoring is necessarily required.

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

In the course of complex parenteral nutrition, the phosphate products should not be mixed with the products containing calcium or magnesium.

4.6. Fertility, pregnancy and lactation

The use of the preparation during gravidity or lactation is not contraindicated.

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. natriumhydrogenfosfát 8,7%. However, there is a possibility of general undesirable effects connected with an unsuitable management of the infusion therapy such as hyper-hydration, hypernatremia, hyperphosphatemia, cardiac failure, edemas, 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	Edemas	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	Hyper-hydration	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, nausea, vomiting, diarrhea, tremor, paresthesia, hypotension, increased body temperature, chest pain, sinus tachycardia and in case of further administration even ventricular fibrillation can occur. Then it is necessary to discontinue further administration of the product.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: infundabilium, ATC code: B05XA09 (Additives to intravenous solutions - electrolyte solutions – sodium phosphate).

Concentrated infusion solution is used for supplementation of phosphates losses.

5.2. Pharmacokinetic properties

Phosphor elimination by urine in adults is the same as phosphor intake. It is about 0.5 g/day. A decreased intake results in an increased reabsorption and so phosphate can be almost completely absorbed by kidneys. The phosphor reabsorption in renal tubules is very similar to that of glucose.

The distribution of phosphate administered intravenously is going on in two phases. In the early phase, which takes only a few minutes, phosphate gets into plasma and ECF. The second phase takes about 4 hours and in that phase a new balanced state of phosphate equilibrium in ICF and ECF is developed. Glucose as well as insulin cause the acceleration of that phase 3-4 times and then the equilibrium will not change.

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

Disodium edetate dihydrate

Aqua pro iniectione

6.2. Incompatibilities

The product must not be mixed with solution containing calcium or magnesium.

6.3. Shelf life

2 years provided that the package is intact.

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/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 larger amount of a 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)

76/919/95-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: 15th February 2017

10. DATE OF REVISION OF THE TEXT

15th February 2017