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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ardeaelytosol conc. kaliumchlorid 7,45% concentrate for solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml of the concentrate for infusion solution contains kalii chloridum 74.5 g.

Electrolyte content:

K^+	1000 mmol/l
Cl^-	1000 mmol/l
Osmotic pressure	4 832 kPa
pH	5.0-7.0

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

Prevention and therapy of hypokalemia, particularly in cases associated with hypochloremic alkalosis.

In case of increased potassium losses in diarrheal diseases, nephrotic syndrome, after a long-term therapy by diuretics, in hyperaldosteronism or others.

Hypokalemia can be either result of potassium loss out of the body or of potassium transfer into cells. Potassium losses occur in gastrointestinal diseases and in case of an increase in potassium elimination by kidneys. Raised losses through gastrointestinal tract are caused by diarrhoea, vomiting, fistulas, drainages.

Excessive potassium losses appear in renal tubular disorders, also in osmotic diuresis, in diuretics therapy or in corticosteroids administration.

Hypokalemia as a result of potassium transfer into cells is developed in case of administration of alkalis in patients suffering from acidosis.

Hypokalemia as a result of insufficient potassium intake can appear in case of anorexia, potassium depletion in a diet or in high potassium content in a diet.

In ionic imbalance of any other cause.

4.2. Posology and method of administration

The posology is individual, guided by potassium level, indication and a general patient's condition.

The product is not administered alone; it is always applied in glucose solution or in any other basic infusion solution via a slow intravenous infusion. Potassium concentration in the infusion solution administered should not exceed 40 mmol/l; the maximum speed of potassium supply into the body is 20 mmol/hour in adults.

The product can be administered to adults or children without any age restriction

4.3. Contraindications

Hyperkalemia – in case of an increase in serum K^+ higher than about 5.5 mmol/l – or conditions that can result in such hyperkalemia (serious traumas with tissue destruction, burns, dehydration, metabolic acidosis, severe haemolysis, renal failure with oliguria or anuria, Addison disease).

4.4. Special warnings and precautions for use

During the therapy, potassium serum levels and other basic parameters important for homeostasis should be necessarily monitored.

It is essential to maintain an adequate speed of infusion.

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

The product should be administered very carefully in case of simultaneous therapy with the drugs that result in potassium level increasing such as nonsteroidal antiphlogistics, beta blockers, heparin, digoxin, ACE inhibitors, aldosterone effect blockers.

Simultaneous and increased calcium supply has an influence on calcium/potassium ions balance which can result in arrhythmia.

4.6. Fertility, pregnancy and lactation

The product has been used in the therapy for many decades. No adverse effects on the course of pregnancy or foetus/new-born health condition have been proved during the given period. Nevertheless, in that period, it should be used with increased caution.

The product can be administered to pregnant and breast-feeding women. Currently, there are no other relevant epidemiologic data available.

4.7. Effects on ability to drive and use machines

The product of Ardeaelytosol conc. kaliumchlorid 7,45% is administered only in medical facilities and that is why the assessment of its impact on ability to drive or use machines is not relevant.

4.8. Undesirable effects

No direct undesirable effects are known with the product of Ardeaelytosol conc. kaliumchlorid 7,45% if correct dosage and speed of administration is observed. In cases of excessive or too rapid administration, hyperkalemia can occur that is manifested by disorders of neuromuscular conduction (muscular weakness, paraesthesia in limbs, paralysis, arrhythmia with the possibility of cardiac arrest), local effects on vascular wall – thrombophlebitis.

Organ system class according to MedDRA database	Character of undesirable effect	Frequency of occurrence
Nervous system disorders	Disorders of neuromuscular conduction	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	Arrhythmia	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.
Vascular disorders	Thrombophlebitis	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.
Metabolism and nutrition disorders	Hyperkalemia	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 case of overdose, hyperkalemia is developed. Hyperkalemia is manifested by disorders of neuromuscular conduction (muscular weakness, paraesthesia in limbs, paralysis, arrhythmia with the possibility of cardiac arrest).

It is necessary to stop potassium supply immediately in case of hyperkalemia symptoms or proof of hyperkalemia. The excess of potassium is eliminated from the body by diuretics with kaliuretic effect after a sufficient hydration; haemodialysis is necessary in severe cases. In case of cardiotoxic symptoms, calcium gluconate infusion is administered under ECG monitoring.

Glucose infusion with insulin added into is used to decrease potassium level in extracellular fluid; possible acidosis is adjusted by means of bicarbonate infusion, hyponatremia is corrected by sodium salts administration.

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: infundabilium, ATC code: B05XA01 (Additives to intravenous solutions – electrolyte solutions – potassium chloride).

One-molar solution of potassium chloride intended for the preparation of infusion solutions with potassium ion concentration according to the individual requirements of the patient.

5.2. Pharmacokinetic properties

a) General information – no active metabolites are generated with inorganic salts.

b) Characterization of the active substance – it is a simple inorganic salt containing ions natural for the body. It is water-soluble, fat-insoluble.

c) Characterization after the administration in patients – it is a product intended for intravenous use. After the IV administration, potassium is distributed in the organism very rapidly. Concentration gradient between intracellular and extracellular compartment is maintained by the activity of sodium-potassium pump. Potassium is eliminated mainly into urine; the amount of potassium eliminated by kidneys depends on potassium serum level, acid base balance, suprarenal hormones elimination and on other factors. A part of potassium is excreted into stool, a small amount into saliva, sweat, bile and pancreatic juice.

5.3. Preclinical safety data

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.

There have been no undesirable effects known from the literature. The product used according to the recommended method is entirely safe.

6. PHARMACEUTIAL PARTICULARS

6.1. List of excipients

Water for injection

6.2. Incompatibilities

The product can be added into most of basic infusion solution.

No other medicinal products should be added into the original concentrated product.

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 larger amount of basic infusion 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)

76/774/95-C

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of the first authorisation: 11th October 1995

Date of the last renewal of the authorization: 19th October 2016

10. DATE OF REVISION OF THE TEXT

2nd July 2020