sp.zn. sukls147891/2020

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Aqua pro iniectione Ardeapharma solvent for parenteral use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Aqua pro iniectione

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solvent for parenteral use
Description of the preparation: clear, colourless solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

The preparation and dilution of injection and infusion medicinal products, alternatively also the preparation and dilution of other liquid sterile pharmaceutical forms, intended for the administration in human or veterinary medicine.

4.2. Posology and method of administration

The dosage and method of administration are dependent on the concentration and volume of the final product.

4.3. Contraindications

There are no known contraindications except the intravenous administration without a dissolved drug.

4.4. Special warnings and precautions for use

The product of Aqua pro iniectione Ardeapharma should not be administered intravenously directly alone, because of potential subsequent haemolysis and hypotonic electrolytes imbalance.

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

No interactions have been known.

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

Not relevant with regard to the nature of the product and its indication.

4.8. Undesirable effects

There have been no direct undesirable effects reported with the product of Aqua pro iniectione Ardeapharma. There is only the possibility of undesirable effects connected with inadequate use of the product such as haemolysis, hypotonic electrolytes imbalance or hyper-hydration. The product has neither undesirable effects nor the risk of overdose in case of observance of the principles for the administration with respect to osmolality, i.e. use in combination with other medicinal products (for their preparation or dilution under established conditions) respecting stable water balance.

Organ system class according to MedDRA database	Character of undesirable effect	Frequency of occurrence
Blood and lymphatic system disorders	Haemolysis	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	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	Hyper-hydration, oedemas	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

Provided that the well balanced water and ionic balance is respected, no overdose is to be taken into consideration

Hyper-hydration and hypotonic electrolytes imbalance can occur in case of the administration of a major amount of hypotonic solution, especially in renal disorders.

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: infundabilium, varium, ATC code: V07AB (Solvents and diluting agents, incl. irrigating solutions).

Solvent for the preparation of solutions of medicinal products intended for injection or infusion administration.

5.2. Pharmacokinetic properties

a) General information – no active metabolites are generated

b) Characterization of the active substances – it contains only water as a solvent

c) Characterization after the administration in patients – it is a product administrated intravenously. The distribution into body compartments depends in the current patient´s condition.

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

No physical or chemical incompatibilities are known.

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 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 250 ml, 1x 500 ml
20x 80 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)

76/926/95-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

2nd July 2020