SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

WATER FOR INJECTIONS "FLEXIVIALS"

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contain:
Water for injections 1 ml

3 PHARMACEUTICAL FORM

Solvent for parenteral use
Clear, colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Preparation and dilution of medicines for parenteral administration.

4.2 Posology and method of administration

Posology

Water for injections "Flexivials" is used for dilution or dissolution of parenteral medicinal products. Dosage and duration of use depend on the instructions given for the medicinal product to be dissolved or diluted.

Paediatric population

The dosage should be based on the instructions given for the medicinal product to be dissolved or diluted.

Method of administration

The method of administration depends on the instructions given for the medicinal product to be dissolved/diluted. The medicinal product should be dissolved or diluted immediately before use.

4.3 Contraindications

There are no contraindications for Water for injections "Flexivials" as such.

4.4 Special warnings and precautions for use

Water for injections "Flexivials" must not be injected as such.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions between Water for injections "Flexivials" and other medicinal products are not known.

4.6 Fertility, pregnancy and lactation

Pregnancy

Generally, Water for injections "Flexivials" can be used during pregnancy.

Breast-feeding

Water for injections "Flexivials" can be used during breasteeding.

4.7 Effects on ability to drive and use machines

Water for injections "Flexivials" has no influence on the ability to drive and use machines.

4.8 Undesirable effects
None known if used according to the instructions given.
If Water for injections "Flexivials" is administered intravenously without additives, it may cause haemolysis and hypotonic disorders in the electrolte metabolism.

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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il/
and emailed to the Registration Holder's Patient Safety Unit at:
drugsafety@neopharmgroup.com

4.9 Overdose

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injections "Flexivials" as diluent. In the event of accidental overdose, the treatment should be discontinued.-In the case of massive haemolyis, intensive treatment must be instituted immediately.

Symptoms and treatment

Not applicable because this medicinal product is used only for preparation and dilution of parenteral preparations.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and diluting agents, including irrigation solutions
ATC code: V07AB

5.2 Pharmacokinetic properties

None

5.3 Preclinical safety data

Preclinical data on Water for injections "Flexivials" reveal no special hazards for humans. Studies of toxicity to reproduction, genotoxicity or carcinogenic potential have not been performed, but based on the chemical properties of water and the fact that water is essential to life, pure water not be expected to generate positive mutagenic or carcinogenic data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Ampoules LDPE Rectangle shape or Round shape. 20 x 5 ml, 20 x 10 ml, 20 x20 ml.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Only to be used if the solution is clear and colourless, and the container and closure are undamaged. The containers are for single use only. After use discard the container and any remaining contents.
Use the liquid immediately after opening the container.

7. MANUFACTURER:

Fresenius Kabi Espana S.A. Spain
Marina 16-18, 08005- Barcelona, Spain

8. REGISTRATION HOLDER:

Neopharm (Israel) 1996 Ltd
Hashiloach 6, POB 7063 Petach Tiqva 4917001

9. LICENSE NUMBER(S)

147-64-33392-00

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