SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

WATER FOR INJECTION

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml solution contain:

Water for injections 100 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 injection 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 as such.

4.4 Special warnings and precautions for use

Special warnings

Water for injection must not be injected as such.

Precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

Interactions between water for injection and other medicinal products are not known.

4.6 Fertility, pregnancy and lactation

Pregnancy

Generally, water for injection can be used during pregnancy.

Breast-feeding

Water for injection can be used during breasteeding.

4.7 Effects on ability to drive and use machines

Water for injection has no influence on the ability to drive and use machines.

4.8 Undesirable effects

None knownif used according to the instructions given.
If water for injection 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/

4.9 Overdose

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injections 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 injection 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.

Following the addition of additives
For microbiological reasons, the product should be used immediately. If it is not used immediately, storage times and conditions prior to use are the responsibility of the user. The ready-to-use

preparation must not be stored longer than 24 hours at 2 to 8^0C, unless dilution has taken place under controlled and validated aseptic conditions.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
See Section 6.3 for storage conditions of the ready-to0use preparation.

6.5 Nature and contents of container

ampoules LDPE Mini-Plasco ® 20x10ml and 20x20 ml.
ampoules LDPE Mini-Plasco-Conncet 20x10ml and 20x20 ml.
ampoules PP Mini-Plasco-Basic 100x10ml and 100x20 ml.
Bottle Plastic containers: 20x100 ml, 10x250 ml, 10x500 ml, 10x1000 ml

6.6 Special precautions for disposal

No special requirements for disposal.
Only to be used if the solution is clear and colousless, 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:

B.Braun Melsungen AG, Germany
Car-Braun str.1, D-34212, Melsungen, Germany

8. REGISTRATION HOLDER:

Lapidot Medical Import and Marketing Ltd.
8 Hashita street, Caesarea Industrial Zone, 38900

9. LICENSE NUMBER(S)

118-21-25556-12/13/00

Approved on 17.11.2020