1.3.1.1 Professional Information for Medicines for Human Use

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

Pour Water For Irrigation B.Braun solution for irrigation.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Pour Water For Irrigation B.Braun Solution for irrigation contains:

Sterile water for irrigation.

3. PHARMACEUTICAL FORM

Pour Water For Irrigation B.Braun:

Clear, and colourless solution.

Water for irrigation.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Sterile water is used for general surgical use where rinsing of instruments or washing of hands is required. Wound irrigation.

4.2. Posology and method of administration

Posology

Pour Water For Irrigation B.Braun is used for:

- Irrigation only.
- Not for injection.
- For single use only.

- Discard any unused portion.

4.3. Contraindications

There are no known contraindications for water for injections as such.

4.4. Special warnings and precautions for use

Pour Water For Irrigation B.Braun must not be used for intravenous administration.

Sterile water for irrigation is hypotonic. It may cause hemolysis of red blood cells.

4.5. Interaction with other medicines and other forms of interaction

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

4.6. Fertility, pregnancy and lactation

Pregnancy

Generally, water for injections can be used during pregnancy.

Breastfeeding

Water for injections can be used during breast-feeding.

Fertility

No data available.

4.7. Effects on Ability to Drive and Use Machines

Pour Water For Irrigation B.Braun has no influence on the ability to drive and use machines.

4.8. Undesirable Effects

None known if used according to the instructions given.

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 SAHPRA via the ‘6.04 Adverse Drug Reactions Reporting Form’. Found under SAHPRA’s publications:

https://www/sahpra.org.za/Publications/Index/8

4.9 Overdose

There is a possibility of fluid absorption, if this occurs in excess hypervolaemia and renal failure may result.

Treat symptomatically paying particular attention to restoring the electrolyte balance.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A.34 Other

Pharmacotherapeutic group: Solvents and diluting agents, incl. irrigating solutions.

ATC code: V07AB.

5.2. Pharmacokinetic properties

None.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

None

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Do not use after expiry date.

Do not freeze.

Do not use unless the solution is clear and free from particles or if the container is damaged or has been previously opened.

Discard any unused portion.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Polypropylene pour bottles with polyethylene cap of 1000 mL capacity.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements for disposal.

Only to be used if solution is clear, colorless and the container and its closure are undamaged.

The containers are for single use only. After use discard container and any remaining contents.

Use the liquid immediately after opening of the container.

7 NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

32/24/0562

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