

PACKAGE LEAFLET: INFORMATION FOR THE USER

Water for Injections Ph. Eur.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you notice any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Water for Injections Ph. Eur., is and what it is used for
2. What you need to know before you use Water for Injections Ph. Eur.
3. How to use Water for Injections Ph. Eur.
4. Possible side effects
5. How to store Water for Injections Ph. Eur.
6. Contents of the pack and other information

1. What Water for Injections Ph. Eur is and what it is used for

Water for Injections Ph. Eur. is sterile water for injections.

This is used for preparation and dilution of medicines that are to be administered into your vein (parenteral use).

2. What you need to know before you use Water for Injections Ph. Eur.

Do not use Water for Injections Ph. Eur.

There are no known situations in which Water for Injections Ph. Eur. should not be used.

Warning and precautions

Water for Injections Ph. Eur. must not be used alone. Your doctor will dissolve or dilute another medicine in water for injection before the ready prepared medicine is administered to you.

Other medicines and Water for Injections Ph. Eur.

There are no known interactions with other medicines.

Water for Injections Ph. Eur. with food and drink

There are no known interactions with food or drink.

Pregnancy and breast-feeding

Water for Injections Ph. Eur. can be used during pregnancy and breast-feeding.

Driving and using machines

Water for Injections Ph. Eur. has no influence on the ability to drive and use machines.

3. How to use Water for Injections Ph. Eur.

This medicine is administered to you by a doctor or healthcare professional.

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

The dosage of **Water for Injections Ph. Eur.** and the duration of the application are in accordance with the instructions pertaining to the medicine to be dissolved or diluted.

If you use more Water for Injections Ph. Eur. than you should

An overdose is very unlikely as this medicine is only for preparation and dilution of parenteral preparations. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. There are no known side effects if the instructions for use are followed.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Water for Injections Ph. Eur.

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container and the outer carton after "EXP". The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

Liquid is used immediately after first opening.

Do not use this medicine if you notice the container is damaged and the liquid is unclear and coloured.

For single use only. Discard any unused content after use.

6. Contents of the pack and other information

What Water for Injections Ph. Eur. contains

Each ml contains 1ml water for injections.

What Water for Injections Ph. Eur. looks like and contents of the pack

Water for Injections Ph. Eur. is a solvent for parental use: it is used to dissolve or dilute medicines that are to be administered into your vein.

It is a clear, colourless liquid.

It is available in:

- Plastic polyethylene ampoules, contents: 10 ml, 20 ml, supplied in packs of:
20 × 10 ml
20 × 20 ml
- Plastic polypropylene ampoules, contents: 10 ml, 20 ml supplied in packs of:
100 x 10 ml,
100 x 20 ml

Not all pack-sizes may be marketed.

Marketing Authorisation Holder

B. Braun Medical Limited
3 Naas Road Industrial Park
Dublin 12

Manufacturer

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

This leaflet was last revised in 06/2015.

The following information is intended for medical or healthcare professionals only:

After preparation of the ready-to-use medicinal product

From a microbiological point of view, the ready-to-use preparations should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

For the preparation of parenteral solutions usual hygiene precautions to maintain sterility must be adhered to.

Recommendations given in the product information of the product diluted or mixed with water for injection should be taken into consideration for further information on compatibility and shelf life.

Water for injection must only be administered after addition of osmotic active substances, as water for injections itself is strongly hypotonic.