

Package leaflet: Information for the user

Water for Injections solvent for parenteral use

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Sterilised Water for Injections is used to dissolve and dilute other medicines that require mixing with water before they can be given as an injection or an infusion (a drip) into your veins, muscles or other tissues in the body.

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

The following sections contain information that you and your doctor should consider before you use Water for Injections.

Do not use Water for Injections

- as an injection or infusion on its own

Water for Injections must only be used to dissolve or dilute necessary drugs.

You should read the Patient Information Leaflet of your medicine or medicines that are being mixed with Water for Injections. This will tell you whether or not you can receive the solution.

Warnings and precautions

Water for Injections should not be used on its own.

Before you use Water for Injections:

- it should always be mixed with one or more medicines

Before you are given medicines mixed with Water for Injections your doctor will check that:

- the medicines are stable in Water for Injections
- the medicines will not interact with each other

Other medicines and Water for Injections

Please refer to the Patient Information Leaflet of your medicine that is being mixed with Water for Injections. Those medicinal products known to be incompatible with water for injections must not be used.

Pregnancy, breast-feeding, and fertility

Please refer to the Patient Information Leaflet of your medicine that is being mixed with Water for Injections.

Driving and using machines

Water for Injections has no influence on the ability to drive and use machines. Any effects on your ability to drive or use machines will depend on which medicines you are using mixed with Water for Injections.

3. How to use Water for Injections

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide how much you need and when and how it is to be given. This will depend on which medicine or medicines you need to take with Water for Injections.

Use only if the Water for Injections is clear, colourless, without visible particles and if the container is undamaged.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Please refer to the Patient Information Leaflet of your medicine that is being mixed with Water for Injections.

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 to:

HPRA Pharmacovigilance Section

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 676 4971

Fax: +353 1 676 2517

Website: www.hpra.ie

Email: medsafety@hpra.ie

By reporting side effects, you can help provide more information of the safety of this medicine.

5. How to store Water for Injections

Do not use Water for Injections after the expiry date, which is stated on the label and carton.

- **Keep this medicine out of the sight and reach of children.**
- Do not freeze.
- Your doctor will inform you how to dispose of unused product or waste material.
- After opening, the product must be used immediately.

This medicinal product does not require any special storage conditions.

For in use shelf life, after reconstitution of the medicinal product, check the Package Information Leaflet of the medicinal product which was reconstituted with Water for Injections.

6. Contents of the pack and other information

What Water for Injections contains

The only ingredient is sterile Water for Injections in one vial.

What Water for Injections looks like and contents of the pack

Water for Injections is a clear, colourless liquid.

Pack sizes (1 vial per pack)

Container details

2 ml, 2.5 ml, 3 ml, 4 ml, 5 ml

In 6 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc.

For the filling size:

2 ml (overage 0.3 ml): Blue/ purple,
 2.5 ml (overage 0.3 ml): Blue/ blue,
 2.5 ml (overage 0.4 ml): Blue/ lime,
 2.5 ml (overage 0.6 ml): Blue/ light blue,
 3 ml (overage 0.4 ml): Blue/ orange,
 4 ml (overage 0.3 ml): Blue/ grey,
 5 ml (overage 0.4 ml): Blue/ green.

5.6 ml, 10 ml

In 10 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc.

For the filling size:

5.6 ml (overage 0.46 ml): Blue/ lime,
 10 ml (overage 0.5 ml): Blue/ blue.

15 ml

In 15 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc.

For the filling size:

15 ml (overage 0.5 ml): Blue/ blue.

20 ml

In 25 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper

and aluminium crimp-cap with polypropylene plastic disc.

For the filling size:

20 ml (overage 1 ml): Blue/ blue.

40 ml, 50 ml

In 50 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc.

For the filling size:

40 ml (overage 1.5 ml): Blue/ blue

50 ml (overage 2 ml): Blue/ blue.

Not all sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

CSL Behring GmbH

Emil-von-Behring-Strasse 76

35041 Marburg

Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

CSL Behring GmbH

Tel: +49 69 30517254

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