

Package leaflet: Information for the user

Water for Injections

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Water for Injections is given to you
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

Water for Injections is pure, sterile water. It is used to dilute medicines before use. For example medicines that are given by:

- injection (given using a needle, for example into your vein)
- infusion (slow injection) into a vein, also called a 'drip'.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE WATER FOR INJECTIONS

Do not use Water for Injections:

You must NOT receive Water for Injections on its own. If injected into your bloodstream on its own it can cause your red blood cells to take in water and burst (haemolysis). This is because Water for Injections does not have the same consistency as your blood.

Water for Injections will always be mixed with one or more medicines by a healthcare professional before you receive it.

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Water for Injections

Water for Injections should not be used on its own. Before you use Water for Injections:

- it will always be mixed with one or more medicines
- your healthcare professional will make sure that the mixture is roughly the same consistency as your blood (isotonic). Depending on the type of medicine you are given, this will mean that:
 - the medicine needs to be diluted with Water for Injections
 - another substance needs to be added to your mixture of Water for Injections and medicine before use.

You will be more likely to suffer haemolysis if you are given large volumes of hypotonic solutions of Water for Injections (solutions that are not as concentrated as your blood). To help prevent this, your doctor will take a blood sample to monitor the balance of the chemicals in your blood (the ionic balance).

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 tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The medicines you are using mixed with Water for Injections may interact with each other.

Water for Injections with food and drink

You should ask your doctor about what you can eat or drink.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Any risk to your unborn baby or your pregnancy will depend on which medicines you are using mixed with Water for Injections. Any risk to your baby during breast-feeding will also depend on which medicines you are using mixed with Water for Injections.

Your doctor will be able to advise you on what risks are involved in taking particular medicines.

Your doctor will only give you medicines during pregnancy or breast-feeding if it is essential.

Driving and using machines

Water for Injections does not affect your ability to drive or 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. Your doctor will be able to advise you on this.

3. HOW WATER FOR INJECTIONS IS GIVEN TO YOU

Water for Injections will be given to you by a doctor or nurse. Your doctor will decide on 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.

Your doctor will also consider your age, weight, condition and what other treatments you are receiving.

You should NOT be given Water for Injections if there are particles floating in the water or if the pack is damaged in any way.

If you use more Water for Injections than you should

If you are given too much Water for Injections (over – infusion) this may lead to haemolysis. Haemolysis is when your red blood cells take in water and burst.

The medicines mixed with Water for Injections may also cause symptoms if administered in too large quantities (over- infusion). Any signs and symptoms of overdose will depend on which medicines you are using mixed with Water for Injections.

If you are accidentally given an overdose your treatment will be stopped and you will be given treatment depending on the symptoms.

You should read the Patient Information Leaflet of the medicines mixed with Water for Injections for a list of possible symptoms of over-infusion.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Not known: frequency cannot be estimated from the available data

You may suffer bursting (haemolysis) of your red blood cells if:

- you use Water for Injections on its own
- Water for Injections is used to make solutions for injection or infusion that are not of a similar consistency to your blood (isotonic).

If a medicine has been added to Water for Injections, the added medicine may also cause side effects. These side effects will depend on the medicine that has been added. You should read the Patient Information leaflet of the added medicine for a list of possible symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

For United Kingdom:

The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

For Ireland:

HPRA 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

Keep this medicine out of the sight and reach of children.

The ampoules should not be used after the expiry date printed on the labeling.

The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use if the ampoule is damaged or if the contents are discoloured.

If only part used, discard the remaining solution.

For single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Water for Injections contains

Water for Injections is a specially prepared form of distilled water. It is a clear colourless sterile liquid and does not contain any other ingredients.

What Water for Injections looks like and contents of pack

Packs of 10, 20, 50 and 100 plastic ampoules containing 2ml, 5ml and 10ml of sterile liquid
(PL 02848/0152)

Packs of 10, 20, 50 and 100 plastic ampoules containing 5ml and 10ml of sterile liquid.

(PA 73/107/7)

(Not all pack sizes may be marketed).

Product Licence Holder

Mercury Pharma International Ltd.,

4045, Kingswood Road, City West Business Park, Co Dublin, Ireland

PL No: PL 02848/0152

Product Authorisation Holder

Mercury Pharmaceuticals (Ireland) Ltd;

4045, Kingswood Road, City West Business Park, Co Dublin, Ireland

PA No: PA 73/107/7

Manufacturer:

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