

Package leaflet: Information for the user

Water For Injections Solvent 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 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, 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 are given 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 a special type of water that has been carefully cleaned and purified so it does not contain any other ingredients. Water for Injections is called a diluent because its main use is for diluting and preparing medicines before use.

Water for Injections is used to dissolve and dilute other drugs 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.

Follow all directions given to you by your doctor carefully. You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN WATER FOR INJECTIONS

The contents of the vials should be examined before use to ensure that the liquid is clear, is not discoloured in any way and does not contain any particles. Ensure the glass container is undamaged.

Do not use Water for Injections

- As an injection or infusion on its own.

Water for Injections must not be injected or infused on its own. It must only be used to dissolve or dilute necessary drugs to be administered by your doctor or nurse.

Warnings and precautions

Talk to your doctor or nurse before using Water for Injections.

 Water for Injections should not be administered alone because it may cause damage to red blood cells (haemolysis).

Other medicines and Water for Injections

Please tell your doctor if you are taking, have recently taken or might take any medicines in addition to the medicine that is going to be dissolved or diluted with Water for Injections.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking the medicine that is going to be dissolved or diluted with Water for Injections.

Driving and using machines

Ask your doctor for advice before taking the medicine that is going to be dissolved or diluted with Water for Injections.

3. HOW WATER FOR INJECTIONS IS GIVEN TO YOU

In the preparation of a medicine for use, the required volume of Water for Injections will vary, depending on the drug to which it is added. Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor or nurse will use the correct amount of Water for Injections to dissolve or dilute the medicine that you are receiving as an injection, or as an infusion (a drip) into your veins.

Your doctor will decide the dose of your medicine that you should receive and how long you will need to take it for. The dose will depend on the other medicine which is being dissolved or diluted with Water for Injections.

If you use more Water for Injections than you should

It is most unlikely that you will be given too much medicine by the doctor or nurse. Your doctor and nurse will be monitoring your progress and checking the medicine that you are given. The signs and symptoms of overdose will be related to those of the medicine which is being dissolved or diluted with Water for Injections. However, if you feel unwell afterwards or have any discomfort, tell your doctor or nurse.

If you forget to take Water for Injections

If you think that you have missed a dose or that you have been given too much of the medicinal product, contact your doctor. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

If given on its own, intravenous injection of Water for Injections may cause damage to red blood cells (haemolysis).

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 (see details below).

United Kingdom

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

or

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.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". 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 the 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.

Marketing Authorisation Holder:

Mercury Pharma Overseas Ltd. Mercury Pharmaceuticals Ltd.

Capital House, 85 King William Street,

London EC4N 7BL. UK

Product Licence Number:

PL 12762/0605

Manufacturer:

Mercury Pharmaceuticals Ltd.

Capital House, 85 King William Street, London EC4N 7BL, UK

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