

PACKAGE LEAFLET

Package leaflet: Information for the user

Water for Injections Ph.Eur.

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.

The name of your medicine is Water for Injections Ph. Eur..

In the rest of this leaflet Water for Injections Ph. Eur. is called Water for Injections.

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

Water for Injections is a special type of water that is sterile. This means that it is very clean and can be injected.

Water for Injections is used to dissolve or dilute some medicines so that they can be given as an injection or an infusion (a drip) into veins, muscles or other tissues in the body.

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

Warnings and precautions

Talk to your doctor or nurse before using Water for Injections. Water for Injections is hypotonic (more dilute than your blood) and it should not be given on its own, because it may cause haemolysis (destroy your red blood cells).

Other medicines and Water for Injections

Tell your doctor if you are using, have recently used or might use any other medicines, including medicines obtained with a prescription.

There are no known interactions when Water for Injections is given with other medicines. Please make sure you read the leaflets for all your medicines, as Water for Injections is added to another medicine such as to dissolve or dilute it.

Pregnancy and breast-feeding

Water for Injections is not known to cause problems during pregnancy or breast-feeding.

As Water for Injections is given with other medicines, it is important that:

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 this medicine.

Your doctor will advise you if you should have this medicine.

3. How to use Water for Injections

A doctor or a nurse will usually give you this medicine. This product is a solvent for use as an injection.

Your doctor or nurse will use the correct amount to dissolve or dilute another medicine that you are receiving as an injection or a drip (your doctor or nurse may call this an infusion).
Water for injections should not be mixed with oily liquids.

Your doctor will decide the amount (dose) of your medicine that you should receive and how long you will need to take it for.

The dose will depend on what other medicine it is being used to dissolve or dilute.

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

4. Possible side effects

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

Remember that you may also get side effects from the other medicines that Water for Injections is being used to dissolve or dilute.

The expected benefit of your medicine will usually be greater than the risk of you suffering any harmful side effects.

**Important: Side effects or symptoms to look out for, and what to do if you are affected.
The first signs of having too much water in your blood are feeling tired and looking pale. If you get any of these symptoms you must seek urgent medical advice.**

Side effects are not known for Water for Injections so please read the leaflet for all your other medicines that the water is being added to dissolve or dilute.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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: HPRA

Pharmacovigilance, Website: www.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 and the label after 'EXP'.
The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.
After first opening:

Only use your medicine if it is a clear and colourless liquid. Open it and use it straight away. Any unused product should be discarded after opening.

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

- The active substance is Water for Injections.

1 ml contains 1 g water for injections, 5 ml contain 5 g water for injections, 10 ml contain 10 g water for injections, 20 ml contain 20 g water for injections.

There are no other ingredients in this medicine.

What Water for Injections looks like and contents of the pack

Water for Injections is a solvent for parenteral use.

Water for Injections is a clear, colourless liquid.

Each plastic ampoule will contain 5 ml (millilitres), 10 ml or 20 ml of your medicine. 5 ml ampoules come in boxes of 20 or 50 ampoules. 10 ml ampoules come in boxes of 20, 50 or 100 ampoules. 20 ml ampoules come in a box of 20 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Noridem Enterprises Ltd., Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.

Manufacturer: DEMO S.A. Pharmaceutical Industry, 21st km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece, **T:** +30 210 8161802, **F:** +30 210 8161587

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Sterilt vand "Noridem", solvens til parenteral anvendelse
Germany	Wasser für Injektionszwecke Noridem 1 g/ml Lösungsmittel zur Herstellung von Parenteralia
Ireland	Water for Injections Ph. Eur.
Norway	Sterilt vann Noridem, oppløsningsvæske til parenteral bruk
Portugal	Água para preparações injectáveis Noridem
Sweden	Vatten för injektionsvätskor Noridem, spädningsvätska för parenteral användning
Spain	Agua para preparaciones inyectables Serra, disolvente para uso parenteral
Austria	Wasser für Injektionszwecke Noridem – Lösungsmittel zur Herstellung von Parenteralia
Greece	WATER FOR INJECTIONS/NORIDEM Διαλύτης για παρεντερική χρήση 100% v/v
Netherlands	Water voor injecties Noridem, oplosmiddel voor parenteraal gebruik

This leaflet was last revised in August 2024.