

**PACKAGE LEAFLET**

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Water for Injections Ph.Eur.**

#### **Water for Injections**

**Please read all of this leaflet carefully. It includes important information on how you should take this medicine correctly and safely.**

- Keep this leaflet. You may need to read it again.
- If you are the parent of a child who is to be given this medicine, read the leaflet replacing 'you' with 'your child' throughout.
- This medicine is prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in the leaflet, please tell your doctor, nurse or pharmacist.
- If you have any further questions, please ask your doctor, nurse or pharmacist.

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#### **In this leaflet:**

1. What Water for Injections is and what it is used for
2. 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. Further information

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.

#### **Take special care with 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).

#### **Using other medicines**

Please tell your doctor if you are taking or have recently taken 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 think you may be pregnant you must tell your doctor
- If you are breast feeding you must tell your doctor.

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

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 your medicine, ask your doctor, nurse or pharmacist.

Like all medicines, Water for Injections can cause side effects, but not everyone 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

**For UK:** Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

**For IE:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

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

Do not use Water for injections after the expiry date given on the carton and the label after 'EXP'. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

After first opening:

Only use your medicine if it is clear and colourless liquid. Open it and use it straight away.

Any unused product should be discarded after opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **What Water for Injections contains**

The active substance is Water for Injections.

1ml contains 1g water for injections, 5ml contain 5g water for injections,

10ml contain 10g water for injections, 20ml contain 20g water for injections.

There are no other ingredients in this medicine.

### **What Water for Injections looks like**

Water for injections is a solvent for parenteral use.

Water for Injections is a clear, colourless liquid.

### **Contents of the pack**

Each plastic ampoule will contain 5ml (millilitres), 10ml or 20ml of your medicine. 5 and 10ml ampoules come in a box of 50 ampoules. 20ml 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, Suit.115, 1065 Nicosia, Cyprus.

**Manufacturer:** DEMO S.A., 21st Km National Road Athens-Lamia, 14568 Krioneri, Athens, Greece.

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark: Sterilt vand "Noridem", solvens til parenteral anvendelse

Germany: Wasser für Injektionszwecke Noridem 1mg/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, 100%, Solvente/Veículo para uso parentérico

Sweden: Vatten för injektionsvätskor Noridem, spädningsvätska för parenteral användning

Spain: Agua para preparaciones inyectables Serra, disolvente para uso parenteral

United Kingdom: Water for Injections Ph. Eur.

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 approved in May 2017.**

**If this leaflet is difficult to see or read please contact the following address for help:**

**Athlone Laboratories, Ballymurray, Co. Roscommon, Ireland.**

**Tel: +353-9066-61109. Email [medical@athlone-laboratories.com](mailto:medical@athlone-laboratories.com).**