

WATER FOR INJECTION / DEMO

Solvent for parenteral use

5 mL, 10 mL plastic ampoules

1. DESCRIPTION OF THE MEDICINAL PRODUCT

1.1 Name of the medicinal product: WATER FOR INJECTION / DEMO.

1.2 Qualitative and Quantitative Composition: Each ampoule contains 100% water for injections.

1.3 Pharmaceutical form: Solvent for parenteral use.

1.4 Description - Packaging: WATER FOR INJECTION / DEMO is a clear, colourless liquid. It is distributed in plastic ampoules of 5 mL and 10 mL.

1.5 Pharmacodynamic properties: Solvents and dilution agents (ATC: V07AB).

1.6 Manufacturer: DEMO S.A. Pharmaceutical Industry, 21st km National Road Athens-Lamia, 145 68 Krioneri, Attiki, Greece, T.: +30 210 8161802, F.: +30 2108161587.

2. WHAT YOU SHOULD KNOW ABOUT THE MEDICINE YOUR DOCTOR HAS PRESCRIBED TO YOU

2.1 General Information: Since WATER FOR INJECTION / DEMO is only the vehicle used for administration of other medicines, pharmacokinetic and pharmacodynamic properties depend on the nature of the medicine that has been added.

2.2 Therapeutic Indications: WATER FOR INJECTION / DEMO is used as a vehicle for dilution or reconstitution of medicines for parenteral administration.

2.3 Contraindications: WATER FOR INJECTION / DEMO should not be administered as is. Contraindications related to the medicine that has been added should be taken into account.

2.4 Special warnings and precautions for use

2.4.1 General: WATER FOR INJECTION / DEMO is hypotonic and therefore it should not be administered as is. It should not be used for intravenous infusion, unless the isotonicity has been adjusted using an appropriate agent. When WATER FOR INJECTION / DEMO is used for dilution of hypertonic solutions, the final solution should be isotonic.

Haemolysis may be induced after infusion of large volumes of hypotonic solutions of water for injections. When large volumes of solutions of water for injections are administered, electrolyte balance should be checked regularly.

2.4.2 Pregnancy: Risks of use during pregnancy depend on the nature of the medicine that has been added.

2.4.3 Lactation: Risks of use during lactation depend on the nature of the medicine that has been added.

2.4.4 Children: There are no special warnings and precautions for use in children.

2.4.5 Elderly: There are no special warnings and precautions for use in the elderly.

2.4.6 Effects on ability to drive and use machines: Not applicable.

2.4.7 Special warnings about the excipients: Not applicable.

2.5 Interaction with other medicinal products and other forms of interaction: None known. Possible clinical interactions of the medicines that are to be dissolved in or diluted with WATER FOR INJECTION / DEMO should be confirmed before use.

Incompatibilities:

WATER FOR INJECTION / DEMO should not be used for dissolution of medicines that are known to be incompatible.

Before addition of other medicines, please confirm that they are:

- soluble and stable in water at the pH value of WATER FOR INJECTION / DEMO
- compatible with each other

2.6 Posology and method of administration:

Recommended dosage: Dosage depends mainly on the nature of the medicines to be added. Rate of administration depends on the dosage scheme of the added medicine. After admixture of the added medicines with WATER FOR INJECTION / DEMO, dosage usually depends on the age, weight and clinical condition of the patient, as well as on laboratory findings.

Method of Administration: The solution is intended for parenteral administration and reconstitution of other medicines. About the recommended volume and the route of administration, please refer to the instructions for use of the added medicine.

Instructions for use and handling: Discard after first use. Discard any unused portion. Use only if the solution is clear and free of any visible particles and the container is not damaged. Ampoules that have been opened should be used immediately. It is necessary that any medicine has been added and completely dissolved under aseptic conditions. Freshly prepared solutions are recommended to be used; otherwise they should be prepared under controlled aseptic conditions.

2.7 Overdose: Haemolysis may be induced after infusion of large volumes of hypotonic solutions using WATER FOR INJECTION / DEMO as a dilution agent. Overdose signs and symptoms are also related to the added medicine. In case of accidental overdose, treatment should be discontinued and the patient's condition should be monitored for known signs and symptoms related to the added medicine.

2.8 Undesirable effects: Intravenous injections of WATER FOR INJECTION / DEMO may cause haemolysis if it is administered as is. Any other adverse effects are related to the added medicines.

2.9 What you should know in case you have missed a dose: Not applicable.

2.10 Expiry date: It is indicated on the label of each ampoule and on the outer carton. In case this date has passed, do not use this medicine.

Shelf life during use: The chemical and physical stability of any added medicine at the pH value of WATER FOR INJECTION / DEMO should be confirmed before use. Unless the dilution is made under controlled and aseptic conditions, the resulting solution should be administered immediately. If not used immediately, the user holds the responsibility for the duration and conditions of storage before use.

2.11 Special precautions for storage: Store below 30°C.

2.12 Date of revision of the text: October 2020.

3. GENERAL INFORMATION FOR THE RATIONAL USE OF MEDICINES

- Read this entire leaflet carefully before you start taking this medicine. It contains important information for you.
- Keep this leaflet. You may need to read it again.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you need more information or advice about your medicine, ask your doctor or pharmacist.
- Always take this medicine exactly as your doctor has told you in order to get the best results from it.
- 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.
- Do not keep your medicines in bathroom medicine cabinets, because heat and humidity can affect their quality. Always keep your medicines in the original container and in a cool and dry place.
- Do not keep medicines that you no longer use or that have already expired.
- Keep all medicines out of the reach and sight of children.

4. GENERAL CLASSIFICATION FOR SUPPLY

This medicine is not subjected to medical prescription.

Product Registration Holder:

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai, 5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia



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