

IFU/Οδηγίες χρήσης

Water for Inhalation

EN

Product Information

Description

Sterile water for respiratory humidification.

Composition

Water for Injections 100% v/v

Indications

Water for Inhalation is used together with a compatible respiratory gas humidifier towards providing a respiratory gas humidifying system for patients in need of invasive- or non-invasive ventilation for their treatment (medical circumstances that require non-invasive ventilation (NIV), humidified high-flow nasal cannula (HHFNC) oxygen therapy and other similar interventions – such as hypoxia, tachypnea, bronchiolitis etc., and in critically ill patients during surgery.

Intended Use

Water for Inhalation is used for the humidification of inspired gases during invasive and non-invasive ventilation.

Intended users

Water for Inhalation is intended to be handled by healthcare professionals.

Patient population

All patients eligible for any kind of respiratory treatment.

Intended clinical benefits

- Management of the dryness of the respiratory mucosa.
- Prevention of hypothermia, disruption of the airway epithelium, bronchospasm, atelectasis, and airway obstruction.
- Reduction in the need for invasive ventilation.
- Reduction in the need for oxygen.
- Reduction of the length of stay to the ICU and/or to the hospital.
- Easy and safe method to assess severity of asthma and to follow response to treatment.

Instructions for use

- 1) Hook the sterile water bottle at a suitable height to the humidifying chamber (min. 50 cm).
- 2) Remove one of both hygienic caps from the bottle top.
- 3) Press the spike of the auto-fill tube through the seal of the hygienic cap.
- 4) If the pressure compensation line is used, please remove the second hygienic cap and act as described before the auto-fill tube.
- 5) Ensure that there are no leaks in the connection.

Contraindications

There are no known contraindications for the use of Water for Inhalation.

Side effects

There is no known side effect.

Warnings – Precautions

- 1) Water for Inhalation is not for parenteral or oral use.
- 2) Water for Inhalation is not suitable for the treatment of wounds.
- 3) Water for Inhalation must be used only if it clear, colourless and without visible particles.
- 4) It should not be used if the bottle is damaged.
- 5) Unused content should be discarded.
- 6) Water for Inhalation should not be heated above 65°C.

- 7) Water for Inhalation should not be opened with contaminated hands or tools.

Storage

Keep under correct storage conditions. Store out of direct sunlight. Please note the expiry date.

Storage and Transport Temperature

Temperature during storage and transport should be kept in the range of 2°C to 25°C.

Contents and Materials

1000ml – PE bottle with sealed perforation outlet

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority.

Key to symbol

				
Consult instructions for use	Medical Device	Do not use if packaging is damaged	Batch number	Distributor
				
Use-by date	Do not re-use	Temperature limit	Sterilized using steam or dry heat	Date of manufacture
				
Low Density Polyethylene	Single sterile barrier system	Manufacturer	Unique device identifier	



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