

NASISOFT

***Sterile solution for inhalation
and intranasal administration***

Description

NASISOFT is a sterile solution for inhalation by nebulizer and/or intranasal administration by direct instillation from the container into the nasal cavities. It is a natural isotonic saline solution in a concentration adjusted to be compatible with human body liquids. **NASISOFT** is used for moistening the respiratory tract, including cases when such cold symptoms are manifested as a cough and nasal congestion.

Qualitative composition

Sodium chloride – 9.0 mg/ml
Sodium Hyaluronate – 1.0 mg/ml
Water for injection

Classification of the product

Medical device –sterilized and pyrogen-free- Class IIa.

Package

4 ml in pre-filled disposable polymer containers, each containing 0.9% saline solution. Each package contains:
10 plastic containers with sterile NASISOFT solution
Or 60 plastic containers with sterile NASISOFT solution

⚠ Only the contents of the package are sterile. The medical device has been sterilized by steam sterilization.

Indications

NASISOFT, when used according to the instructions, may be administered to newborns, children, pregnant and nursing women, and adults, for the following intended uses:

- For nasal cavity care and for use in patients with diseases of nasal mucosa, accompanied by dryness of the nasal mucosa or by mucus formation (atrophic, allergic, infectious, drug-induced rhinitis).
- To eliminate dryness of the nasal mucous membrane caused by being in air-conditioned premises, including air-conditioned cars or centrally-heated premises and on flights.
- After nasal cavity surgery.

Route of administration

By inhalation

The solution can be inhaled by means of a nebulizer using a facemask, an actuator or a nasal cannula, and following the nebulizer manufacturer's instructions for use.

Use one, 4-ml vial twice a day or according to medical prescription.

By intranasal administration

Intranasal administration of the solution can be performed by squeezing the plastic container and allowing the content to flow into each nasal cavity. Use one, 4-ml vial from 1 to 4 times a day or according to medical prescription.

Apply for up to 4 weeks or according to medical prescription.

Warnings and special precautions for use

- The solution is only intended for use via inhalation or intranasal administration. Do not inject.
- Do not use if the solution is not transparent and colorless.
- Do not use after the expiry date.
- Do not use if the package is opened or damaged.
- The product must be used immediately after opening.
- The product is intended for single use. After use, the unused product is no longer sterile.
- Do not reuse. Once the product has been used for the first time, any residuals of the product are not suitable for repeated use as the product is no longer sterile.
- Do not re-sterilize. Repeated sterilization may cause cross-contamination.
- Do not freeze.
- The product must not be administered orally.
- Use by children should be under the supervision of adults.
- This product includes small parts, which can pose a choking hazard. Always keep this product out of the reach of children under the age of three.

Side effects

NASISOFT is contraindicated in case of individual hypersensitivity to any component of the product. In persons with individual intolerance to the solution components allergic reactions are possible.

Isotonic saline solution can cause reversible constriction of the bronchia when inhaled by very sensitive patients with bronchial asthma or a hyperreactive bronchial system. In particularly susceptible subjects, pre-medication with bronchodilators that can help prevent bronchospastic reactions is advisable at the start of the treatment. Pre-medication with bronchodilators must be carried out under the control of a doctor.

In case of the onset of bronchospasms or persistent cough, interrupt the treatment and inform the treating doctor.

How to use

For inhalation by nebulizer:

- Check the expiry date indicated on the package. Do not use after the expiry date.
- Take one of the plastic containers with NASISOFT from the strip of 10 plastic containers.
- Open the plastic container by turning the stopper.
- Use the solution in conjunction with the nebulizer following the device manufacturer's instructions for use.

For intranasal administration:

- Check the expiry date indicated on the package. Do not use after the expiry date.
- Take one of the plastic containers with NASISOFT from the strip of 10 plastic containers.
- Open the plastic container by turning the stopper.
- Squeeze the solution from the plastic container inside the nasal cavities.

Shelf life













2 years in intact packaging.

How to store

Store at a temperature from 5° to 30° C (inclusive), away from direct light and heat sources, in adequately closed packaging. The expiry date applies to the product when correctly stored in intact packaging.

Disposal

The product must be disposed of in accordance with applicable laws on municipal waste.

Symbols used on the packaging			
	Do not reuse - for single use		Manufacturer
	Lot number		Sterilized using steam or dry heat
	Expiry date		Do not re-sterilize
	Do not use if the package is opened or damaged		Protect from light and heat
	Consult instructions for use		Temperature limits for storage
	Non - pyrogenic		Date of manufacture



Medical device according to Directive 93/42/EEC

1936



Diaco

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