

INSTRUCTIONS FOR USE of medical device

SNOTTY Nasal Spray

Composition

1 mL of spray contains: xylitol 120 mg, sodium chloride 9 mg, benzalkonium chloride 0.2 mg, purified water up to 1 mL.

Nature and contents of container

Nasal spray in 30 mL vial with a nozzle, No.1.

Product description

SNOTTY is a nasal spray that cleans the nasal passages and sinuses, eliminating pollutants and irritants. SNOTTY quickly relieves nasal congestion in patients with upper respiratory tract infections and allergies.

Xylitol is the main component of the medical device. In conditions of low pH, xylitol stabilises the protein structures of cells. Due to its osmotic properties, it regulates salt metabolism on the mucosal surface of the nose and nasopharynx. High xylitol concentrations (12%) prevent microorganisms from adhering to the mucosal cells and the formation of biofilms, and have an antimicrobial effect on some pathogens as well.

Xylitol liquefies and facilitates the removal of mucus, retains moisture, whereby moisturizing and soothing irritated nasal mucosa, facilitating breathing and improving the quality of sleep in patients with acute and chronic infectious and allergic conditions of the nasal cavity, paranasal sinuses and nasopharynx. The presence of xylitol provides a sweet taste.

The concentrations of the medical device components ensure the hyperosmolarity of the solution, whereby removing excess moisture and eliminating mucosal swelling of the nasal passages and sinuses.

The components of the medical device do not react with the human body and are inert; they do not exert pharmacological, immunobiological and metabolic effects.

Non-sterile.

Intended use

SNOTTY is a spray for intranasal administration, that facilitates breathing by cleaning, liquefying and improving the secretion.

Indications

As an adjunct to the therapy for infectious and allergic conditions of the nasal cavity, paranasal sinuses and nasopharynx.

As a product that promotes the removal of nasal secretions and the elimination of nasal congestion in the case of difficult nasal breathing.

For daily nasal hygiene.

Contraindications

Hypersensitivity to any component of the medical device.

Target group (population)

Children ≥ 6 years old and adults.

Method of administration

Prior to the first use, remove the stopper from the vial.

Use twice daily, in the morning and in the evening. If needed, the dosage frequency can be increased.

The duration of use should be determined individually.

Children shall self-administer the product under the supervision of adults.

Method of administration for adults:

- 1) prior to procedure, wash your hands with soap and carefully free the nasal passages from secretions by quickly exhaling sharply through the nose, while blocking one nasal passage with a finger;
- 2) remove the protective cap from the vial, insert the tip into the nasal passage and perform 2–4 sprays (breathe through the mouth or hold the breath while inhaling); when spraying into the right nasal passage, the head should be thrown slightly back and tilted to the left, and vice versa, the head should be tilted to the right when spraying into the left nasal passage;
- 3) repeat for the other nasal passage;
- 4) clean the tip of the vial with a clean tissue and set the protective cap;
- 5) after spraying, it is advisable to stay in a supine position with a head thrown back for 2 minutes, then free the nasal passages from the liquefied secretions.

Method of administration for children:

- 1) prior to procedure, wash your hands with soap and carefully free the nasal passages of the child from secretions;
- 2) remove the protective cap from the vial, insert the tip into the nasal passage (be careful to avoid injury) and perform 2–4 sprays (breathe through the mouth or hold the breath while inhaling), when spraying into the right nasal passage, the head of the child should be thrown slightly back and tilted to the left, and vice versa, the head of the child should be tilted to the right when spraying into the left nasal passage;
- 3) repeat for the other nasal passage;
- 4) clean the tip of the vial with a clean tissue and set the protective cap;
- 5) after spraying, it is advisable for the child to stay in a supine position with a head thrown back for 2 minutes, then seat the child to keep his/her head straight and help free the nasal passages from the liquefied secretions.

Side effects

Hypersensitivity reactions, irritation or swelling of the nasal mucosa.

In the event of any adverse reactions, the medical device should be discontinued immediately and the physician and manufacturer informed.

Restrictions, precautions, and warnings

- Use SNOTTY as per the instructions for medical use. Do not use in a way other than that described in the instructions for use of medical device. If you have questions, consult your physician prior to use.
- Do not use the same vial for multiple patients. The use of one vial by more than one individual can cause the spread of infection.
- Do not use concurrently with other products for intranasal administration. If there is a need for intranasal use of another medical device or medicinal product, there should be an interval of at least 15 minutes between their administrations.

- Do not heat the vial. When stored in the refrigerator, if necessary, the device should be kept for 15 to 30 minutes at ambient temperature prior to use.
- Do not mix with any solutions, medicines, etc.
- There are no available clinical data on the efficacy and tolerability of medical device during pregnancy and breastfeeding. This patient population should consult a physician prior to use of medical device.
- The package of the medical device contains small plastic parts that can be swallowed by babies. To avoid the risk of aspiration, the medical device should be kept out of the reach of children.
- Prior to use, check the integrity of the package and the shelf life. Do not use the device, if the original packaging is damaged or if the shelf life has expired.
- Dispose in accordance with the local waste disposal requirements.

Incompatibility

No known.

Overdose

No cases of overdose have been reported.

Storage conditions

Store in the original container at $\leq 25^{\circ}\text{C}$, protected from light. Do not freeze. Keep out of reach of children.

Shelf life

3 years. Shelf life is valid while observing the storage conditions in an original container.

In-use shelf life: 6 months.

Name and address of the manufacturer

Yuria-Pharm LLC, 10, M. Amosova St., Kyiv, 03038, Ukraine.

Tel: +38 (044) 275-92-42, +38 (044) 275-01-08.

E-mail: uf@uf.ua

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Manufacturing site: 108, Kobzarska St., Cherkasy, 18030, Ukraine








Tel.: (044) 281-01-01.



If you have complaints on a medical device or you would like to leave feedback, please use one of the following ways:

- 1) send a message to feedback@uf.ua;
- 2) send a text message to +38 (095) 275-33-01 using the Viber, Telegram or WhatsApp applications;
- 3) call +38 (095) 275-33-01 (charging according to your operator's rates) or +38 (0800) 401-771 (free of charge from any number in Ukraine).

Graphical symbols and their interpretation	
	Manufacturer
	Date of manufacture

	Consult instructions for use
	Caution
batch 	Batch code
	Use-by date
	Do not use if package is damaged
	Upper limit of temperature
	Conformity mark to the technical regulations

Date of last revision of the instructions for use: May 31, 2023.

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