INSTRUCTIONS FOR USE
of medical device

Sterile solution for inhalation administration
OKISTAR Hyal 7%

Composition
4 ml of solution contains: sodium chloride – 70 mg/ml, hyaluronic acid – 1 mg/ml; water for injection.

Contents of packaging
4 ml in polymer container, 10 or 60 containers in a cardboard package.

Description
OKISTAR Hyal 7% is a sterile solution for inhalation administration facilitating breathing by liquefying the secretion and improving its discharge from the mucous membrane of the lower respiratory tract in patients with inflammatory respiratory diseases due to osmotic effect.

Mechanism of action
7% sodium chloride solution facilitates breathing due to the osmotic effect, helps to liquefy the secretion of the bronchial mucosa and to discharge it.
Hyaluronic acid is a natural component (polysaccharide) that performs a number of important biological functions in the body. Due to the hydrophilic properties of its molecule, hyaluronic acid provides a high degree of hydration in the mucous membranes of the respiratory tract, which in a combination with sodium chloride solution promotes moisturizing, creates conditions for improving mucociliary clearance. Furthermore, due to the high degree of the hyaluronic acid molecule hydration, a barrier is formed on the surface of the mucous membrane of the respiratory tract preventing the adhesion (sticking) of antigens (viruses, bacteria, allergens).
Inclusion of hyaluronic acid into the hypertonic saline solution reduces the occurrence of adverse reactions and improves the medical device tolerability while usage.

Intended purpose
OKISTAR Hyal 7% is indicated to facilitate the mobilisation of the viscous secretions in the airways.

Indications
Conditions in which viscous secretions occurs in the airways, such as:
- cystic fibrosis;
- bronchiectasis.

Contraindications
Individual hypersensitivity to the components of a medical device.

Target group (population)
OKISTAR Hyal 7% is intended for use in children and adults with the need to facilitate the mobilisation of the viscous secretions in the airways.

Method of use
The solution inhalation can be performed by means of nebulizer applying a special face mask, mouthpiece, pacifier mouthpiece or nasal cannula.
Familiarize yourself with the instructions for use of the nebulizer before the procedure. Follow the operating instructions for the nebulizer model you are using.

Administration in children (over 6 years old): the recommended dose is 1 to 4 ml of solution. The dose, duration and frequency of administration are prescribed by a doctor. Administration can be started with the minimal dose and if needed it may be increased.
Administration in adults (over 18 years old): use 1 container twice a day. If needed, the frequency of use can be increased up to 4 times a day.

Prepare the nebulizer for use.
1. Open the polymer bag and take the single-dose container out of it. Make sure the container is not damaged. Do not remove the container from the bag unless necessary.
2. Shake the removed container. Leave the other containers in the polymer bag and put them into the cardboard box.
3. Holding the container by its upper edge, rotate the other edge to open the container.
4. Insert the container into the nebulizer with the open edge down and give a slight press. Make sure that all the solution flew into the nebulizer.
5. Assemble the nebulizer and use it as intended.
6. After inhalation, it is required to rinse a mouth with water.
7. When using a face mask for inhalation, wipe the skin with a wet napkin to remove residual solution after the procedure.
8. Wash the nebulizer after usage, dispose the solution residues.

Adverse reactions
In persons with individual intolerance of the solution components, hypersensitivity reactions may occur. In individual cases, dizziness, hyperemia of mucous membrane, cough, bronchial spasm, throat irritation, nasal congestion, dry mouth, respiratory obstruction may appear.
In the event of any adverse reactions, the medical device should be discontinued immediately and the physician and manufacturer should be informed.

Limitations, precautions and warnings
- Solution is intended to be used only via inhalation.
- The first administration of a solution should be carried out under the care of a physician or qualified medical staff. Administration of solution by children should be performed under the supervision of adults.
- The safety of medical device application during pregnancy or lactation has not been studied, thus it is not recommended to use the device during pregnancy or lactation.
- Prior to application, verify the package integrity and check its shelf life. Do not use the device after the expiration date or if the package integrity is damaged.
- Do not mix with other solutions or medicinal products.
- For single use only. Repeated use can lead to infection. Do not re-use.
- Dispose according to the requirements of local disposal regulations.

Storage conditions
Store in a place protected from sunlight at a temperature of +5 °C to +30 °C. Keep out of the reach of children.

Shelf life
2 years. Shelf life is valid if the storage conditions are observed and the package is not damaged.

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ВІДДІЛ МЕДИКО-РЕГУЛЯТОРНОЇ АНАЛІТИКИ

Name and address of the manufacturer

Yuria-pharm LLC, 10, M. Amosova Str., Kyiv, Ukraine, 03038.
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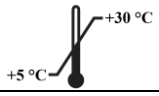
E-mail: uf@uf.ua
www.uf.ua
Manufacturing site address: 108, Kobzarska Str., Cherkasy, Ukraine, 18030.

If you have any comments on the medical device or would like to give us feedback, please use the following options to contact us:

1) email us at feedback@uf.ua;
2) send a text message via Viber, Telegram or WhatsApp to the number: +38 (095) 275-33-01;
3) call us at +38 (095) 275-33-01 or +38 (0800) 401-771 (charged in accordance with your operator's tariff plan).

Graphical symbols and their interpretation	
	Sterile medical device in primary packaging. Sterilized using steam or dry heat
	Do not re-use
	Consult instructions for use
	Manufacturer
	Temperature limit
	Date of manufacture
	Use-by date
	Batch code
	Mark of compliance with Directive 93/42/EEC on medical devices and the Notified Body number
	Authorized representative in the European Community
	Non-pyrogenic
	Do not use if package is damaged
	Do not resterilize

Date of last revision of instructions for use: 16.03.2023.
Version: 04.