

## INSTRUCTIONS FOR USE of medical device

### Sterile solution for inhalation and intranasal administration LORDE

#### Composition

4 ml of solution contains: sodium chloride – 30 mg/ml, water for injection.

#### Contents of packaging

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

#### Description

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

#### Intended purpose

LORDE is intended to reduce mucosal edema, to thin secretion and facilitate breathing.

#### Indications

Laryngitis and cystic fibrosis. It is also used in acute and chronic diseases of the nasal pharynx, nasal cavity and sinuses, adenoid hypertrophy in children, perennial and seasonal allergic rhinitis.

#### Contraindications

Individual hypersensitivity to the components of the device.

#### Target group (population)

Individuals who need to reduce mucosal edema, to thin secretion and facilitate breathing.

#### Method of use

##### Administration via inhaler

Familiarize yourself with the instructions for use of the inhaler before the procedure. Follow the operating instructions for the inhaler model you are using.

The solution inhalation can be performed by means of nebulizer applying a special face mask, mouthpiece, pacifier mouthpiece or nasal cannula.

*Administration in children (from birth):* use 1 to 4 ml of solution. The dose, duration and frequency of administration are prescribed by a doctor.

*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.

1. Prepare the nebulizer for use.
2. 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.
3. Shake the removed container. Leave the other containers in the polymer bag and put them into the cardboard box.
4. Holding the container by its upper edge, rotate the other edge to open the container.
5. 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.
6. Assemble the nebulizer and use it as intended.
7. Wash the nebulizer after usage, dispose the solution residues.



### Intranasal administration

Adults – 3 drops; children – 1–2 drops into each nasal passage 3–4 times a day.

*Adults.* Prior to the procedure, it is required to wash the hands with soap and release the nasal passages carefully from secretion with a rapid forceful exhalation through the nose. To prevent the solution outflow, it is required to lie down or sit down, throw back the head and then drip the solution. After drops instillation, it is advisable to stay in a supine position with a head thrown back for 2 minutes.

*Children.* Prior to procedure it is required to wash the hands with soap and release the nasal passages of child from secretion carefully. After cleaning the nose from secretion, put the drops into each nasal passage. While drops instillation into the right nostril, the child's head should be thrown back slightly and inclined leftward and vice versa, the child's head should be inclined rightward while drops instillation into the left nostril. After drops instillation, sit the child and clean the nasal passages from the liquefied mucosa.

### **Adverse reactions**

In persons with individual intolerance of the solution components hypersensitivity reactions may occur. In individual cases, hyperemia of the nasal mucosa, dizziness, cough or bronchial spasm may appear.

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

### **Limitations, precautions and warnings**

- Solution is intended to be used only via inhalation and intranasal administration.
- 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!
- 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.

### **Authorized representative in the European Community**

Diaco Biofarmaceutici S.R.L.

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### **Name and address of the manufacturer**

Yuria-pharm LLC, 10, M. Amosova Str., Kyiv, Ukraine, 01038.

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

E-mail: uf@uf.ua

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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).

<b>Graphical symbols and their interpretation</b>	
	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 re-sterilize

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