INSTRUCTIONS FOR USE
of medical device

Sterile solution for inhalation and intranasal administration
BREATHER TREAT

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

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

Description
BREATHER TREAT 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. The solution stimulates the protective properties of the upper respiratory tract mucous membranes due to the ability to actively liquefy and discharge of secretion formed during infectious and allergic diseases. It is used in a combined therapy of respiratory diseases, as well as using an inhalation system.

Intended purpose
BREATHER TREAT is intended to reduce rhinedema, to liquefy secretion and facilitate breathing.

Indications
Acute respiratory viral infections (ARVI), influenza, 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 is available.

Target group (population)
Individuals who need to reduce rhinedema, to liquefy secretion and facilitate breathing.

Method of use
Administration through the inhalation system
Solution inhalation can be carried out through the inhalation system applying a special face mask, mouthpiece, or nasal cannula.
Familiarize yourself with the instructions for use of the inhalation system before the procedure. Follow the operating instructions for the inhalation system model you are using.
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 inhalation system for use.
2. Open the foil bag and separate the single-dose container. Make sure the container is not damaged.
3. Shake the separated container. Leave the other containers in the foil bag and put them into the cardboard box. Do not remove the container from the bag unless necessary.
4. Holding the container by its upper edge, rotate the other edge to open the container.

5. Insert the container into the inhalation system with the open edge down and give a slight press. Make sure that all the solution flew into a tank of device.
6. Close the tank of inhalation system and use it as intended.
7. Wash the inhalation system after usage, dispose the solution residues.

Intranasal administration
Adults – 3 drops; children – 1–2 drops into each nasal passage 3–4 times a day.
Method of administration for adults: prior to 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. While drops instillation into the right nasal passage, the head should be thrown back slightly and inclined leftward and vice versa, the head should be inclined rightward while drops instillation into the left nasal passage. After drops instillation, it is advisable to stay in a supine position with a head thrown back for 2 minutes, then release the nasal passages from the liquefied secretion. Wipe the solution residues on the face with a napkin.
Method of administration for 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 nasal passage, 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 nasal passage. After drops instillation in children, it is advisable to stay in a supine position with a head thrown back for 2 minutes, then help the child to sit down and release the nasal passages from the liquefied secretion. Wipe the solution residues on the face with a napkin.

Adverse reactions
In persons with individual intolerance of the solution components, hypersensitivity reactions may occur. In individual cases, hyperemia of 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. Apply the device as per the instruction for medical use. Consult your physician before using if you have questions.
- 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 reach of children.

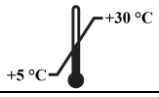
Shelf life
2 years. Shelf life is valid if the storage conditions are observed and the package is not damaged.

Authorized representative in the European Community
Diaco Biofarmaceutici S.R.L.
Via Flavia, 124, 34147, Trieste, Italy.
E-mail: info@diaco.it.
www.diaco.it

Name and address of the manufacturer
Yuria-pharm LLC, 10, M. Amosova Str., Kyiv, Ukraine, 03038.
Tel.: +38 (044) 275-92-42, +38 (044) 275-01-08.
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 use if package is damaged
	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

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