# Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

# **BABYAF SALINE NASAL DROPS**

# Active ingredient

sodium chloride 0.9% w/v

Inactive ingredients and allergens: See section 2 "Important information about some of this medicine's ingredients" and section 6 "Additional information".

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use the medicine according to the instructions in the section about dosage in this leaflet. Consult your pharmacist if you need further information. Contact your doctor if disease symptoms worsen or do not improve after 3 days.

# 1. What is this medicine intended for?

This medicine is intended to relieve nasal congestion in infants and small children.

## Therapeutic group: Nasal products

**Therapeutic activity:** Moisturizes the nasal mucosa and thus eases mucous exudation and nose blowing.

# 2. Before using this medicine

## Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

# Special warnings about using this medicine

## Before treatment with BABYAF SALINE NASAL DROPS, tell your doctor if:

You are suffering or have suffered in the past from impaired function of the heart and/or blood vessels, liver impairment or hypertension.

## Additional warnings:

Do not use this medicine frequently or for a prolonged period without consulting a doctor. If you are sensitive to any food or medicine, inform your doctor before taking this medicine.

Do not use this medicine if there is a change in the color of the solution or when it becomes cloudy.

## **Drug Interactions**

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

# 3. How to use this medicine?

# Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. The recommended dosage is usually:

1-2 drops in each nostril 3-4 times daily.

Do not exceed the recommended dose.

If there is no improvement in the child's condition within 3 days, consult your doctor.

Attention:

Do not swallow. This medicine is intended for external use only.

Ensure measuring the dose with a dropper.

Directions for use:

Blow the nose gently. Pull the child's head backwards, or lie him on the bed. Drip the drop/s into each nostril and keep his head tilted back for a few minutes to enable dispersion of the medicine throughout the nasal area.

To avoid spreading of the infection, do not use the same bottle for more than one person.

Do not exceed the recommended dose.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

# 4. Side effects

Like with all medicines, using BABYAF SALINE NASAL DROPS may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

## Side effects requiring special attention:

Hypertension (such as flushed face), rash or local inflammation (which did not exist before using the drug) - (rare): **stop the treatment and contact your doctor.** 

## Additional side effects

Rash, irritation or local burning.

# If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <u>https://sideeffects.health.gov.il</u>

# 5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package/bottle. The expiry date refers to the last day of that month.

#### Storage conditions

Store below 25°C. After first opening, can be used for 12 months.

# 6. Additional information

## In addition to the active ingredient, this medicine also contains:

benzalkonium chloride, purified water

## What the medicine looks like and contents of the pack:

A clear and colorless solution.

The pack contains one plastic bottle with a dropper, containing 10 ml solution.

#### Registration holder's and manufacturer's name and address:

Sam-On Ltd., 25 Ehud Kinnamon (Haavoda) St., Bat Yam 59602

Revised in 01/2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 58-90-27441