

**PATIENT LEAFLET IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

Af Tiponet Saline Solution For Babies Nasal Drops

Composition:

Sodium Chloride 0.9% w/v.

Inactive ingredients and allergens in the medicine – see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Use the medicine according to the instructions in section 3 – "How should you use the medicine?" in this leaflet.

Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 3 days.

1. What is the medicine intended for?

The medicine is intended for the relief of nasal congestion in children and infants.

Therapeutic class: nasal preparations

Therapeutic activity: moisturizes the nasal mucosa and thus eases mucus secretion and nose blowing.

2. Before using the medicine

Do not use this medicine if:

You or your child is sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 "Additional information").

Special warnings regarding the use of the medicine:

Before treatment with Af Tiponet Saline Solution For Babies, inform the doctor if:

You or your child suffers or has suffered in the past from impaired function of the heart and/or blood vessels, impaired liver function or hypertension.

Additional warnings:

Do not use this medicine frequently or for a prolonged period of time without consulting the doctor. If you or your child is sensitive to any type of food or medicine, inform the doctor before taking this medicine.

Do not use this medicine when 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 non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

Important information about some of the ingredients of the medicine:

The medicine contains benzalkonium chloride, which may cause intranasal irritation or swelling, especially if given for a prolonged period.

This medicine contains 0.01 ml of benzalkonium chloride in each 100 ml, a concentration equivalent to 0.0001 ml/ml.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The generally accepted dosage is:

2 drops in each nostril, 1-4 times a day.

Do not exceed the recommended dose.

If the condition is not improved within 3 days, refer to the doctor.

Method of administration:

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

Method of use:

- Blow the nose gently.
- Tilt the child's head backwards, or lay him down and tilt his head to the side.
- Drip the drops into each nostril and keep his head tilted for a few minutes to allow the medicine to disperse in the nasal cavity.

In order to avoid spreading the infection, the same bottle should not be used by more than one person.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Af Tiponet Saline Solution For Babies may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and refer to a doctor if one or more of the following rare side effects appear:

- Hypertension (such as redness in the face).
- Local rash or inflammation that was not present before using the preparation.

Additional side effects:

Local rash, irritation or burning.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store in a cool place, at a temperature below 25°C.
- The medicine can be used for up to one month after first opening the bottle, and no later than the expiry date that appears on the package.
- Do not use this medicine if there is a change in the color of the solution or if it becomes cloudy.

6. Additional information

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

Purified Water, Benzalkonium Chloride Solution.
What does the medicine look like and what are the contents of the package?

A bottle containing a clear and colorless solution.

Approved package sizes: 20 ml.

Manufacturer and license holder: Ben Shimon Floris Ltd., Industrial Park Misgav, D.N. Misgav 2017400, Israel.

This leaflet was revised in 09/2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

134-08-31368-00