PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed without a doctor's prescription

AF Tipa – Metered Dose Nasal Spray 0.5 mg/ml

The active ingredient and its concentration: Oxymetazoline hydrochloride at a concentration of 0.05%.

Inactive and allergenic ingredients: see "Important information about some of the ingredients of the medicine" and section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Use the preparation according to the instructions in the Dosage section in this leaflet. Consult a pharmacist if you need further information. Refer to the doctor if the symptoms worsen or do not improve after 3 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

For temporary relief of nasal congestion, resulting from a cold, sinusitis, hay fever or other allergies of the upper respiratory tract.

Therapeutic group: Sympathomimetics.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6).
- Do not use this medicine concomitantly with monoamine-oxidase inhibitors (MAOI – for treatment of Parkinson's disease and depression) or within 14 days after completing treatment with them. Medicines from this group may increase the hypertensive effect of oxymetazoline.
- You have narrow-angle glaucoma (high intraocular pressure).
- You have had your pituitary gland removed.
- You are suffering from inflamed skin or lining of the nose.
- You have acute coronary disease or left-sided heart failure, manifested by signs of asthma.

Before treatment with the medicine, consult the doctor if you are suffering or have suffered in the past:
- from impaired coronary arteries
- from hypertension
- from an overactive thyroid
- from diabetes
- from difficulty passing urine due to an enlarged prostate

Special warnings regarding use of the medicine:
- Prolonged use may cause nasal congestion. Use for more than one week is not recommended. Refer to a doctor if the symptoms worsen or do not improve after 3 days.

Children and adolescents
This medicine is not usually intended for infants and children below 6 years of age.

Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:
The hypertensive effect of oxymetazoline may increase when used together with: Certain types of antidepressants: tricyclic antidepressants, maprotiline, or monoamine-oxidase inhibitors (MAOI), or within 14 days of completing treatment with them.

Pregnancy, breastfeeding and fertility
Pregnancy
Oxymetazoline has not been associated with an adverse effect on pregnancy. It can be used by pregnant women if used as recommended. Exercise caution in patients with hypertension or with signs of reduced blood flow to the placenta. Frequent or prolonged use at high dosages may reduce blood flow to the placenta.
Breastfeeding
It is not known whether oxymetazoline is secreted into breast milk. Due to the lack of data on the use of oxymetazoline during breastfeeding, the medicine should not be used during breastfeeding.
Fertility
There is no information on the effect of the medicine on fertility in women or men.

Driving and operating machinery
No effect on the ability to drive or operate machinery has been observed.

Important information about some of the ingredients of the medicine
The medicine contains 0.059 mg of benzalkonium chloride in each spray dose, a quantity which is equivalent to 0.54 mg benzalkonium chloride per 1 ml.
Benzalkonium chloride (a preservative) may cause irritation or swelling in the nose, especially with prolonged use.
The medicine contains 0.272 mg benzyl alcohol in each spray dose, which is equivalent to 2.47 mg benzyl alcohol per 1 ml.
Benzyl alcohol may cause allergic reactions.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
Do not use the preparation for more than 3 consecutive days, unless prescribed by the doctor.
Refer to the doctor if the signs of the ailment (symptoms) worsen or do not improve after 3 consecutive days.
The usual dosage is generally:
2-3 sprays in each nostril, twice a day, in the morning and in the evening. The preparation works for up to 12 hours.
Do not exceed the recommended dose.
Shake well before use.
Instructions for use:
- Remove the plastic cover and spray twice in the air before the first use.
- Blow your nose gently. With your head upright, spray the medicine into each nostril (while simultaneously blocking the other nostril with a finger) as follows: breathe in a few short inhalations while rapidly and sharply squeezing the bottle, in accordance with the dosage. Wait 3-5 minutes. Gently blow your nose again and repeat the procedure if necessary.
- Rinse the tip of the spray bottle with hot water, but make sure that water is not drawn into the bottle. Dry with a clean paper tissue and close tightly.
- To avoid spreading infection, do not use the same bottle for more than one person.

Use the spray correctly. Consult a pharmacist if you need further information.
Do not swallow. For external use only.

If you took an overdose or if a child or anyone else has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the designated time, do not take a double dose to compensate for the forgotten dose.

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

4. SIDE EFFECTS

As with any medicine, use of AF Tipa may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Uncommon side effects – effects occurring in 1-10 in 1,000 users:
Sneezing, dryness or irritation in the nose, mouth or throat, nasal congestion (stuffy nose).

Rare side effects – effects occurring in 1-10 in 10,000 users:
Anxiety, fatigue, irritability, sleep disturbances in children, rapid, strong or irregular heartbeat (palpitations), raised blood pressure, swelling of the nasal lining, headache, nausea, flushing, rash, visual disturbances.

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

Reporting side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il
Additionally, side effects can be reported to Padagis via the following address:
Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- The medicine can be used up to the expiry date, even after opening.
- Store below 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Purified water, polyethylene glycol, povidone, carboxymethylcellulose sodium, microcrystalline cellulose, monobasic sodium phosphate, benzyl alcohol, dibasic sodium phosphate, benzalkonium chloride, edetate disodium.
- What the medicine looks like and the contents of the package: A 30 ml plastic bottle with a sprayer for multiple use.
- Registration holder: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Name of Manufacturer: Perrigo Company, Allegan, Michigan, USA.
- Revised in March 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 13133.31012.