

## **PACKAGE LEAFLET: Information for the user**

### **SINUS P**

Nasal spray, solution – 0.25 mg / ml

(Oxymetazoline hydrochloride)

**Read all this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if they have the same symptoms.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not included in this leaflet.

#### **What is in this leaflet:**

1. What Sinus P is and what it is used for
2. Before you use Sinus P
3. How to use Sinus P
4. Possible side effects
5. How to store Sinus P
6. Other information

#### **1. WHAT SINUS P IS AND WHAT IT IS USED FOR**

Sinus P belongs to a group of medicines called sympathomimetics. It contains the active substance oxymetazoline hydrochloride, which is a nasal decongestant and has adrenergic activity. It helps to open up the nasal passages by reducing the excessive nasal secretions and reducing the swollen blood vessels. It helps the child breathe more easily, opens the nasal and paranasal sinuses and Eustachian tube, and relieves the accompanying symptoms of the common cold. The effects start within minutes and last for up to 12 hours.

Oxymetazoline hydrochloride also has anti-inflammatory and antiviral effect on specific viruses that are often associated with respiratory problems.

Sinus P is used for:

- rhinitis associated with colds;
- allergic rhinitis;
- inflammation of the nasal sinuses;
- inflammation of the middle ear (otitis media).

## **2. BEFORE YOU USE SINUS P**

**Do not give your child Sinus P if:**

- he/she is allergic (hypersensitive) to oxymetazoline or to other ingredients of Sinus P (listed in section 6);
- he/she is taking monoamine oxidase inhibitors (MAOI) for the treatment of depression or has taken them in the last 14 days;
- he/she has a dry inflammation of the mucous membrane on the nose with scabs (atrophic inflammation on the lining of the nose, rhinitis sicca);
- he/she has had an operation to remove the pituitary gland or an operation on the nose or sinuses (transsphenoidal hypophysectomy);
- he/she has increased eye pressure (narrow angle glaucoma);
- he/she has cardiovascular diseases, suffers from chronic heart failure (cardiac asthma), ischemic heart disease.

**Take special care with Sinus P if your child:**

- has increased blood pressure (hypertension);
- has a heart rhythm disorder (arrhythmia);
- has congenital disorder of the enzyme in the biosynthesis of heme (porphyria);
- has diabetes mellitus;
- has increased activity of the thyroid gland (hyperthyroidism).

Talk to your doctor if your child suffers from one of these conditions. In these cases, this medicine should only be used under medical supervision.

Avoid frequent and prolonged uses of the medicine. It can lead to a rebound congestion.

This medicine should not be used in children younger than 2 years old.

Sinus P 0.25 mg / ml nasal spray, solution should be used in children from the age of 2 to 7 years old.

### **Taking other medicines**

Please tell your doctor or pharmacist if your child is taking / using or has recently taken / used any other medicines, including medicines obtained without a prescription.

These medicines include:

- tricyclic antidepressants or maprotiline (drugs used in the treatment of depression); in case of an overdose, absorption of oxymetazoline may increase the effect on blood pressure in patients who simultaneously take these medicines;
- mono amino oxidase inhibitors (MAOI) (drugs used in the treatment of depression); patients can experience hypertensive crisis [(high blood pressure, higher than 180/110 mm Hg), severe headache, chest pain, shortness of breath, swelling];
- beta blockers, methyldopa, or other antihypertensive drugs; their effect may be reduced;
- digoxin or digitoxin (used for heart failure); it can cause irregular heartbeat (dysrhythmias) if it is taken at the same time;
- bromocriptine and rasagiline (used in Parkinson's disease); it can affect the treatment if it is taken at the same time;
- ergotamine or methysergide; used for migraine relief;
- amphetamine-like psychostimulants; medicines or supplements to reduce appetite or make you more alert;
- thyroid hormones, e.g., levothyroxine.

Do not give your child other medicines for cough and cold while using Sinus P, without previous consultation with a doctor or pharmacist.

### **Driving and using machines**

The ability to drive and use machines should not be affected when used as directed in the recommended doses.

### **Important information on some of the excipients of Sinus P**

Sinus P contains benzalkonium chloride, which may cause irritation or swelling inside the nose, especially if used for a long time.

### **3. HOW TO USE SINUS P**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### **Do not exceed the recommended dosage and duration of therapy.**

The recommended dose is:

#### Children from 2 to 7 years:

Should use 1-2 inhalations of Sinus P 0.25 mg / ml in each nostril twice a day (not more often than every 10 – 12 hours); follow the recommended procedure for using the spray.

#### **Do not give your child more than two doses in 24 hours.**

#### This medicine should not be used in children younger than 2 years old.

In the treatment without medical supervision, this drug may only be used in recommended doses and not longer than 3 days.

If your child's condition does not improve or if it even worsens after 3 days since the beginning of treatment, consult a doctor. A doctor may prescribe a longer treatment.

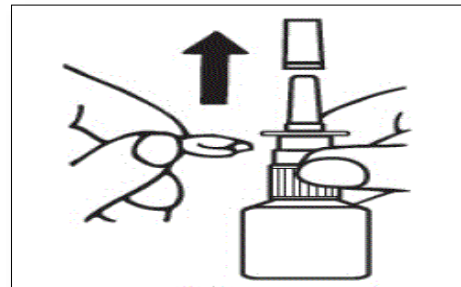
The nasal spray is intended only for one patient. Because of the danger of passing on the infection, it should not be used by more people. After use, wipe the applicator with a clean cloth.

### Instructions on how to use the spray:

1. Before using the medication, you should remove any existing nasal fluid by carefully blowing your child's nose. Clear the nose.



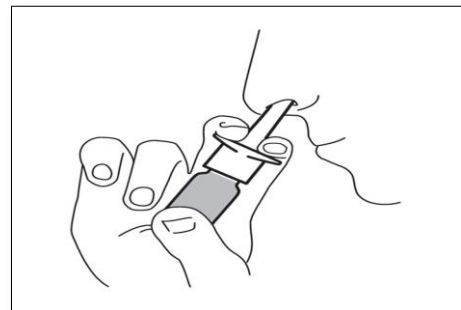
2. Remove the cap and the safety clip.



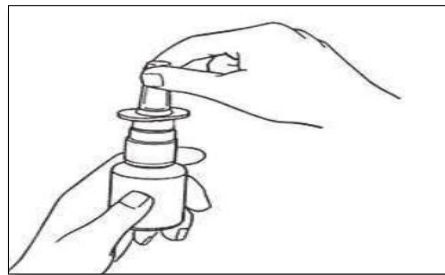
3. Hold the spray with your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle as shown in the diagram. If this is the first time that you are using this product or have not used it for some time, it is necessary to prime the sprayer. To do this, hold the container away from your body and press the sprayer several times until a fine liquid mist comes out.



4. Close one nostril of your child's nose and put the nozzle in the other nostril.
5. Ask your child to breathe in through the nose and while breathing in press down the mechanism with your fingers once to release the spray.
6. Repeat steps 4 and 5 with the other nostril.



7. After use, wipe the nozzle with a clean tissue or handkerchief and replace the cap.



### **If you use more Sinus P than you should**

In case of overdose or accidental swallowing of the medicine by your child, contact your doctor immediately so that you can be provided with immediate help.

The symptoms that you can expect are: burning sensation in the nose, dryness of mucus membrane of the nose and sneezing, insomnia, headache, narrowing of pupils, blood pressure disorder, increased heart rate (tachycardia) or slow heart rate (bradycardia), excessively low body temperature (hypothermia) and disturbances of consciousness. **Some of these symptoms are serious and may occur after taking a small dose of this medicine, so be very careful to keep it away from the reach of children.**

After a dose reduction, these symptoms usually disappear within 12 to 36 hours.

### **If you forget to give your child Sinus P**

If you forget to give your child one dose of Sinus P, give it as soon as you remember.

If it is almost time for the next dose, then skip the forgotten dose and give your child the subsequent dose at the usual time.

Do not use a double dose to make up for a forgotten dose.

### **If you stop using Sinus P**

Transient nasal congestion may occur in rare cases.

Talk to your doctor or pharmacist if you have any additional questions.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Sinus P can cause side effects, although not everybody gets them.

Side effects are listed below according to their frequency:

**Very common:** can affect more than 1 in 10 patients.

**Common:** can affect 1 to 10 patients among 100.

**Uncommon:** can affect 1 to 10 patients among 1,000.

**Rare:** can affect 1 to 10 patients among 10,000.

**Very rare:** can affect less than 1 patient among 10,000.

**Not known:** frequency cannot be estimated from the available data.

**If you notice any of the following side effects on your child, stop using Sinus P and contact your doctor:** high blood pressure (hypertension), unpleasant feelings of rapid or strong heartbeats, slow heartbeat, dizziness, nausea, headache, insomnia, irritability.

##### **Common side effects**

Irritation at the site of application, stinging, dryness and/or irritation of nasal mucosa, sneezing.

##### **Uncommon side effects**

Hypersensitivity reactions (angioedema, skin rash, itching), congestion, nose bleeding, high blood pressure (hypertension), unpleasant feelings of rapid or strong heartbeats (palpitations, tachycardia), slow heart rate (bradycardia).

##### **Rare side effects**

Irritability, insomnia, fatigue (drowsiness, sedation), headache, dizziness, arrhythmia.

##### **Very rare side effects**

Hallucinations, convulsions, apnea (babies and neonates).

##### **Unknown side effects**

Nausea, swelling of the mucous membrane of the nose (rhinitis medicamentosa).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE SINUS P**

Keep out of the reach and sight of children!

Do not store above 25°C.

Do not use Sinus P after the expiry date which is stated on the label.

## **6. OTHER INFORMATION**

**What Sinus P 0.25 mg / ml nasal spray, solution contains**

**The active substance** is oxymetazoline hydrochloride.

1 ml of solution contains 0.25 mg oxymetazoline hydrochloride.

1 spray (0.05 ml) of solution contains 0.0125 mg oxymetazoline hydrochloride.

**The excipients** are: sodium chloride, disodium hydrogen phosphate dihydrate, potassium phosphate monobasic, disodium edetate, propylene glycol, benzalkonium chloride, purified water.

### **Content of the pack**

Cardboard box with a plastic container with a mechanical sprayer, that contains 10 ml of solution.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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**This leaflet was last revised in January 2024.**