

PATIENT INFORMATION LEAFLET

respibien 0.5 mg/ml solution nasal spray **Oxymetazoline, hydrochloride**

Before you begin taking this medicine, read this entire leaflet carefully since it contains important information.

Follow the instructions contained in this leaflet. Always take this medicine precisely as prescribed by your doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- Talk to a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet?

1. What **respibien** is and what it is used for
2. What you need to know before you take **respibien**
3. How to take **respibien**
4. Possible side effects
5. How to store **respibien**
6. Contents of the package and other information

1. What respibien is and what it is used for

This medicinal product belongs to a group of medicines called sympathomimetics. It is a nasal decongestive medicine containing oxymetazoline as its active ingredient. When administered through the nose, oxymetazoline produces a local constriction of the blood vessels, decongesting the nasal mucous membrane.

It is recommended for the local and temporary relief of nasal congestion in adults, adolescents and children over the age of 6.

Talk to a doctor if your symptoms worsen or do not improve after 3 days.

2. What you need to know before you take respibien

Do not take respibien:

- if you are allergic to oxymetazoline, other nasal decongestants or any of the other excipients of this medicine (listed in Section 6).
- If you have recently had an operation on your head (if you have had any type of cranial, transnasal or transoral surgery).

Warnings and precautions

Talk to your doctor or pharmacist before taking **respibien** if:

- You are being treated with antidepressant medications, phenothiazine (a tranquilizer) or methyldopa (to lower blood pressure).
- If you suffer from or have suffered from (even if only once) any of the following diseases or symptoms:
 - o If you have high blood sugar levels (diabetes mellitus).
 - o If you have high blood pressure (arterial hypertension).

- If you have any disease of the heart or the circulatory system.
- If you have any prostate condition that makes it difficult to urinate (prostatic hypertrophy).
- If you have any thyroid condition (hyperthyroidism).
- If you have ever suffered from insomnia or vertigo when being treated with other sympathomimetics, such as those used, for example, to treat heart disease, hypotension (low blood pressure) or asthma, among others.

In rare cases, because its effects are temporary, with long-term use, oxymetazoline may increase nasal congestion instead of decreasing it; this is known as the rebound effect.

On rare occasions, insomnia may occur after taking this medication. If this occurs, avoid taking it in the evening or at night.

Do not exceed the dosage recommended in Section 3: How to take respibien.

To avoid contagion, the medication must not be used by more than one person and the applicator must be cleaned after every use with a clean, moist cloth.

Children

Not to be taken by children under 6 years of age.

Children may be especially prone to the occurrence of side effects from this medicine.

Other medicines and respibien

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This medicine must not be taken by patients who are taking or who have taken during the last 2 weeks: medicine used to treat depression (tricyclic antidepressants or monoamine oxidase inhibitors (MAOIs)), or a medication used to lower blood pressure called methyldopa.

It must also not be taken if being treated with phenothiazine (a tranquilizer) or any medication used to treat asthma.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, or if you believe that you might be pregnant or have the intention to become pregnant, please ask your doctor or pharmacist before taking any medicine.

This medicine must not be taken during pregnancy or while breast-feeding.

Driving and using machines

Although no side effects are expected in this regard, if you feel sleepy or dizzy, do not drive or operate tools or heavy machinery.

respibien contains benzalkonium chloride. This medicine can cause an inflammation of the nasal mucous membrane, especially with long-term treatment, due to the benzalkonium chloride in its formula. If you suspect you are having this reaction (persistent nasal congestion), whenever possible, you should take a nasal medication that does not contain this excipient.

3. How to take respibien

Follow the instructions contained in this leaflet. Always take this medicine exactly as prescribed by your doctor or pharmacist. Check with your doctor if you are not sure.

The recommended dose is:

Adults, adolescents and children over 6 years of age:

1 spray in each nostril, no more than 2 times in 24 hours.

This medication is taken nasally.

Before using this medication, you should remove any existing nasal fluids by carefully blowing your nose.

If this is the first time that you have taken this product or have not taken 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.

To avoid contagion, after each use and before closing the container, the end of the applicator must be cleaned with a clean, moist cloth. In addition, only one person may use each container.

If your condition worsens or does not improve after 3 days of treatment, cease the treatment and see your doctor.

Use in children

Not to be taken by children under 6 years of age.

Patients over 65 years of age

Please ask your doctor or **pharmacist**, as elderly patients are more sensitive to the **side effects of this medicine**.

If you take more respibien than you should

In the case of overdose or overly prolonged use, you may experience: headache, trembling, insomnia, excessive sweating, palpitations, tachycardia, increased blood pressure or sleep disorders.

In the case of overdose or accidental ingestion, see your doctor or pharmacist indicating the medicine and the amount ingested.

If you forget to take respibien

Do not take a double dose to make up for the forgotten doses.

If necessary, resume taking it as indicated in Section 3: How to take respibien.

4. Possible side effects

Like all medicines, **respibien** may have side effects, although not everyone suffers from them.

While taking oxymetazoline, the following side effects have been observed, the frequency of which has not been able to be determined with accuracy.

The most common side effects are:

Irritation at the site of application, dryness, itchy nasal mucous membranes and sneezing.

Rare side effects are:

Anxiety, restlessness, insomnia, hallucinations, trembling and sleep disorders in children. Tachycardia, palpitations, increased blood pressure. Headaches, nausea, rashes (redness of the skin).

Excessive or prolonged use of this medication may result in nasal congestion.

If you experience side effects, talk to your doctor or pharmacist, even if the side effects are not listed in this leaflet.

5. How to store respibien

Keep this medicine out of sight and reach of children.
Please do not store above 25°C.

Expiration date

Do not take **respibien** after the expiration date shown on the container, after the letters “EXP”. The expiration date is the last day of the month shown.

Medicines should not be disposed of via wastewater or household waste. If you have any questions, ask your pharmacist how to dispose of containers and medicines that you no longer need. This way, you will help protect the environment.

6. Contents of the package and additional information

What respibien contains

- The active ingredient is oxymetazoline hydrochloride. Each ml contains 0.5 mg (65 micrograms per spray) of oxymetazoline hydrochloride.
- Other ingredients are: benzalkonium chloride, glycine (E-640), povidone (E-1201), sorbitol (E-420) and purified water.

What the product looks like and contents of the package

respibien is a colourless or slightly yellow solution to be used as a nasal spray. It comes in 15 ml containers.

Marketing Authorisation Holder and Manufacturer

Laboratorios Cinfa, S.A.
C/ Olaz-Chipi 10- Polígono Industrial Areta.
31620 Huarte (Navarre) - Spain

This leaflet was last revised in: May 2012

Other sources of information

Detailed information about this medicinal product is available on the Spanish Agency of Medicines and Medical Devices (AEMPS): www.aemps.gob.es/