

Package leaflet: information for the user

respibien 0.5 mg/ml solution nasal spray

Oxymetazoline hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse 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 use respibien.
3. How to use respibien.
4. Possible side effects.
5. How to store respibien.
6. Contents of the pack and other information.

1. What respibien is and what it is used for

This medicine belongs to the group of medicines known as sympathomimetics. It is a nasal decongestant medicine which contains oxymetazoline as an active substance. Oxymetazoline administered via the nose causes local constriction of the blood vessels, decongesting the nasal mucosa.

It is indicated for local and temporary relief of nasal congestion in adults and children over 6 years of age. You must talk to a doctor if you do not feel better or if you feel worse after 3 days of treatment.

2. What you need to know before you take respibien

Do not use respibien:

- If you are allergic to oxymetazoline, to other nasal decongestants or any of the other ingredients of this medicine (listed in section 6).
- If you are taking monoamine oxidase inhibitors (MAO inhibitors, used for the treatment of Parkinson's disease and depression). MAO inhibitors may increase the hypertensive effects of oxymetazoline.
- If you have narrow-angle glaucoma.
- If you have recently undergone surgery of the head (if you have suffered any brain, transnasal or transoral surgical procedure).
- If you have inflammation of the skin and mucosa in your nasal vestibule and crusting in your nose (dry rhinitis).
- If you suffer from acute heart disease or cardiac asthma.
- If you have ever suffered from insomnia or vertigo when taking treatment with other sympathomimetic medicines, including, but not limited to any that are used to treat heart disease, hypotension (low blood pressure) or asthma.
- In children under 6 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking respibien if:

- you have or have had any of the following diseases or symptoms, even if they have only happened once:

- high blood sugar levels (diabetes mellitus).
- high blood pressure (arterial hypertension).
- any disease of the heart or the circulatory system.
- any prostate disease with difficulty urinating (prostatic hyperplasia).
- any thyroid disease (hyperthyroidism).

In rare cases, due to its temporary use and when it is used for a long time, oxymetazoline may increase rather than decrease nasal congestion. This is known as a rebound effect.

Rarely, insomnia may occur after using this medicine. If this happens, avoid taking it late in the evening or at night.

Do not exceed the dose recommended in section 3 *How to use respibien*.

To prevent spreading germs, the medicine should not be used by more than one person and the applicator should always be cleaned after each use with a clean, damp cloth.

Children

Do not use in children under 6 years of age.

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

Other medicines and respibien

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

This medicine should not be used by people who are taking or have taken any of the following in the last 2 weeks: medicines used to treat depression (tricyclic antidepressants, maprotiline or monoamine oxidase inhibitors [MAOIs]) or a medicine to lower blood pressure called methyldopa.

Also, you should not use it if you are on treatment with phenothiazine (tranquilizer) or medicines to treat asthma.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine should not be used during pregnancy or while breastfeeding.

Driving and using machines

Although no problems are expected in this regard, if you feel drowsy, do not drive or use dangerous machines or tools.

respibien contains benzalkonium chloride.

This medicinal product contains 0.2 mg of benzalkonium chloride in each ml.

Benzalkonium chloride may cause irritation or inflammation in the nose, especially when used for prolonged periods of treatment.

3. How to use respibien

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. If in doubt, ask your doctor or pharmacist.

The recommended dose is:

Adults and children over 6 years of age:

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

Use on children under 6 years of age: This medicine cannot be used in children under 6 years old (see section 2. Do not take respibien).

Older patients (over 65 years of age)

Talk to your doctor or pharmacist as older patients are more sensitive to the side effects of this medicine.

How to use

This medicine is for nasal use.

Before applying this medicine, you must eliminate existing nasal fluids by blowing your nose well.

If it is your first time using this product, or if you have not used it for some time, you will need to charge the spray pump. To do this, while holding the container away from your body, press the spray pump several times until a fine mist comes out.

To prevent spreading germs, after each use and before closing the container, clean the applicator tip with a clean, damp cloth. In addition, each container should only be used by 1 person.

If you do not feel better or if you feel worse after 3 days of treatment, stop this treatment and ask your doctor.

If you take more respibien than you should

Due to the application of excessive or very continued doses, or if the product is accidentally swallowed, you may notice: headaches, shaking, insomnia, excessive sweating, palpitations, tachycardia, increased blood pressure or sleep disorders.

In children, these effects can include: hallucinations, excitability, urticaria, nausea and vomiting, hysteria, sleepiness or drowsiness, abnormal gait, facial oedema.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

If you forget to take respibien

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

If necessary, take it again as indicated in section 3 *How to use respibien*.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During the period of use of oxymetazoline, the following side effects have been reported, although their frequency has not been clearly established.

The most common side effects are:

Stinging in the application site, dryness, sneezing and irritation of the nose, mouth and throat. Rare side effects are: Anxiety, restlessness, insomnia, hallucinations, tremors, fatigue, irritability and sleep disturbances in children. Tachycardia, palpitations, increased blood pressure. Headache, nausea, skin rash (redness of the skin), inflammation of the nasal mucosa and visual impairment.

Excessive or continuous use of this medicine may lead to rebound nasal congestion.

Reporting of side effects

If you experience any type of side effect, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store respibien

Keep this medicine out of the sight and reach of children.

Please do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. If in doubt, ask your pharmacist how to dispose of the medicines and containers that you no longer need. These measures will help protect the environment.

6. Contents of the pack and other information

What respibien contains

- The active substance is oxymetazoline hydrochloride. Each ml of solution for nasal spray contains 0.5 mg (65 micrograms per spray) of oxymetazoline hydrochloride.
- The 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 pack

respibien is a colourless or slightly yellowish nasal spray solution. It is supplied in 15 ml containers.

Marketing licence holder and manufacturer:

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta,
31620, Huarte (Navarra) - Spain

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