

PACKAGE LEAFLET: INFORMATION FOR THE USER

OPERIL

0,5 mg/ml nasal spray, solution

OXYMETAZOLINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What OPERIL is and what it is used for
2. Before you take OPERIL
3. How to take OPERIL
4. Possible side effects
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6. Further information

1. WHAT OPERIL IS AND WHAT IS IT USED FOR

OPERIL contains Oxymetazoline which is a nasal decongestant. The nasal decongestant in this product helps to open up the nasal passages by reducing the excessive nasal secretions and reducing the swollen blood vessels. It helps you 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 about 12 hours.

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

OPERIL is used for:

- Rhinitis associated with colds
- Allergic rhinitis
- Inflammation of the nasal sinuses
- Inflammation of the middle ear (otitis media)

2. BEFORE YOU TAKE OPERIL

Do not take OPERIL

- If you know your child is allergic (hypersensitive) to oxymetazoline or other ingredients of OPERIL (listed in section 6)
- If a child has a dry inflammation of mucous membrane of the nose with scabs (atrophic inflammation of the lining of the nose).

Take special care with OPERIL

- has chronic heart failure
 - has increased blood pressure (hypertension)
 - has a heart rhythm disorder (arrhythmia)
 - has increased eye pressure (narrow angle glaucoma)
 - has congenital disorder of the enzyme in the biosynthesis of heme (porphyria)
 - has diabetes
- has increased activity of the thyroid gland (hyperthyroidism).

In these cases, this medicine should only be used under medical supervision.

This medicine should not be used in children under two years.

Avoid frequent and prolonged use of the medicine.

Taking other medicines

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

If case of an overdose, absorption of oxymetazoline may increase the effect on blood pressure in patients who simultaneously take medicines for the treatment of depression (tricyclic antidepressants or maprotiline).

Patients who also receive MAO inhibitors for the treatment of depression can experience hypertensive crisis (high blood pressure (> 180/110 mm Hg), severe headache, chest pain, shortness of breath, swelling).

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take OPERIL Spray if you are pregnant, likely to get pregnant or are breast-feeding. There are no information on the effect of OPERIL on fertility in humans.

Driving and using machines

The studies about the effects on the ability to drive and use machines have not been conducted. In recommended doses Oxymetazoline should not affect the ability to drive and use machines.

Important information about certain ingredients of OPERIL

OPERIL contains benzalkonium chloride, which may cause skin reactions.

3. HOW TO USE OPERIL

OPERIL 0.5 mg / ml nasal spray, solution is intended only for adults and children older than 7 years. Children from 2 to 7 years should use Operil 0.25 mg / ml nasal spray, solution.

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

Check with your doctor or pharmacist if you are not sure.

Recommended dosage

Adults and children older than 7 years: 1-2 inhalations of OPERIL 0.5 mg / mL in each nostril two to three times a day; follow the recommended procedure for using the spray.

The maximum daily dose of OPERIL 0.5 mg / mL for each nostril should be 2 sprays three times a day.

In the treatment without medical supervision OPERIL may only be used in recommended doses and not longer than five to seven days.

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

To avoid possible spread of infection, this spray should be used by one person only. After use, wipe the nose with a clean handkerchief.

If you use more OPERIL than you should

In case of overdose or swallowing of the medicine, contact your doctor immediately so that you can be provided with immediate medical help. The symptoms that you can expect: burning sensation in the nose, dryness of mucous membrane of the nose and sneezing, insomnia, headaches, narrowing of pupils, disorders of blood pressure, increased heart rate (tachycardia) or slow heart rate (bradycardia), excessively low body temperature (hypothermia) and disturbances of consciousness. After a dose reduction this symptoms usually disappear within 12 to 36 hours.

If you forget to use OPERIL

If you miss a dose, take the next dose at the usual time and continue to use the medicine as instructed by a doctor.

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

If you stop using OPERIL

Transient nasal congestion.

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

How to use the spray:

1. Clear the nose.
2. Remove the cap.
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 below.
4. Close one nostril and put the nozzle in the other nostril. Tilt you head forward slightly and keep the spray upright.
5. Start to breathe in through your nose and while breathing in press down with your fingers once to release a spray.
6. Repeat Steps 4 and 5 with the other nostril.
7. Wipe the nozzle with a clean tissue or handkerchief and replace the cap.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **OPERIL** can cause side effects, although not everybody gets them. Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Uncommon side effects

High blood pressure (hypertension), unpleasant feelings of rapid or strong heartbeats or slow heart rate.

Rare side effects

Dizziness, headache, insomnia, irritability, in hypersensitive patients- transient dryness and burning sensation in the nose, dry mouth and throat, sneezing.

Unknown

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

If you notice any of the following side effects, stop using OPERIL and contact your doctor:

high blood pressure (hypertension)
unpleasant feelings of rapid or strong heartbeats
slow heart beat
dizziness
nausea
headache
insomnia
irritability

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 OPERIL

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use **OPERIL** after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What OPERIL contains

The active substance is oxymetazoline hydrochloride. 1 ml of solution contains 0.5 mg oxymetazoline hydrochloride, corresponding to 0.44 mg of oxymetazoline.

1 Spray (0.05 mL) of solution contains 0.025 mg of oxymetazoline hydrochloride.

Other ingredients: benzalkonium chloride, sodium hydroxide (for pH correction), sodium dihydrogen phosphate dihydrate (for pH correction), disodium hydrogen phosphate dihydrate (for pH correction), purified water.

What OPERIL looks like and contents of the pack

Operil 0.5 mg / ml nasal spray contains 10 ml of clear colorless solution. In the cardboard box there is a plastic container with a mechanical sprayer.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

LEK farmacevtska družba d. d., Verovškova 57, Ljubljana, R. Slovenia