

Package leaflet: Information for the user

Oxymetazoline Dr.Max 0.5 mg/ml nasal spray, solution 0.5 mg/ml nasal spray, solution

Oxymetazoline hydrochloride

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

Always use 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 get 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 Oxymetazoline Dr.Max is and what it is used for
2. What you need to know before you use Oxymetazoline Dr.Max
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1. What Oxymetazoline Dr.Max is and what it is used for

Oxymetazoline Dr.Max belongs to a group of medicines called sympathomimetics which acts producing local vasoconstriction and nasal decongestion.

This medicine is indicated for local and temporary relief of nasal congestion produced by rhinitis.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you use Oxymetazoline Dr.Max

Do not use Oxymetazoline Dr.Max

- if you are allergic to oxymetazoline or any of the other ingredients of this medicine (listed in section 6);
- if you are taking and have taken antidepressant drugs (depression treatment) in last 14 days;
- if you are using other sympathomimetic decongestants;
- if you have high fluid pressure inside the eye (narrow-angle glaucoma);
- if you have recently had neurosurgery (trans-sphenoidal hypophysectomy or other surgery exposing meninx);
- if you suffer from heart disease or circulatory system disease;
- if you have a dry inflammation of the nasal mucous membrane with formation of crusts (rhinitis sicca).

Do not use Oxymetazoline Dr.Max in children below 12 years.

Warnings and precautions

Talk to your doctor or pharmacist before using Oxymetazoline Dr.Max

- if you have high blood sugar levels (diabetes mellitus);
- if you have high blood pressure (arterial hypertension);
- if you suffer from prostatic disease (prostatic enlargement);
- if you suffer from thyroid disease (hyperthyroidism);
- if you have adrenal gland tumour (pheochromocytoma);
- if you are taking adrenergic bronchodilators (asthma treatment), phenothiazines (tranquillizers) or methyldopa (to lower the blood pressure);
- if insomnia occurs (very rare occasions), try to avoid applying the treatment late in the evening or during the night.

The use of the dispenser by more than one person may spread infection.

Children

Do not administer to children under the age of 12 years. Children could be especially prone to side effects.

Other medicines and Oxymetazoline Dr.Max

Tell your doctor or pharmacist if you are taking, have recently taken or used any other medicines. This includes medicines obtained without a prescription, homeopathic, medicinal plants and other products related with the health, as it could be necessary to interrupt the treatment or adjust the dose of some of them.

Some medicines could interact with Oxymetazoline Dr.Max, in this case it could be necessary to change the dose or interrupt the treatment. It is important to inform your doctor or pharmacist if you are taking any of the following medicines: antidepressants (monoamine oxidase inhibitors (MAOI) or tricyclic antidepressants), phenothiazines (tranquilizers), anti-asthmatics, antihypertensives or methyldopa (to lower the blood pressure), bromocriptine (for treatment of Parkinson's disease), cardiac glycosides (digoxin, to control heart rate), and ergot alkaloids (treatment of acute migraine headaches).

Pregnancy and breast-feeding

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

Pregnancy

Oxymetazoline products should not be used during pregnancy.

Breast-feeding

This medicine should not be taken whilst breast-feeding without asking the doctor, as it could pass to breast-milk.

Driving and using machines

Although effects are not expected, if you feel drowsiness or dizziness do not drive and use machines.

Oxymetazoline Dr.Max contains Benzalkonium chloride

Oxymetazoline Dr.Max contains benzalkoniumchloride which may cause bronchospasms (unexpected constrictions of the airways causing breathlessness).

3. How to use Oxymetazoline Dr.Max

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.

The recommended dose is one spray in each nostril, maximum 2 times per day.

Do not use for longer than 3 days without medical prescription.

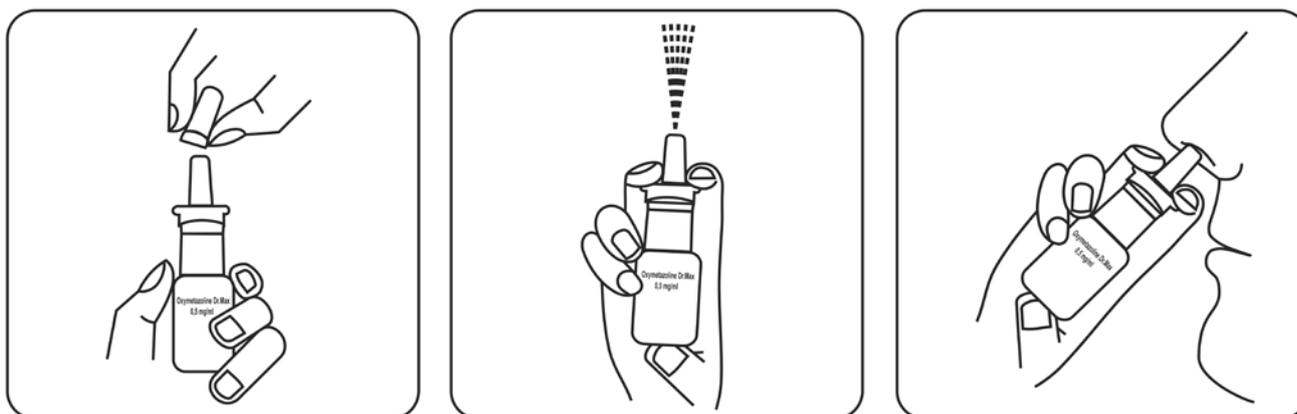
One nasal spray before going to bed will keep the nostrils clear during the entire night.

Use in children

Do not administer to children under the age of 12 years. Children could be especially prone to side effects.

Instructions for the correct medicine administration

Before using this product for the first time, it is necessary to load the spray. For this purpose, hold the bottle away from your body, push the spray several times pointing down until pulverised liquid comes out.



1. Remove the protection cap of the bottle.
2. Hold the bottle and put middle and index fingers in the upper zone and the thumb underneath
3. Aim the bottle into the nose and press.

Nasal fluids should be eliminated before the application by blowing the nose.

After each use and before closing the bottle, the applicator should be cleaned with a clean and damp cloth.

Inform your doctor or pharmacist if you feel that the effect of your medicine is too strong or too weak.

If you use more Oxymetazoline Dr.Max than you should

If excessive doses are applied or in case of continual use, or if Oxymetazoline Dr.Max is accidentally ingested orally, headache, shaking, sleep disorders, excessive sweating, palpitations and nervousness may occur. If this occurs, reduce the doses and ask your doctor or pharmacist if you are not sure about the correct dosage.

In the event of an overdose or accidental ingestion, you should inform your doctor, pharmacist or the nearest urgency service immediately.

If you forget to use Oxymetazoline Dr.Max

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

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.

- Common (*occurs in less than 1 in 10 patients*): stinging, dryness and/or irritation of nasal mucosa or sneezing. Excessive or continued use may cause nasal congestion due to a rebound effect.

- Rare (*occurs in less than 1 in 1 000 patients*): anxiety, fatigue, irritability, disturbed sleep in children, rapid heartbeat, palpitations, raised blood pressure, blocked nose, swelling of the nasal lining, headache, nausea, flushing, rash and visual disturbances.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#)*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxymetazoline Dr.Max

Do not store above 30 °C.

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

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Use within 30 days of first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxymetazoline Dr.Max contains

- The active substance is oxymetazoline hydrochloride 0.5 mg/ml.
- The other ingredients (excipients) are benzalkonium chloride, disodium phosphate anhydrous, sodium dihydrogen phosphate dihydrate, glycine, sorbitol, purified water.

What Oxymetazoline Dr.Max looks like and contents of the pack

Oxymetazoline Dr.Max is a solution for nasal use in plastic bottle with plastic spray pump and plastic cap. Each bottle contains 15 ml of solution.

Marketing Authorisation Holder and Manufacturer

Dr.Max Pharma Limited
First Floor Roxburghe House
273-287 Regent Street
London W1B 2HA
United Kingdom

Manufacturer

ITALFARMACO, S.A.
San Rafael, 3
28108 – Alcobendas
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	Oxymetazolin Dr.Max 0,5 mg/ml
Malta	Oxymetazoline Dr.Max 0.5 mg/ml nasal spray, solution
Poland	Oxymetazoline Dr.Max
Slovakia	Nazoxin

This leaflet was last approved in March 2015