

Package leaflet: Information for the patient
Otrivine-Antistin® Eye Drops,

Xylometazoline 0.05% w/v & Antazoline 0.5% w/v

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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, pharmacist or nurse 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, pharmacist or nurse. 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 2 days.

What is in this leaflet

1. What Otrivine-Antistin is and what it is used for
2. What you need to know before you use Otrivine-Antistin
3. How to use Otrivine-Antistin
4. Possible side effects
5. How to store Otrivine-Antistin
6. Contents of the pack and other information

1. What Otrivine-Antistin is and what it is used for

Otrivine-Antistin contains two active ingredients. Xylometazoline hydrochloride is a decongestant and antazoline sulphate is an anti-allergic agent.

Otrivine-Antistin helps to make your eyes feel more comfortable by relieving the redness and itching caused by allergies such as hay fever, or house dust allergy.

2. What you need to know before you use Otrivine-Antistin

Do not use Otrivine-Antistin:

- if you are allergic to xylometazoline hydrochloride or antazoline sulphate or any of the other ingredients of this medicine (listed in section 6)
- if you have a condition called narrow angle glaucoma
- if you wear contact lenses of any type
- if you are taking, or in the last 14 days have taken, one of a group of anti-depressant drugs called monoamineoxidase inhibitors.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Otrivine-Antistin:

- if you have high blood pressure, a heart condition (e.g. long QT syndrome), a thyroid problem or diabetes
- if you are pregnant or breast-feeding
- if you suffer from dry eyes
- if you have difficulty in urinating (passing water)
- if you have an adrenal tumour (phaeochromocytoma).

Children and adolescents

Do not give this medicine to children younger than 12 years of age due to possible systemic effects (see also **Otrivine-Antistin contains boric acid**).

Other medicines and Otrivine-Antistin

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Tell your doctor if you are taking any of the following:

- Any drugs which may cause drowsiness including some painkillers, sedatives, alcohol and antipsychotics
- Atropine and some antidepressants
- Digoxin and some other drugs used for high blood pressure or anxiety such as atenolol and propranolol
- If you are going to have an anaesthetic you should tell your doctor you are using Otrivine-Antistin.

Your doctor will know which medicines should be avoided whilst using Otrivine-Antistin.

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.

Driving and using machines

Some people may experience blurred vision after using Otrivine-Antistin. If you are affected, you should not drive or use machinery.

Otrivine-Antistin contains benzalkonium chloride

This medicine contains 2.8 micrograms benzalkonium chloride in each drop, which is equivalent to 0.1 mg/ml.

Benzalkonium chloride may cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

Otrivine-Antistin contains boric acid

Do not give to a child less than 2 years old as this medicine contains boron and may impair fertility in the future.

3. How to use Otrivine-Antistin

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

The recommended dose is:

Adults: One or two drops in each eye, two or three times each day.

Use in children and adolescents:

One drop in each eye, two or three times each day.

These drops should not be used in children under 12 years of age.

Elderly: One drop in each eye, two or three times each day.

Do not exceed stated dosage.

If your symptoms have not improved after 2 days you must go and see your doctor because Otrivine-Antistin might not be the right medicine for you. You may have an infection and need an antibiotic.

How to use your eye drops

1. Wash your hands
2. Remove the cap and hold the bottle between your thumb and forefinger
3. Tilt your head backwards
4. Rest one hand on your cheek and gently pull down your lower eyelid

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5. Look upward
6. Squeeze the bottle to release one or two drops into the eye
7. Close your eye for a short time
8. Repeat for the other eye

Note: Do not touch your eye or the surrounding area with the tip of the dropper. Follow the instructions carefully. If there is anything you do not understand, ask your pharmacist.

If you need to use more than one kind of eye drops wait 5 minutes between treatments.

Otrivine-Antistin should not be used for more than 7 consecutive days without talking to your doctor or pharmacist.

If you use more Otrivine-Antistin than you should

If you use Otrivine-Antistin for more than 7 days you may find that the itching, redness and/or swelling of the eyes or eyelids returns. Using too much Otrivine-Antistin, or using it for too long, or too often, can cause serious side effects, especially in children.

If you accidentally swallow the eye drops consult a doctor.

4. Possible side effects

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

Otrivine-Antistin is suitable for most people, but, like all medicines, it can sometimes cause side effects.

Uncommon ($\geq 1/1,000$ to $< 1/100$):

- Nosebleeds

Not Known (frequency cannot be estimated from the available data):

- Eye stinging
- Eye redness, blurred vision, headache, drowsiness, enlarged pupils
- Allergic reactions: rash, swelling, itching of the eye area, eye irritation
- Changes in heart beat rhythm, raised blood pressure, nausea, pallor, sweating

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via:

UK

The Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Otrivine-Antistin

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

Do not store above 25°C.

The drops are sterile until the seal on the bottle is broken. Do not use if the seal is broken when you receive the bottle. Take it back to the pharmacist.

Do not use the drops for longer than 28 days after first opening the bottle.

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

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 Otrivine-Antistin contains

- The active substances are xylometazoline hydrochloride (0.5 milligrams/ml) and antazoline sulphate (5 milligrams/ml).
- The other ingredients are benzalkonium chloride, boric acid, disodium edetate, sodium tetraborate and water for injections.

What Otrivine-Antistin looks like and contents of the pack

Otrivine-Antistin is a clear colourless solution. Each bottle contains 10 ml of eye drops.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Laboratoires THEA
12, rue Louis Blériot
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Manufacturer

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This leaflet was revised in 12/2021.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd in UK, telephone number 0345 521 1290, or THEA Pharma Ltd in IE, telephone number +44 (0)345 521 1290.

Otrivine-Antistin is a registered trade mark.