

Otrivine-Antistin® Eye Drops,

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

Patient Information Leaflet

Please read this leaflet carefully before you start to use the eye drops. It contains important information. Keep the leaflet in a safe place because you may want to read it again.

Do not share these eye drops with anyone else just in case you have an eye infection which you could pass on.

If you have any other questions, or if there is something you don't understand, please ask your pharmacist.

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.

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1. What Otrivine Antistin Eye Drops are and what they are used for

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

Otrivine Antistin Eye Drops 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. Things to consider before you start to use Otrivine Antistin

DO NOT use Otrivine Antistin if:

- you think you may be allergic to any of the ingredients of the eye drops (These are listed at the end of the leaflet.)
- you have a condition called narrow angle glaucoma
- you wear contact lenses of any type
- you are taking, or in the last 14 days have taken, one of a group of anti-depressant drugs called monoamineoxidase inhibitors.

You should also ask yourself these questions before starting to use Otrivine Antistin:

- Do you have high blood pressure, a heart condition, a thyroid problem or diabetes?
- Are you pregnant or breast-feeding?
- Do you suffer from dry eyes?
- Do you have difficulty in urinating (passing water)?
- Do you have an adrenal tumour (phaeochromocytoma)?

If the answer to any of these questions is YES, talk to the pharmacist because Otrivine Antistin might not be suitable for you.

Are you taking other medicines?

Some medicines can interfere with your treatment. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

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

Will there be any problems with driving or using machinery?

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

Other special warnings

The eye drops contain benzalkonium chloride as a preservative. This can sometimes irritate the eyes.

3. How to use Otrivine Antistin

The usual dosage is:

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

Elderly and children 12 years and over: One drop in each eye, two or three times each day.

These drops should not be used in children under 12.

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
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.

What if you use too much?

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

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

Sometimes people notice that the drops make their eyes sting.

Very occasionally people have noticed that their red eyes get worse, or that they have blurred vision, headache, drowsiness or enlarged pupils.

Allergic reactions have been reported causing rash, swelling and itching of the eye area and eye irritation.

Certain sensitive people have experienced changes in heart beat rhythm, raised blood pressure, sleeplessness, nausea, pallor and 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

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@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 all medicines out of the reach and sight of children.

Do not store the drops 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 the drops after the expiry date which is printed on the outside of the pack.

Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Further information

These eye drops contain 0.05% w/v xylometazoline hydrochloride and 0.5% w/v antazoline sulphate. They also contain the inactive ingredients benzalkonium chloride, boric acid, disodium edetate, sodium tetraborate and water for injections. Each bottle contains 10 ml of eye drops.

The product licence/authorisation holder is

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Otrivine Antistin Eye Drops are made by

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This leaflet was revised in April 2015.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at Spectrum THEA Pharmaceuticals Ltd, telephone number 0845 521 1290.

Otrivine Antistin is a registered trade mark.