

PACKAGE LEAFLET: INFORMATION FOR THE USER

ATROPINE 1.0 % w/v EYE DROPS, SOLUTION

atropine sulfate

Read all of this leaflet carefully before you start using 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. See section 4.
- In this leaflet Atropine 1.0 % w/v eye drops, solution will be called Atropine eye drops.

What is in this leaflet

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

1. WHAT ATROPINE EYE DROPS IS AND WHAT IT IS USED FOR

Atropine eye drops contain atropine sulfate which belongs to groups of medicines called mydriatics (medicines that widen the pupil) and cycloplegics (medicines used to relax the muscles which enable the eyes to focus).

Atropine eye drops are used to treat inflammation in the eye (uveitis or iritis) and before certain eye examinations.

This medicine is also used to diagnose eye problems such as blurred vision (refraction) in children below 6 years and children with cross eyes or squint (convergent strabismus).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ATROPINE EYE DROPS

Do not use Atropine eye drops:

- if you are allergic to atropine sulfate or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from increased pressure in the eye (closed angle or narrow angle glaucoma).

Warnings and precautions

Talk to your doctor or pharmacist before using Atropine eye drops if:

- you normally wear contact lenses (see Section 3 below: Precautions for use of Atropine eye drops)
- you are pregnant, trying to become pregnant or you are breast-feeding
- you have a high temperature (fever)

- you have dark coloured eyes, as it is more difficult to widen the pupils (care should be taken to avoid using more eye drops than you should)
- you suffer from any heart problems such as faster heart beat (tachycardia).

If the weather is very warm consult your doctor or pharmacist before using Atropine eye drops.

Eye tests

Your doctor may want to check your eyes before and during your therapy, particularly if you have had any eye disorders. If you have not had your eyes checked recently, tell your doctor.

Other medicines and Atropine eye drops

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

Other medicines may interfere with the actions of Atropine eye drops. Tell your doctor if you are using any of the following medicines:

- any other eye medicines, as they may delay the absorption of Atropine eye drops.
- muscle relaxants such as hyoscyamine as these may increase the effect of Atropine eye drops.

Pregnancy, breast-feeding and fertility

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

There are no human data on the effect of atropine sulfate on male or female fertility.

Driving and using machines

This medicine is used to widen pupils and can cause blurred vision. You should not drive or operate machinery until the effects of the drops have worn off.

Atropine eye drops contain benzalkonium chloride

This medicine contains 0.10 mg benzalkonium chloride in each ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also 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.

3. HOW TO USE ATROPINE EYE DROPS

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for:

Adults:

Inflammation of the eye (uveitis/iritis):

1 or 2 drops to be dropped into the eye(s), up to a maximum of 4 times daily.

Eye disorder which may cause blurred vision (refraction):

1 or 2 drops to be dropped into the eye(s) one hour before examination.

Elderly and patients with increased pressure in the eyes:

Discuss your treatment with your doctor or pharmacist.

Children:

Inflammation of the eye (uveitis/iritis):

1 drop to be dropped into each eye, up to a maximum of 3 times daily.

Eye disorder which may cause blurred vision (refraction):

1 drop to be dropped into each eye, twice daily for 1-3 days before examination.

Instructions for use

Atropine eye drops are only to be used in the eyes

- gently pull the lower eyelid downwards and outwards
- place one or two drops into the gap between the lid and the eye
- blink a few times
- take care not to touch the dropper nozzle on the eye lid or any other surface
- if applying the drops to your own eyes you are advised to use a mirror.

Precautions for use of Atropine eye drops

Atropine eye drops are for external use only.

Do not swallow.

- if you swallow Atropine eye drops tell your doctor or nearest hospital casualty unit **immediately**.
- **do not wear soft contact lenses** when using these drops. Remove soft contact lenses prior to application and wait at least 15 minutes before reinsertion.
- known to discolour soft contact lenses
- you should protect the eyes from bright light, particularly when pupils are widened (dilated)
- you should wash your hands after using the eye drops and care should be taken to avoid getting the product into the mouth
- Atropine eye drops should be discarded 4 weeks after first opening.

If you use more Atropine eye drops than you should

If you feel you may have used too much of your medicine contact your doctor or your nearest hospital casualty unit.

If you forget to use Atropine eye drops

Do not use a double dose to make up for the forgotten dose. Use the next dose at usual time.

If you stop using Atropine eye drops

Please speak to your doctor or pharmacist before stopping any medicine.

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.

Possible side effects include:

- an allergic reaction, the symptoms of which include skin rashes and red, swollen or watery eyes (pink eye, conjunctivitis). If these side effects occur **you should stop using** Atropine eye drops and speak to your doctor or pharmacist.

- increased sensitivity to light (photophobia). Eyes should be protected from bright light, particularly when pupils are widened (dilated).
- dry mouth
- difficulty in swallowing and talking
- flushing and a dry skin
- slower heart beat (bradycardia) followed by faster heart beat (tachycardia)
- feeling your heart beat (palpitations)
- irregular heart beat (arrhythmia)
- reduced lung fluids
- urgent desire to pass urine
- inability to pass urine
- constipation
- confusion (particularly in the elderly)
- feeling sick (nausea)
- being sick (vomiting)
- giddiness.

If Atropine eye drops are absorbed into your blood stream the following side effects may occur:

- difficulty in controlling movements (ataxia)
- restlessness
- excitement
- urgent desire to pass urine
- seeing or hearing things that are not real (hallucinations).

If you use Atropine eye drops for a long period of time you may experience:

- local irritation (itching around the eye)
- temporary stinging
- blood shot eyes (hyperaemia)
- swelling of eyelids (oedema)
- redness of eye (conjunctivitis)
- increase in pressure in eyes (glaucoma).

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ATROPINE EYE DROPS

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 carton label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

Do not use the eye drops more than four weeks after first opening the bottle.

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 Atropine eye drops contain

- The active substance is atropine sulfate. Each ml of eye drops solution contains 10 mg of atropine sulfate.
- The other ingredients are: benzalkonium chloride, hydrochloric acid, concentrated (for pH adjustment) and water for injections. See section 2, "Atropine eye drops contain benzalkonium chloride".

What Atropine eye drops look like and contents of the pack

Atropine eye drops are a clear, colourless solution. It is supplied in plastic bottle with a nozzle and tamper evident plastic screw cap. Each bottle contains 10 ml of this medicine.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 12/2023.