

**Package leaflet:
Information for the patient**

Atropine 1% 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.

What is in this leaflet

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

1. What Atropine is and what it is used for

Atropine sulfate 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). This medicine is used to treat inflammation in the eye (uveitis or iritis) and before certain eye examinations. It 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

Do not use Atropine:

- if you are allergic to atropine sulfate or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to a group of medicines called belladonna alkaloids (atropine belongs to this group).
- if you have or think you may have closed angle glaucoma (increased pressure in the eyes).

Warnings and precautions

Talk to your doctor or pharmacist before using Atropine.

Ask your doctor for advice before using Atropine because it may cause:

- Increased pressure in the eyes, especially if the space between the coloured part of your eye (iris) and clear layer at the front of the eye (cornea) is narrow or if the space between your iris and cornea is narrow angle (more closed). Ask your doctor if you are unsure. The pressure in your eyes should be measured regularly, including before start of treatment.
- Behavioural change, especially in elderly patients, but such a reaction may occur at any age.
- Sensitivity to light. You have to protect your eyes from light.

Talk to your doctor before using Atropine if you have a fever or if you are exposed to high ambient temperatures.

Children

- Talk to your doctor if Atropine is used in children. Serious adverse effects may occur in children, especially children who have a low body weight, Down Syndrome, spastic paralysis, epilepsy or brain disorders. See also 'How to use Atropine'.
- Children should be constantly monitored for at least 30 minutes after the use of this medicine.
- If Atropine drops outside of the eye, rinse the area immediately.

Other medicines and Atropine

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

In particular, tell your doctor if you are using any of the following:

- antihistamines (anti-allergy medicines)
- medicines used to treat depression

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.

Atropine must not be used during pregnancy unless your doctor has decided that it is required.

Atropine must not be used during breast-feeding.

Driving and using machines

This type of medicine may cause drowsiness, blurred vision and sensitivity to light. Do not drive or use tools or machines if you get any of these symptoms. Patients using Atropine should not drive or perform dangerous activities until their vision clears.

You should decide whether you are able to drive or perform activities that require attention and concentration. Some medicines can affect your ability to drive and use machines because of their effects or side effects. You will find a description of the effects and side effects in other sections of this leaflet. Read all the information in this leaflet carefully. If you are not sure, ask your doctor or pharmacist.

Atropine contains benzalkonium chloride

This medicine contains 0.105mg benzalkonium chloride in each ml of solution.

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 in 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

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):

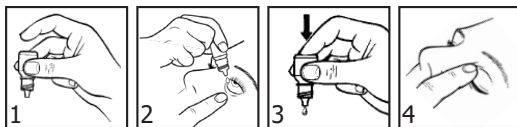
1 drop to be dropped into each eye, up to a maximum of 3 times daily.

Eye disorder which may cause blurred vision (refraction):

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

How to use Atropine

If the protective strip is broken when unscrewing the cap, remove it before using the medicine.



1. Wash your hands and sit in front of a mirror.
2. Unscrew the bottle cap.
3. Hold the bottle between the thumb and forefinger pointing it downwards (**Fig.1**).
4. Tilt your head back. Pull down the lower eyelid with a clean finger to form a "pocket" between the lower eyelid and the eye. The drop should fall into this place (**Fig.2**).
5. Place the tip of the bottle close to the eye. Use a mirror if it helps.

6. Avoid contact between the tip of the bottle and the eye or eyelid, adjacent area, or other surfaces. This can contaminate the solution in the bottle.
7. Do not squeeze the bottle. It is designed such that only a gentle press at the bottom is sufficient (**Fig.3**).
8. Press the bottom of the bottle gently to release a drop of Atropine.
9. After using Atropine, close the eyelid and gently press the inner corner of your eye with your finger for 2 minutes (**Fig.4**). This will prevent Atropine from reaching the body.
10. If you need to use Atropine for both eyes, repeat steps 5 to 10 for the other eye.
11. Screw the cap tightly after use.

If a drop falls outside the eye, immediately clean the area with lukewarm water and try again.

If you are using other drops or ointment, wait at least 5 minutes before using the next medicine. The eye ointments should be applied last.

If you use more Atropine than you should

If you have swallowed a large dose or if a child has swallowed the medicine by accident, contact your doctor, hospital or poison information centre for advice.

If you used more than the required dose of Atropine, rinse the eye with lukewarm water. Do not use the medicine until it is time for your next dose.

Possible symptoms of overdose are: redness and dryness of the skin (sometimes skin rash in children), visual disturbance, fast and irregular pulse, fever, abdominal swelling in infants, convulsions, hallucinations and loss of coordination.

If you forget to use Atropine

If it is time for your next dose, continue as per your regular dosing schedule. Do not use a double dose to make up for a forgotten dose.

If you stop using Atropine

Do not stop using this medicine even if your symptoms have disappeared. If you stop using it too soon, the symptoms may reoccur.

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.

Affecting the eyes

Common (may affect up to 1 in 10 people):

- photosensitivity
- eye pain
- visual disturbance

Rare (may affect up to 1 in 1,000 people):

- increased pressure in the eyes

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

- swelling of the eyelid
- blurred vision
- dilation of the pupils (prolonged effect of the drug)
- conjunctivitis
- redness of the eyes
- swelling of the eyes
- secretion of the eyes

Systemic reactions

Common (may affect up to 1 in 10 people):

- hallucinations
- confusion
- agitation
- increased heart rate
- constipation
- flushing
- fever

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

- allergy
- confusion
- dizziness
- headache
- coordination disorders
- slurred speech
- anxiety
- hyperactivity

- convulsions
- inability to recognize other people
- unusual drowsiness
- slow heart rhythm
- low blood pressure
- dilated blood vessels
- difficulty breathing
- intestinal obstruction
- bloating
- vomiting
- decreased intestinal motility
- inflammation or redness of the skin
- rashes
- difficulty urinating
- decreased secretion of salivary and sweat glands, pharynx, bronchi and nose.

Additional side effects in children

Children, especially those with low weight and central nervous system disorders (epilepsy, brain trauma or Down syndrome) are at increased risk of toxic effects. These may manifest as disorders of the central nervous system (similar to those mentioned above, e.g. slurred speech, anxiety, hallucinations, hyperactivity, confusion) and can lead to hyperpyrexia. Toxic effects can also manifest as disorders of heart, lung and gastrointestinal systems.

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 (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

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

This medicine does not require any special storage conditions.

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. Use within 28 days after first opening. Keep the bottle tightly closed.

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 contains

- The active substance is 10mg atropine sulfate.
- The other ingredients are: benzalkonium chloride, boric acid, hypromellose, hydrochloric acid and/or sodium hydroxide (for pH adjustment) and water for injections.

What Atropine looks like and contents of the pack

Atropine eye drops are presented in sterile white opaque LDPE bottles sealed with sterile LDPE applicator-droppers and sterile screw caps with a protective ring.

1 bottle of 5ml or 10ml, with a package leaflet per carton box.

Marketing Authorisation Holder

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