

PACKAGE LEAFLET: Information for the user

ATROPINE

Eye drops, solution – 1 %

(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

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2. What you need to know before you use Atropine
3. How to use Atropine
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1. WHAT ATROPINE IS AND WHAT IT IS USED FOR

Atropine belongs to a group of medicines called antimuscarinic drugs. These drugs cause mydriasis (widening of the eye pupil) and cycloplegia (relaxation of the muscles which enable the eye to focus).

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ATROPINE

Do not use Atropine if:

- you are sensitive (allergic) to atropine sulfate or to any of the excipients of this medicine, because allergic reactions may occur, including anaphylaxis;
- you suffer from narrow-angle glaucoma or other forms of glaucoma;
- you suffer from myasthenia gravis.

You should avoid the use of Atropine in children, especially in children with brain damage, spastic paralysis, or *Down* syndrome.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine if:

- you normally wear contact lenses, because atropine dries the eyes and makes contact lenses difficult to maintain; soft contact lenses must not be worn whilst using this medicine (see “Important information about some of the excipients of Atropine”);
- you are pregnant, trying to become pregnant or you are breast-feeding;
- you have a high temperature (fever);
- you have dark coloured eyes, because 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 your medicine.

Use Atropine carefully in the elderly, as they might be more vulnerable to the side effects of this medicine.

Other medicines and Atropine

Please contact your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines, including medicines obtained without a prescription.

The most clinically relevant interactions with other medicines are observed after systemic absorption of atropine.

It is especially important that your doctor be aware of the fact that you are treated with:

- other antimuscarinics (such as brompheniramine, chlorpheniramine, clemastine, dimenhydrinate, promethazine, thioridazine, amitriptyline, clomipramine, amoxapine,

- clozapine, disopyramide), which enhance the M-cholinolytic effects of atropine;
- cholinomimetic drugs and cholinesterase inhibitors, which antagonize atropine effects.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

Atropine crosses the placenta, but it is not known to be harmful. However, it is recommended to avoid use in pregnancy. (Category C)

Breastfeeding

Although atropine passes in small amounts in milk, it is recommended to avoid its use during breastfeeding.

Driving and using machines

This medicine can cause side effects such as blurred vision, dizziness and other effects that may impair your ability to drive a car or to operate machinery. Thus, you should avoid driving and using machines during treatment with Atropine.

Important information about some of the excipients of Atropine

This medicinal product contains 1 mg benzalkonium chloride / 10 ml. Benzalkonium chloride may be absorbed by soft contact lenses and may change their colour. 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

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

In iritis and uveitis:

For adults: 1 – 2 drops of 1% solution into the eye, 2 – 3 times daily.

For the production of mydriasis and cycloplegia:

For adults: 1 drop of 1% solution into the eye, 1 hour before the procedure.

You should avoid the use of Atropine in children, especially in children with brain damage, spastic paralysis, or *Down* syndrome.

The method of administration of Atropine – eye drops, solution 1% is:

- Wash well your hands.
- Do not touch the place of exit of the solution.
- Look up.
- Pull down your lower eyelid to form a pouch.
- Put the tip of the plastic vial close to your lower eyelid without touching it.
- Release the required number of drops into the pouch.
- Close your eye for about 2 minutes.
- Excess solution that emerges can be removed with a sterile gauze.

Eye drops can cause a burn sensation, but that feeling does not last more than a few minutes.

Otherwise consult your doctor or pharmacist.

If you use more Atropine than you should

If you use more Atropine than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital or call the emergency to get an opinion on the risk and advice on the actions that should be taken.

Side effects from overdose with Atropine – eye drops, solution 1% occur rarely.

However, the side effects that may occur as a result of overdose with Atropine include:

anticholinergic effects, cardiovascular disorders (tachycardia, atrial arrhythmia, atrio-ventricular disorders) and disorders in the central nervous system (confusion, anxiety, irritability, hallucinations and convulsions).

If you forget to use Atropine

If you forget to use a dose of Atropine, use it as soon as you remember. If it is almost time for the next dose, use it and pass the forgotten dose. Do not use an extra dose of Atropine to make up a forgotten dose.

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Atropine 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 this medicine and talk to your doctor or pharmacist;
- dilatation of eye pupil (mydriasis), visual disorders, paralysis of accommodation i.e. cycloplegia and increased intraocular pressure;
- contact dermatitis and eczematoid dermatitis;
- dry mouth, difficulty in swallowing and talking, thirst, reduced lung fluids;
- slower heart beat (bradycardia) followed by faster heart beat (tachycardia);
- feeling your heart beat (palpitations);
- also high fever, skin rash and dryness, urticaria, nausea and vomiting, confusion, tiredness, fatigue, drowsiness, hallucinations, arrhythmia etc.

Inform your doctor or pharmacist if you get these side effects or any other side effect not mentioned in this leaflet.

5. HOW TO STORE ATROPINE

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

Do not use Atropine after the expiry date which is stated on the label of the packaging.

Store in a dry place, below 25°C.

Do not freeze.

Keep in the original package to protect from light.

6. FURTHER INFORMATION

What Atropine contains

The active substance is atropine sulfate.

1 ml solution contains 10 mg atropine sulfate.

The excipients are benzalkonium chloride and water for injections.

Content of the Pack

Carton box containing one sterile plastic vial of 10 ml solution.

Marketing Authorisation Holder (MAH) and Manufacturer

PROFARMA sh.a.,

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Tirana, Albania.

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