

 PACKAGE LEAFLET:
Information for the patient

ATROPINE

Eye drops, solution – 1% – 10 ml
(Atropine sulphate)

Read this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet

1. What Atropine is and what it is used for
2. Before you use Atropine
3. How to use Atropine
4. Possible side effects
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6. Other information

1. WHAT ATROPINE IS AND WHAT IT IS USED FOR

Atropine is a belladonna alkaloid, the prototype of the antimuscarinics and selective competitive antagonist of M-cholinergic receptors.

It is a competitive antagonist of acetylcholine on postganglionic nerve ending, affecting endocrine glands receptors in the smooth muscles, cardiac muscles and the central nervous system.

Blocking of M receptors on iris circular muscles causes mydriasis, while blocking of M receptors on ciliary muscles causes cycloplegia. It is absorbed from mucous membranes, skin and eyes. Atropine is rapidly cleared from the blood and the half-life is about 4 hours. Atropine is metabolised in the liver and is excreted in the urine as unchanged drug and metabolites.

Atropine is used to produce mydriasis and cycloplegia for ophthalmic examination.

Atropine is also used in the treatment of iritis and uveitis.

2. BEFORE YOU USE ATROPINE

Do not use Atropine if you:

- are sensitive (allergic) to atropine or to any of the excipients of the drug, as the allergic reactions can occur including anaphylaxis;
 - suffer from narrow-angle glaucoma or other forms of glaucoma;
 - use contact lenses, because drying of eye secretions, makes difficult their maintenance;
 - suffer from myasthenia gravis;
 - have to drive a car or to use the machines, see section "Driving and using machines".
- You should avoid the use of Atropine in children,

especially in children with brain damage, spastic paralysis, or Down syndrome.

Take special care with Atropine if you:

- are taking other antimuscarinics;
- concurrently take cholinomimetic drugs and cholinesterase inhibitors, as these antagonize atropine effect;
- are pregnant or are planning to have a baby. Tell your doctor immediately if you become pregnant during treatment with atropine;
- are breastfeeding.

Taking other medicines

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

The more important clinically 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, thyridazine, amitriptyline, clomipramine, amoxapine, clozapine, disopyramide), which enhance the M - cholinolytic actions of atropine;
- cholinomimetic drugs and cholinesterase inhibitors, which antagonize atropine effect.

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

Atropine – eye drops, solution 1 % (ophthalmic preparation) can cause side effects such as blurred vision, dizziness and other effects that may impair your ability to drive a car or to use machines. Thus, you should avoid driving and using machines during treatment with Atropine.

Important information about some of the ingredients of Atropine:

Atropine - eye drops, solution 1% contains benzalkonium chloride which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.

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 bottle 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, solutions can cause any 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Side effects caused by atropine are mainly related to its pharmacological actions on muscarinic receptors and at high doses, on nicotinic receptors. These effects are dose-related and are usually reversible when therapy is stopped.

The most common side effects of Atropine - eye drops solution are:

- dilatation of eye pupil (mydriasis), visual disorder, paralysis of accommodation i.e. cycloplegia and increased intraocular pressure;

- contact dermatitis and eczematoid dermatitis;
- also high fever, skin rash, urticaria, vomiting, confusion, tiredness, fatigue, drowsiness, hallucinations, tachycardia, dry mouth, 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 out of the sight and reach of children.

Do not use Atropine after the expiry date which is stated on the package.

Keep in dry and cool places at a temperature not more than 25°C.

Do not refrigerate.

Keep in the original package to protect from light and humidity.

Shelf life after opening is 2 weeks.

6. OTHER INFORMATION

What Atropine contains:

The active substance is atropine sulphate.

1 ml solution contains 10 mg atropine sulphate.

Other ingredients: benzalkonium chloride, water for injections.

Contents of the pack

Carton box with sterile plastic bottle with 10 ml.

Explanatory of the illustration icons on the packaging:

 According to medical prescription.

 Content.

 Warning.

 Eye drops.

Marketing Authorisation Holder (MAH) and Manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel.Fax. 00355 42 362 800
Tirana - ALBANIA

This leaflet was last revised in July 2013.

PAY ATTENTION, all the layers are visible.

If you have to print this document please check or uncheck the specific layers.

SPECIFICATION



CROPPING AREA 12 x 19 cm