

atropocil®

Atropine sulfate 1%

10 mg/ml eye drops, solution

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

What is in this leaflet

1. What Atropocil is and what it is used for
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1. What Atropocil is and what it is used for

Atropocil has mydriatic and cycloplegic properties which are conferred by the presence in its composition of atropine sulfate at 10 mg/ml. Atropocil's mydriatic effect, being quite persistent, is recommended over the use of other mydriatics with faster action in cases of ocular inflammations, such as iritis and keratitis. Accommodation recovery can be reached quickly by using a miotic agent.

Atropocil eye drops solution is indicated as a mydriatic and cycloplegic agent, used in:

- Iritis;
- Iridocyclitis;
- Uveitis;
- Scleritis;
- As a preventive agent for postoperative inflammations in the iris and ciliary body;
- Some ocular exams.

2. What you need to know before you use Atropocil

Do not use Atropocil

- If you are allergic (hypersensitive) to atropine sulfate or to any of the other ingredients of this medicine (listed in section 6).
- If you suffer from ocular hypertonia and open angle glaucoma.

Warnings and precautions

Talk to your doctor or pharmacist before using Atropocil.

It is recommended caution in the use of Atropocil in:

- Patients with benign prostatic hyperplasia (BPH);
- Heart or coronary insufficiency;
- Ataxia;
- Cases of sensitivity to belladonna alkaloids;
- Paralytic ileus.

Atropine, as all parasympatholytic drugs, increases intraocular pressure. It is advisable to determine the intraocular pressure before using Atropocil.

Particular caution is recommended for the use in children and elderly, due to the risk of occurring systemic effects.

Other medicines and Atropocil

Since Atropocil may be absorbed systemically, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This medicine should not be used in association with other medicines containing mydriatic agents in their composition.

The effects of atropine and other antimuscarinics can be enhanced by concomitant use of other medicines with antimuscarinic properties such as amantadine, some antihistaminics, phenothiazine antipsychotics and tricyclic antidepressants.

Monoamine oxidase inhibitors (MAOI) may enhance the antimuscarinic effects of atropine, when it is absorbed systemically.

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.

Atropocil may be absorbed systemically, so it should only be used in pregnant women in cases of absolute need and under medical surveillance.

The use of Atropocil during breastfeeding is contraindicated.

Driving and using machines

The use of Atropocil can cause blurred vision (abnormal vision). In these cases, it is not advisable to drive or to use machines.

Atropocil contains benzalkonium chloride

Benzalkonium chloride may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses.

3. How to use Atropocil

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

Prolonged use of this medicine, without medical supervision, could be harmful to health.

Do not exceed the recommended dose.

Atropocil should only be used according to medical prescription and under medical surveillance.

The recommended dose is:

- 1 drop 2 to 3 times a day, 3 to 5 days before the exam or surgery.
- In case of funduscopy or angiography: 1 drop in two applications with a 30 minutes time gap between the applications.

Method of administration:

Remove the cap of the container and exert a slight pressure on it to release the liquid drop by drop at the recommended dose. Avoid the contact between the dropper container and the eye. There is a risk, particularly in children, of absorption of the compounds through the nasal mucosa, after being dragged by lachrymal secretion and drained through the lachrymal duct. Therefore, the corner of the eye should be pressed for a few minutes (2 to 3 minutes) after the application of eye drops solution on the conjunctiva.

Treatment duration:

The duration of the treatment should be determined by the ophthalmologist based on the patient's clinical condition.

Children:

This medicine should not be used in newborns and children up to 3 months of age.

Elderly and patients with renal or hepatic insufficiency:

There is no need for posologic adjustment.

Like with other eye drops, use Atropocil within up to 28 days, after first opening the bottle.

As an exclusive ophthalmological medicine, its dropper container cannot be used for other purposes.

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.

Symptoms that only require medical attention if they persist:

- Blurred vision, eye irritation not present prior to the application of the medicine, photophobia, palpebral swelling.

Symptoms that require medical attention (consequence of systemic absorption):

- Trembling, state of confusion, nervousness and unusual behaviour, dry skin, fever, face redness, swollen stomach in children, tachycardia, somnolence, tiredness or weakness, vertigo, xerostomia.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. how to store Atropocil

- Do not store above 25°C.
- Keep this medicine out of the sight and reach of children.
- Keep the dropper container tightly closed.
- Keep the dropper container in the outer carton, in order to protect from light and moisture.
- 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.

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 to protect the environment.

6. Contents of the pack and other information

What Atropocil contains

The active substance is atropine sulfate.

The other ingredients are monosodium phosphate, disodium phosphate, sodium chloride, benzalkonium chloride at 0.1 mg/ml, highly purified water, hydrochloric acid solution or sodium hydroxide solution (for pH adjustment).

What Atropocil looks like and contents of the pack

Atropocil is a sterile eye drops solution presented in a sterile dropper container with the capacity of 10 ml. The solution is clear and colourless.

Marketing Authorisation Holder and Manufacturer

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Portugal

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Minister,
Union of Arab Pharmacists