

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

lopidine 0.5% Ophthalmic solution

Active ingredient and quantity:

apraclonidine (as hydrochloride) 0.5%

1 ml of solution contains apraclonidine 5 mg

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

lopidine 0.5% is used as a short-term adjunctive therapy for chronic glaucoma in patients on maximally tolerated medical therapy who require additional intraocular pressure reduction to delay laser treatment or glaucoma surgery.

Therapeutic group: Antiglaucoma medicines and miotics

2. Before using this medicine

Do not use this medicine if:

- You are **sensitive (allergic)** to apraclonidine, clonidine or to any of the other ingredients in this medicine (see section 6 'Additional information').
- If you have a history of **severe** or unstable **heart disease** or **circulatory problems**.
- If you are taking monoamine oxidase inhibitors antidepressants or tricyclic antidepressants.
- If you are taking medicines of the class of sympathomimetics that are taken either orally or via injection.
- **In CHILDREN.**

Special warnings about using this medicine

Take special care:

- lopidine 0.5% is for ophthalmic use only.
- lopidine 0.5% may not continue to control your intraocular pressure after you have used it for a period of time. Your doctor will examine you often while you are using lopidine 0.5% to see whether the eye drops are still helping you.
- As lopidine 0.5% decreases the pressure in your eye(s), you should have your eye pressure checked regularly to ensure that the pressure in your eye(s) remains under control.

Before using lopidine 0.5%, tell your doctor if you have a **medical history of, or are taking medicine to treat**, any of the following conditions:

- Any **heart disease** (including angina, heart attacks or heart failure)

- **High blood pressure** or other **circulatory problems** (including stroke, Raynaud's disease and fainting spells)
- **Kidney or liver** problems
- **Depression**
- **Parkinson's** disease
- **Diabetes** or **low blood sugar** level. lopidine 0.5% may hide the signs and symptoms of a sudden reduction in blood sugar levels such as a fast heart beat or trembling
- You are due to have an **operation**

If any of these apply, you may still be able to use lopidine 0.5%, **but discuss it with your doctor first.**

Children and adolescents

This medicine is not intended for children and adolescents under the age of 18. There is no information about the safety and effectiveness of using this medicine in children and adolescents.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- **lopidine 0.5% must not be used** together with monoamine oxidase inhibitor (MAOI) antidepressants or tricyclic antidepressants. **lopidine 0.5%** must also not be used together with medicines of the class of sympathomimetics that are taken either orally or via injection.
- **lopidine 0.5% may increase the effect** of some medicines used to treat depression, asthma, high blood pressure, heart medicines containing digoxin or digitoxin, some forms of mental illness and Parkinson's disease.
- **lopidine 0.5% may interact with** certain pain killers, sedatives, anaesthetics, tricyclic antidepressants, phenothiazines, cough and cold medicines, glaucoma medicines such as timolol, brimonidine or dipivefrine, eye drops used to whiten the eye.

Using this medicine and alcohol consumption

Do not consume alcohol during treatment with lopidine 0.5% as it may increase the effects of the medicine.

Pregnancy and breast-feeding

lopidine 0.5% is not recommended during pregnancy.

Stop breast-feeding while using lopidine 0.5%.

If you are pregnant, think you may be pregnant, are planning to become pregnant or breast-feeding, **consult your doctor or pharmacist** before using this medicine.

Driving and using machines

You may **feel sleepy and dizzy** while using this type of medicine. If you do, **do not drive or operate machinery while using this medicine.**

Important information about some of this medicine's ingredients

This medicine contains benzalkonium chloride

This medicine contains 0.1 mg/ml of benzalkonium chloride which is equivalent to 0.01%.

Iopidine 0.5% contains a preservative (benzalkonium chloride) which may be absorbed by soft contact lenses and change their colour. You should remove contact lenses before using this medicine. 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, contact your doctor.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dose is usually:

1 drop into your eye(s), 3 times each day.

Do not exceed the recommended dose.

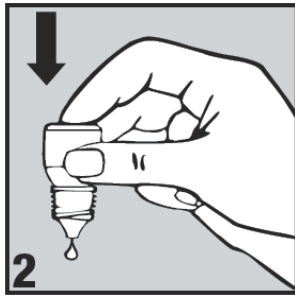
Do not swallow. This medicine is intended for external use, in the eyes only. Remove the loose collar from the cap when the bottle is first opened.

How to use:

- Wash your hands before use.
- Twist off the bottle cap.
- Hold the bottle pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a finger until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).

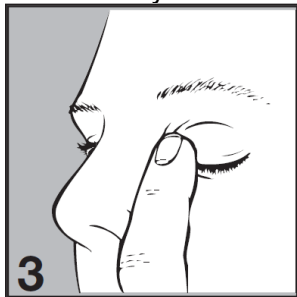


- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- **Do not touch your eye or eyelid**, surrounding areas or other surfaces with the dropper. It could infect the drops.
- **Gently press on the base** of the bottle to release one drop at a time (picture 2).



Do not squeeze the bottle, only a gentle press on the bottom is needed.

- After using lopidine 0.5%, press a finger into the corner of your eye, by the nose (picture 3). This helps to stop the medicine from being absorbed into the rest of the body.



- If you use drops in both eyes, repeat the steps for your other eye.
- Put the bottle cap firmly back on immediately after use.
- **If a drop misses your eye**, try again.
- **If lopidine 0.5% is swallowed**, see your doctor immediately.

If you are using other eye drops or eye ointment, leave at least 5 minutes between each medicine. Eye ointment should be applied last.

If you have accidentally taken a higher dose

Rinse the eye(s) with lukewarm water. Do not put in any more drops until it is time for your next dose.

In case of accidental ingestion, symptoms of overdose may include decreased blood pressure, drowsiness, decreased heart rate, hypoventilation (reduced rate and depth of breathing), and convulsions.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

Continue with the next dose as planned. However, if it is almost time for your next dose, skip the missed dose and take the next dose at the regular time. **Do not take a double dose to make up for the forgotten dose.**

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using lopidine 0.5% may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Discontinue use and contact your doctor immediately
If your vision gets worse straight after using lopidine 0.5%.

Contact your doctor immediately

lopidine 0.5% can cause allergic reactions in the eye. If you experience one or more of the **following eye symptoms** - redness, itching, discomfort, watery eyes, abnormal sensation, eye and eyelid swelling, poor vision, **contact your doctor immediately**.

Additional side effects

Very common side effects - affect more than one in ten users:

Effects in your eyes: Increased redness, itching, inflammation.

Common side effects - affect 1-10 in 100 users:

Effects in your eyes: discomfort, watery eyes, swelling of the eyelid, gritty feeling in the eye, dry eye, eyelid crusting.

General effects (in other areas of your body that are not your eye): dry mouth, inflammation inside the nose, dermatitis (inflammation of the skin), dry nose, weakness, headache, unusual taste.

Uncommon side effects – affect 1-10 in 1000 users:

Effects in your eyes: bumps under the eyelids, swelling of the eye, abnormal vision, pain, inflammation and irritation of the eye or eyelids, corneal (the front part of your eye) surface damage, sensitivity to light, redness of the eyelid, raising or pulling up of the eyelids, enlarged pupil, reduced vision, blurred vision, drooping of eyelid, discharge or whitening of the eye.

General effects: chest pain, swelling of your hands, feet or extremities, irregular heartbeat, constipation, nausea, feeling tired, sore throat, runny nose, muscle aches, poor coordination, sleepiness, dizziness, tingling feeling, nervousness, depression, difficulty sleeping, shortness of breath or difficulty breathing, changes in sense of smell, facial swelling, irritability, widening of blood vessels.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the carton/label. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C.
- Do not keep in the refrigerator or freezer.
- Keep the bottle tightly closed in the outer carton.
- **To prevent infection, use up to 28 days after the first opening of the bottle.**

6. Additional information

In addition to the active ingredient, this medicine also contains:

sodium chloride, sodium acetate (trihydrate), benzalkonium chloride, hydrochloric acid and/or sodium hydroxide, purified water.

What the medicine looks like and contents of the pack:

A clear, colourless to pale yellow solution supplied in a 5 ml plastic bottle with a screw cap.

Registration holder's name and address:

Truemed Ltd., 10 Beni Gaon St., Poleg Industrial Park, P.O.Box 8105, Netanya 4250499

Manufacturer's name and address:

Essential Pharma Switzerland GmbH
Landis + Gyr-Strasse 1 c/o LacMont AG,
6300 Zug, Switzerland

Revised in July 2025

Registration number of the medicine in the Ministry of Health's National Drug Registry: 068-60-28209

PL-1077 01-12.24