

PACKAGE LEAFLET – INFORMATION FOR THE USER
IOPIDINE® 5mg/ml EYE DROPS
(apraclonidine hydrochloride)

This product is available as the above name but will be referred to as lopidine throughout the remainder of this leaflet.

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 your pharmacist.
- This medicine has been prescribed for you. **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 lopidine is and what it is used for
2. What you need to know before you use lopidine
3. How to use lopidine
4. Possible side effects
5. How to store lopidine
6. Contents of the pack and other information

1. WHAT IOPIDINE IS AND WHAT IT IS USED FOR

lopidine contain apraclonidine (as hydrochloride) as the active substance.

lopidine belongs to a group of medicines known as alpha agonists.

It is used in the treatment of chronic glaucoma in people who are already receiving other medicines to treat this disease.

In these people, lopidine helps to reduce the fluid pressure in the eye and can delay the need for pressure relieving eye surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE IOPIDINE

Do not use lopidine:

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

Ask your doctor for advice.

Warnings and precautions

Take special care:

- Only use lopidine for dropping in your eye(s).
- lopidine may not continue to control your eye pressure after you have used them for a period of time. Your doctor will examine you often while you are using lopidine to see whether the eye drops are still working for you.
- As lopidine 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.

If you **have a history** of, or are **taking medicine to treat**, any of the following:

- 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.** lopidine may hide the signs and symptoms of a sudden reduction in blood sugar such as a fast heart beat or trembling.
- If you are due to have an **operation**.

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

Using lopidine with food, drink and alcohol

No alcohol should be consumed during treatment with lopidine as it can increase its effects.

Other medicines and lopidine

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. **lopidine must not be used** if you are taking monoamine oxidase inhibitor antidepressants or tricyclic antidepressants. lopidine must also not be used if you are taking medicines of the class of sympathomimetics that are taken either orally or via injection. **lopidine may increase the effects** 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; and **may interact with** - some pain killers - sedatives - anaesthetic - tricyclic antidepressants - phenothiazines - cough and cold remedies - glaucoma medications such as timolol, brimonidine or dipivefrine - eye drops used to whiten the eye.

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** before taking this medicine.

lopidine should not be used during pregnancy or breast-feeding.

Driving and using machines

This type of medicine may cause you to **feel sleepy and dizzy**. If you do, you should **not drive or operate machinery**.

Important information if you wear Contact Lenses

lopidine contains benzalkonium chloride

This medicine contains 0.1 mg of benzalkonium chloride in each ml of the product which is equivalent to 0.01%.

IOPIDINE contains a preservative (benzalkonium chloride) which 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 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.

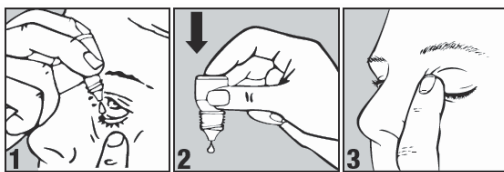
3. HOW TO USE IOPIDINE

The recommended dose

The recommended dose is 1 drop into your eye(s), 3 times each day.

Remove the loose collar from the cap when the bottle is first opened.

Always use lopidine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.



How to use

- Wash your hands before you start.
- 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, press a finger into the corner of your eye, by the nose (picture 3). This helps to stop lopidine getting 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 is swallowed**, see your doctor immediately.
- **If you forget to use lopidine**
- Continue with the next dose as planned. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- **Do not take a double dose to make up for a forgotten dose.**
- **If you use more lopidine than you should** rinse it all out with warm water. Do not put in any more drops until it is time for your next regular 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 convulsion.

If you are using other eye drop or eye ointment medicines

Leave at least 5 minutes between each medicine. Eye ointments should be administered last.

If you have any further questions on the use of lopidine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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

If your vision gets worse straight after using lopidine, **stop use** and **see your doctor immediately.**

- **You may experience some or all of the following effects in your eye(s):**

Very Common (may affect more than 1 in 10 people):
increased redness - itching - inflammation.

Common (may affect upto 1 in 10 people):

discomfort - watery eyes – swelling of the eyelids - gritty feeling in the eye – dry eye – eyelid crusting.

Uncommon (may affect upto 1 in 100 people):

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 – increase in pupil size – reduced vision – blurred vision – drooping of eyelid – discharge or whitening of the eye.

- **You may also experience effects in other areas of your body including:**

Common (may affect upto 1 in 10 people): dry mouth – inflammation inside the nose – dermatitis - dry nose - weakness - headache - unusual taste.

Uncommon (may affect upto 1 in 100 people): chest pain – swelling of your hands, feet or extremities - irregular heart beat - 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 - unusual sense of smell – facial swelling – irritability – widening of blood vessels.

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 at: 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 IOPIDINE

- **Keep out of the sight and reach of children.**
- Do not use after the expiry date printed on the bottle or carton label. The expiry date refers to the last day of the month.
- Do not store above 25°C. Do not refrigerate or freeze. Protect from light. Keep the container in the outer carton. Discard contents 28 days after first opening.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- If the solution becomes discoloured or show any other signs of deterioration, you should ask your doctor or pharmacist who will advise you what to do.
- **Do not pass this medicine on to others.** It may harm them, even if their symptoms are the same as yours.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Each ml of eye drops, solution contains 5mg apraclonidine (as hydrochloride).

The drops are clear colourless to pale yellow solution in a plastic dropper bottle containing 5ml.

lopidine also contain the following inactive ingredients:

benzalkonium chloride 0.1 mg/ml as a preservative, sodium acetate, sodium chloride, and purified water. Very small amounts of hydrochloric acid and/or sodium hydroxide may have been added to regulate the acidity/alkalinity of the product to ensure comfort in the eye.

POM

PLGB: 15814/1409

Manufactured by Essential Pharma Limited, Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara, CBD 1070, Malta.

Procured from within the EU and repackaged by the Product Licence holder: O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.

Leaflet revision and issue date (Ref.) 04.06.2024

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