

Package Leaflet : Information for the User

IOPIDINE 1%w/v eye drops solution (Apraclonidine Hydrochloride)

Read all of 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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IOPIDINE eye drops will be put in by your doctor. This leaflet is provided to give you information on your medicine.

1. What IOPIDINE is and what it is used for

IOPIDINE eye drops contain apraclonidine which is used to control or prevent the pressure in the eye increasing after laser surgery.

2. Before you are given IOPIDINE

This medicine may not be suitable for you. If it is not suitable your doctor may want to give you another medicine so it is important you check all of the points below:

IOPIDINE will not be used

- * in children (this medicine is not for anyone under the age of 18);
- ** If you are **allergic** to clonidine, apraclonidine or any of the ingredients listed in the “**Other ingredients**” section of this leaflet (section 6)
- * if you have a history of any severe or unstable and uncontrolled heart disease (including chest pain, angina, heart attacks or heart failure);
- * if you are currently taking monoamine oxidase inhibitor antidepressants

If you think any of the above conditions apply to you or if you are not sure, talk to your doctor first.

Special care will be taken using IOPIDINE.

Ask your doctor for advice if:

- * **you suffer from, or are taking medication for:**
 - heart disease (including chest pain, angina, heart attacks or heart failure);
 - high blood pressure;
 - circulatory problems (including stroke, Raynaud’s disease or Buerger’s disease);
 - vasovagal attacks (fainting spells);
 - reduced kidney or liver function;

If any of the above apply to you, you may be at greater risk for effects on your heart or circulatory system so your blood pressure and heart rate will be closely monitored.

- * **you suffer from depression**, as medicines like clonidine have been associated with depression;
- * **you suffer from diabetes** or low blood sugar, as this medicine may hide the signs and symptoms of a sudden reduction in blood sugar such as a fast heartbeat or trembling;
- * **you regularly drink alcohol**, as IOPIDINE may increase its effect;
- * **you have had an extreme response to other medicines** that lower the pressure inside your eye, so your eye pressure should be monitored closely;

If any of the above applies to you, or if you are not sure, talk to your doctor first.

Using other medicines

IOPIDINE will not be used

- * **if you are taking monoamine oxidase inhibitors (used to treat depression)** e.g. phenelzine, isocarboxazid, tranlycypromine, moclobemide
- * **if you are taking tricyclic antidepressants (often used to treat depression)** e.g. amitriptyline, imipramine, doxepin, mianserin, trazodone, dosulepin, lofepramine;
- * **if you are currently using medicines containing sympathomimetic agents.**

These agents are used to treat many diseases, including asthma e.g. salbutamol, terbutaline, bambuterol, Parkinson's disease and heart disease and also may be present in cough and cold remedies.

Special care will be taken using IOPIDINE

- * **if you are using eye drops to treat glaucoma** which contain sympathomimetics e.g. phenylephrine, brimonidine, dipivefrine as your blood pressure may increase; or
- * **if you are taking sleeping tablets, sedatives or painkillers**, as IOPIDINE may increase their effects;
- * **if you are taking or have taken neuroleptics** (major tranquillisers used to treat some forms of mental illness e.g. chlorpromazine, flupentixol, haloperidol) as your blood pressure could become too low;

When there might be effects on your blood pressure then your blood pressure and heart rate will be closely monitored.

Discuss any medicines you are taking with your doctor before you are given IOPIDINE, including medicines obtained without a prescription.

Using IOPIDINE with food and drink

IOPIDINE should be used with caution if you regularly drink alcohol or have recently drunk alcohol.

Use during pregnancy and breastfeeding

Iopidine should not be used if you are pregnant, planning to become pregnant or are breastfeeding,

Your doctor should have discussed this with you. If not, ask your doctor for advice before taking any medicine.

Driving and using machines

This type of medicine may cause you to feel sleepy. If you are affected, do not drive or use any tools or machines.

3. How IOPIDINE is given to you

Adults and elderly

IOPIDINE comes in a specially designed container which can be used only once. Your doctor will put in one drop 1 hour before your laser surgery and another drop immediately after surgery.

After being given IOPIDINE, you will be instructed to press a finger to the corner of your eye, by your nose. This helps to stop IOPIDINE getting into the rest of the body.

If more than one ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

Children

This medicine is not for use in children.

4. Possible side effects

Like all medicines, IOPIDINE can have side effects, although not everybody gets them.

When used before and after laser surgery, you may experience some or all of the following reactions **in your eyes**.

Common

(may affect up to one in 10 people treated)

- redness in the eye or eyes.
- one pupil getting bigger
- Inability to close eye
- an eye disorder (whitening of the surface of the eye)
- an unusual or uncomfortable feeling in your eyes
- your eye feeling dry

Uncommon

(may affect up to one in 100 people treated)

- bleeding on the surface of your eye (conjunctival haemorrhage);
- eye inflammation (which may include pain, heat, redness or swelling of the eye); or
- your upper eyelid lifting up.
- extremely low pressure inside the eye (your doctor will see this during eye tests);
- reduced or dim vision;
- bleeding on the surface of your eye;
- blurred vision;
- eye allergy;
- your upper eyelid lifting;
- your eye itching;
- an eye disorder (whitening of the surface of the eye);
- eye irritation;

Or, you may suffer reaction in **other areas of your body**.

Common

(may affect up to one in 10 people treated)

- a dry feeling in your nose
- a bad or unusual taste in your mouth;

Uncommon

(may affect up to one in 100 people treated)

- an irregular heartbeat.

- difficulty sleeping;
- disturbed dreams;
- fainting spells;
- burning or tingling sensations;
- a lower sex drive;
- feeling irritated;
- a slow heartbeat or palpitations;
- dizziness or feeling faint when you sit up or stand up;
- diarrhoea;
- being sick or vomiting;
- pain or discomfort in your stomach.
- headaches;
- tiredness;

Rare

(may affect up to one in 1000 people treated)

- reduced sensation or numbness;
- shortness of breath;
- a runny nose or too much saliva;
- a dry feeling, or burning in your nose;
- a dry mouth;
- increased sweating;
- itching skin;
- pain in your arms or legs;
- heaviness or pain in your chest;
- feeling hot or cold.

Not known (frequency cannot be estimated from available data);

- decreased blood pressure
- increased blood pressure

If you experience an allergic reaction, feel unusually dizzy or lightheaded, or experience irregular heartbeats, you should tell your doctor immediately.

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 HPRA Pharmacovigilance Website : www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How IOPIDINE is stored

- This medicine should not be used after the expiry date shown as 'EXP' on the package and plastic container. The expiry date refers to the last day of that month.
- This medicine should not be stored above 25°C and should be kept in the outer carton to protect it from the light.
- Keep out of the sight and reach of children.
- The medicine should be used immediately after opening the container.

6. Further information

The active substance is apraclonidine 1% w/v (10mg/ml) (as hydrochloride).

Other ingredients are sodium acetate, sodium chloride and purified water. Very small amounts of hydrochloric acid or sodium hydroxide may have been added to make the drops comfortable for your eyes.

IOPIDINE eye drops solution is pale yellow and comes in a container of 0.25 ml.

The marketing authorisation holder

Essential Pharma Limited,
Vision Exchange Building
Triq it-Territorjals, Zone 1,
Central Business District,
Birkirkara, CBD 1070,
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The manufacturer of IOPIDINE is:

SA Alcon-Couvreur NV
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This leaflet was last revised in June 2022