NOVARTIS

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

# IOPIDINE® 0.5% Eye Drops (solution)

The active ingredient and its quantity:
apraclonidine (as hydrochloride) 0.5%
1 ml of solution contains 5 mg apraclonidine

Inactive and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Further Information".

**Read this leaflet carefully in its entirety before using the medicine since it contains information that is important for you.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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

## 1. WHAT IS THE MEDICINE INTENDED FOR?

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

**Therapeutic group:** alpha agonist

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine:**

- if you are **sensitive (allergic)** to apraclonidine, clonidine or any of the additional ingredients contained in this medicine listed in section 6.
- if you have a history of **severe** or unstable **heart disease** or **circulatory problems.**
- if you are taking monoamine oxidase inhibitor antidepressants or tricyclic antidepressants.
- if you are taking medicines of the sympathomimetics class that are taken either orally or via injection.
- **in children**.
  Consult the doctor.

**Special warnings regarding use of this medicine**

- Iopidine 0.5% is for intraocular use only.
- After using for a time, Iopidine 0.5% may stop helping to regulate intraocular pressure. While you are using Iopidine 0.5% drops, the doctor will check you frequently to see whether the eye drops are still helping you.
- Iopidine 0.5% decreases intraocular pressure. You should routinely undergo an intraocular pressure examination to ensure that the pressure in the eye remains under control.

Consult the doctor if you have a **medical history of, or if you are taking medicine to treat** 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)
- **Liver or kidney** problems
- **Depression**
- **Parkinson's** disease
- **Diabetes** or **low blood sugar.** Use of Iopidine 0.5% may mask the signs and symptoms of a sudden reduction in blood sugar levels, such as a fast heartbeat or trembling
- If you are due to have an **operation**

**If any of these conditions apply to you**, you can still use Iopidine 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 on the safety and efficacy of use of this medicine in children and adolescents under the age of 18.

**Drug interactions**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.** In particular, if you are taking:

- **Do not take Iopidine 0.5%** together with monoamine oxidase (MAO) inhibitor antidepressants or tricyclic antidepressants. **Do not take Iopidine 0.5%** together with medicines of the sympathomimetics class that are taken either orally or via injection.
- **Iopidine 0.5% 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.
- **Iopidine 0.5% may interact with** some painkillers, sedatives, anesthetics, tricyclic antidepressants, phenothiazines, cough and cold medicines, glaucoma medications such as timolol, brimonidine or dipivefrine, eye drops used to whiten the eye.

**Use of the medicine with food, drink and alcohol**

**Do not consume alcohol** during the course of treatment with Iopidine 0.5%, since it may increase the effects of the medicine.

**Pregnancy and breastfeeding**

Iopidine 0.5% is not recommended during pregnancy. Breastfeeding should be discontinued during treatment with Iopidine 0.5%. If you are pregnant, think you may be pregnant, are planning a pregnancy or are breastfeeding, **consult the doctor or pharmacist** before using the medicine.

**Driving and operating machinery**

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

**Important information about some of the ingredients of this medicine**

**The medicine contains the preservative benzalkonium chloride**

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

Iopidine 0.5% contains a preservative (benzalkonium chloride) which may be absorbed by soft contact lenses and discolor them. Remove contact lenses before using the medicine; they can be put back no less than 15 minutes after instilling the medicine into the eye.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disturbances in the cornea (the clear layer in the front of the eye). If you have an unusual sensation in the eye, stinging or pain in the eye after using the medicine, refer to a doctor.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

1 drop in the eye, 3 times a day.

**Do not exceed the recommended dose.**

Do not swallow. This medicine is intended for external use, only in the eye.

Remove the loose collar from the cap after first opening the bottle.

**Instructions for use:**

- To avoid contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle closed tightly.
- The bottle of drops may not be full; this is to allow better control of the drip rate.
- Do not squeeze the bottle; pressing gently on the base of the bottle is enough to release a drop.
- How to use the drops: First, wash your hands. Hold the bottle upside down, between your thumb and index finger. Tilt your head back. With your index finger, pull the lower eyelid downward to create a type of "pocket" (Fig. 1). Bring the bottle close to the eye and use a mirror if needed. Gently instill the medicine, by releasing one drop into the "pocket" that has formed (Fig. 2). Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes.
- In addition to the instructions provided above, immediately after instilling the drops into the eye, press on the inner corner of the eye with your middle finger (Fig. 3). Continue pressing for 1 to 2 minutes after instilling into the eye. This helps prevent absorption of the medicine into the body and thus helps prevent side effects.
- After using the medicine, wash your hands thoroughly to clean them of remnants of the medicine.
- To avoid spreading the infection, do not use the same bottle of medicine for more than one person.


- If you have to instill drops into both eyes, repeat all the steps in the second eye. Close the bottle tightly immediately after use.

**If you did not manage to instill into the eye** – try again.

If you are using another eye preparation (eye drops or ointment), wait at least 5 minutes between use of this preparation and another preparation to treat the eye. Apply the eye ointment last.

**If you took more Iopidine 0.5% than required,** rinse the eye with lukewarm water. Do not instill additional drops until it is time for the next dose.

In case of accidental swallowing, symptoms of overdose may include reduced blood pressure, sleepiness, reduced heart rate, hypoventilation (low breathing rate and depth) and convulsions.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

**If you forgot to take Iopidine 0.5%,** continue with the next dose as planned. But, if it is almost time for you to take the next dose, skip the forgotten dose and continue by taking at the usual time. **Do not take a double dose to compensate for a forgotten dose.**

Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

## 4. SIDE EFFECTS

As with any medicine, use of Iopidine 0.5% may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

**Discontinue use and refer to a doctor immediately:**

**If your vision gets worse** immediately after using Iopidine 0.5%.

**Refer to a doctor immediately:**

Iopidine 0.5% may cause allergic reactions in the eye, whose signs are redness, itching, discomfort, watery eyes, abnormal sensation, eye and eyelid swelling, poor vision. If you experience one or more of these symptoms, **refer to a doctor immediately**.

**Additional side effects:**

**Very common side effects – effects that occur in more than one user in ten:**

Eye effects: increased redness, itching, inflammation.

**Common side effects – effects that occur in up to one user in 10:**

Eye effects: discomfort, watery eyes, swelling of the eyelids, gritty feeling in the eye, dry eye, eyelid crusting.

General effects: dry mouth, inflammation inside the nose, dermatitis (skin inflammation), dry nose, weakness, headache, unusual taste.

**Uncommon side effects – effects that occur in up to one user in 100:**

Eye effects: bumps under the eyelids, swelling of the eye, abnormal vision, pain, inflammation and irritation of the eye or eyelid, 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, poor vision, blurred vision, drooping of eyelid, discharge or whitening of the eye.

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

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.**

**Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects or by entering the link: https://sideeffects.health.gov.il/

## 5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
  Do not use the medicine after the expiry date (exp. date) that appears 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 store in a refrigerator or freezer.
- Keep the bottle closed tightly in the outer package.
- The preparation can be used up to 28 days after first opening the bottle.
- Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

## 6. FURTHER INFORMATION

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

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

**What the medicine looks like and the contents of the package:** a clear, colorless to light yellow solution, provided in a 5 ml plastic bottle, with a screw-on cap.

**Registration Holder and Importer and its Address:** Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in May 2021 according to MOH guidelines.

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