

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

The medicine is dispensed with  
a doctor's prescription only.

## PATANOL 0.111% Eye Drops

### Active ingredient:

Olopatadine hydrochloride 0.111%.

Inactive and allergenic ingredients appear in section 6 - "Further Information".

Important information about some of the ingredients of the medicine: see section 2 "Before using the medicine".

**Read this leaflet carefully in its entirety before using the medicine.** 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 you. 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?

The preparation is intended for temporary prevention of eye irritation secondary to allergic conjunctivitis. It acts by both preventing release of particles that cause an allergic reaction and by preventing their activity in the inflammatory process.

**Therapeutic group:** anti-histamine, anti-allergic.

### 2. BEFORE USING THE MEDICINE:

#### Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient olopatadine or any of the additional ingredients contained in the medicine (see section 6).
- you are breastfeeding.

### Special warnings regarding use of the medicine

**Before treatment with Patanol, tell the doctor if**

Remove contact lenses before using Patanol.

### Children and adolescents:

**Patanol is not intended for children under 3 years of age.** Do not use the medicine in children under 3 years of age, due to lack of data establishing the safety and efficacy in this population.

### Drug interactions:

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

If you are using another type of eye drops and/or eye ointment, wait at least 5 minutes between each medicine. Use the eye ointment last.

### Pregnancy, breastfeeding and fertility:

The medicine is not recommended for use during pregnancy.

**If you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy, consult a doctor or pharmacist before using the medicine.**

Do not use the medicine during breastfeeding. If you are breastfeeding, consult the doctor before commencing treatment with Patanol.

### Driving and operating machinery:

You may experience blurred vision for a short time after instilling Patanol into the eye. Do not drive or operate machinery until the blurred vision passes.

### Important information about some of the ingredients of the medicine:

#### Patanol contains benzalkonium chloride

This preparation contains 0.5 mg benzalkonium chloride in every 5 ml, which is equivalent to a concentration of 0.1 mg/ml.

The preservative in Patanol, benzalkonium chloride, may be absorbed by soft contact lenses and discolor them. Remove contact lenses before using this preparation; they can be reinserted 15 minutes after instilling the medicine into the eye.

Benzalkonium chloride may also cause eye irritation, especially if you are suffering from dry eyes or from disorders of the cornea (the clear layer at the front of the eye). If you have an abnormal eye sensation, stinging or pain in the eye after using the drops, refer to your 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:

One drop into the eye or eyes, twice a day - morning and evening. **Do not exceed the recommended dose.**

Only use the medicine in both eyes if the doctor has instructed you to do so.

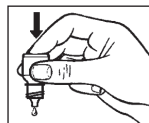
**Attention:** This medicine is intended for use in the eyes only.

#### Direction 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.
- How to use the drops: First, wash your hands. Tilt your head back. Using your index finger, pull the lower eyelid downward to create a type of "pocket" (Fig. 1).
- Do not touch the eye or eyelid, the surrounding area or other surfaces with the dropper. This may lead to contamination of the drops left in the bottle.
- Instill the medicine into the "pocket" that has been formed (Fig. 2).
- Do not squeeze the bottle. It was designed such that only gentle pressure at the bottom of the bottle is required.
- Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes.
- After using the medicine, wash your hands thoroughly to clean them of remnants of the medicine.
- To avoid spreading infection, do not use the same bottle of medicine for more than one person.
- If the drop did not enter the eye, instill again.
- If you have to use the drops in both eyes, repeat all the steps in the other eye.



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**If you accidentally took a higher dosage,** wash the eye thoroughly with warm water. Do not instill any more into the eye until it is time for the next dose.

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 the medicine** at the required time, take a dose as soon as you remember and then return to your normal dosing regimen. However, if it is almost time to take the next dose, skip the forgotten dose and return to your normal dosing regimen at the next administration. Do not take two doses together to compensate for the forgotten dose. Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

### If you stop taking the medicine

Do not stop taking the medicine without consulting with 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 Patanol 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.

The following side effects were observed with use of Patanol:

#### Common side effects - effects that occur in 1-10 in 100 users:

##### Eye effects:

eye pain, eye irritation, dry eye, an abnormal eye sensation, eye discharge.

##### General effects:

headache, fatigue, dry nose, bad taste in the mouth.

#### Uncommon side effects - effects that occur in 1-10 in 1,000 users:

##### Eye effects:

blurred vision, reduced vision, abnormal vision, corneal disorder, eye surface inflammation with or without eye surface damage, inflammation or infection of the conjunctiva, eye discharge, sensitivity to light, increased tear production, itchiness of the eye, redness of the eye, unusual sensation in the eyelid, itching, redness, swelling or crusting of the eyelid.

##### General effects:

abnormal or reduced sensation, dizziness, runny nose, dry skin, skin inflammation.

#### Side effects of unknown frequency (effects whose frequency has not yet been determined):

##### Eye effects:

eye swelling, corneal swelling, change in pupil size.

##### General effects:

shortness of breath, worsening of allergy symptoms, facial swelling, drowsiness, general weakness, nausea, vomiting, sinus infection, skin redness and itching.

In very rare cases, patients with severe corneal damage (the clear layer at the front of the eye) developed cloudiness on the cornea due to calcium build-up during treatment.

**If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in the 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](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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.
- Store at a temperature of 4-25°C.
- After first opening, can be stored at the recommended temperature for 4 weeks. After that, discard the bottle and use a new bottle to prevent infections. Record the date the bottle was opened on the package of the bottle.
- Do not discard medicines via waste water or household waste. Consult with a pharmacist regarding disposal of medicines 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, Dibasic sodium phosphate (Anhydrous), Benzalkonium chloride, Hydrochloric acid and/or Sodium hydroxide, Purified water.

#### What the medicine looks like and the contents of the package:

Patanol is a solution provided in a package containing a plastic bottle with a screw-on cap, containing 5 ml clear and colorless to pale yellow liquid.

Registration Holder and its address: Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

Manufacturer and its address:

ALCON LABORATORIES, INC. USA  
FORT WORTH, TEXAS 76134, 6201 SOUTH FREEWAY USA

for Alcon Pharmaceuticals Ltd., Fribourg, Switzerland, P.O.B. 61  
1701 FRIBOURG SWITZERLAND

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 127 08 30575

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