

PART III: CONSUMER INFORMATION

Pr PATANOL[®]
olopatadine hydrochloride ophthalmic solution,
0.1% w/v (as olopatadine)

This leaflet is part III of a three-part "Product Monograph" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PATANOL[®] solution. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

PATANOL[®] solution is used for the prevention and treatment of signs and symptoms of allergic conjunctivitis.

Allergic conjunctivitis: Some materials (allergens) like pollens, house dust or animal fur may cause allergic reactions resulting in itching, redness as well as swelling of the surface of your eye.

What it does:

PATANOL[®] solution is a medicine for treatment and control of allergic conditions of the eye. It works in two different ways by reducing and controlling the intensity of the allergic reaction.

When it should not be used:

PATANOL[®] solution will not be used if you are allergic (*hypersensitive*) to olopatadine HCl or any of the other ingredients which are listed below.

Tell your doctor if you have allergies.

Do not use PATANOL[®] solution in children under the age of three years.

What the medicinal ingredient is:

olopatadine hydrochloride

What the important nonmedicinal ingredients are:

Other ingredients include: benzalkonium chloride, sodium chloride, dibasic sodium phosphate and purified water. Tiny amounts of hydrochloric acid or sodium hydroxide are sometimes added to maintain proper pH balance.

What dosage forms it comes in:

PATANOL[®] solution is a clear liquid (a solution) supplied in a plastic (DROPTAINER[®]) bottle with a screw cap containing 5 mL, 10 mL or 15mL.

WARNINGS AND PRECAUTIONS

This medicine must not be taken by mouth.

BEFORE you use PATANOL[®] solution talk to your doctor if:

You have any allergies to PATANOL[®] solution or any of its ingredients or components of the container.

If you wear contact lenses

Do not use the drops while your contact lenses are in your eyes. Wait at least ten minutes after using the eye drops before putting your lenses back into your eyes. A preservative in PATANOL[®] solution (benzalkonium chloride) can affect soft lenses.

Pregnancy or breast-feeding

If you are pregnant, or might get pregnant, talk to your doctor before you use PATANOL[®] solution. If you are breast - feeding, do not use PATANOL[®] solution; it may get into your milk.

Driving and using machines

You may find that your vision is blurred for a time just after you use PATANOL[®] solution. Do not drive or use machines until your vision is clear.

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor if you are taking or have recently taken any other medicines, even products you have bought yourself without prescription.

PROPER USE OF THIS MEDICATION**Usual dose:**

The recommended dose is one to two drops in each affected eye twice daily.

Directions for Use:

1. Get the bottle of PATANOL[®] solution ready, along with a mirror, if needed.
2. Wash your hands.
3. Take the bottle and twist off the cap, being careful not to touch the dropper tip. After cap is removed: if tamper evident snap collar is loose, remove before using product.
4. Hold the bottle, pointing it down, between your thumb and middle finger.
5. Tilt your head back and look at the ceiling. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in there.
6. Bring the bottle tip close to the eye. Use the mirror if it helps.
7. Gently press the bottom of the bottle with your forefinger to release one drop at a time. Don't touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops left in the bottle. Don't squeeze the bottle: it is designed so that just a gentle press on the bottom is needed.
8. If you use drops in both eyes, repeat the steps for the other eye.
9. Put the bottle cap firmly back on immediately after use.

Overdose:

If you get too much in your eyes, rinse it all out with warm water. Don't put in any more drops until it's time for your next regular dose.

Missed Dose:

If you forget to use PATANOL[®] solution, use a single drop as soon as you remember, and then go back to your regular routine. Do not use a double dose to make up for the one missed.

If you are using other eye drops, wait at least five to ten minutes between putting in PATANOL[®] solution and the other drops.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

A small number of people who use PATANOL[®] solution may get side effects. They can be unpleasant, but most of them disappear rapidly.

You can usually continue using the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist.

The most frequent side effect is discomfort in the eye such as burning and stinging. This has been reported by less than one (1) in 100 people.

If you notice any side effects, other than discomfort, please inform your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature or between 4-30°C.
Keep out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax: 866-678-6789

By email: cadrmp@hc-sc.gc.ca

By regular mail:

**National AR Centre
Marketed Health Products Safety and Effectiveness
Information Division
Marketed Health Products Directorate
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9**

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Novartis Pharmaceuticals Canada Inc. at 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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