

PART III: CONSUMER INFORMATION

PATANOL®
olopatadine hydrochloride ophthalmic solution

This leaflet is part III of a three-part "Product Monograph" published when PATANOL® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PATANOL. Contact your doctor or pharmacist if you have any questions about the drug.

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

PATANOL 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 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 should not be used if you are allergic (*hypersensitive*) to olopatadine hydrochloride, any of the other ingredients or components of the container (see **What the important non-medicinal ingredients are**).

Tell your doctor if you have allergies.

Do not use PATANOL in children under the age of three years.

What the medicinal ingredient is:

olopatadine hydrochloride

What the important non-medicinal ingredients are:

Preservative: benzalkonium chloride

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

What dosage forms it comes in:

Ophthalmic solution (eye drops): 0.1% w/v, supplied in a plastic dispenser bottle with a screw cap containing 5 mL, 10 mL or 15 mL.

WARNINGS AND PRECAUTIONS

Pregnancy or breast-feeding: If you are pregnant, or planning to become pregnant, talk to your doctor before you use PATANOL.

If you are breast-feeding, do not use PATANOL; it may get into your breast milk.

Use of PATANOL and use of contact lenses

- Do not wear contact lenses if your eyes are red.
- PATANOL contains a preservative, benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses. Do not use the drops while wearing contact lenses.
- Remove your contacts before applying PATANOL and wait at least 15 minutes before putting your contacts back in.

Use of PATANOL with other eye drops or ointments

- If you use other eye drops, wait at least 5 minutes between putting in PATANOL and the other drops.
- Apply eye ointments last.

Driving and using machines: You may find that your vision is blurred for a time just after you use PATANOL. 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 or natural health products.

There are no known drugs that interact with PATANOL.

PROPER USE OF THIS MEDICATION

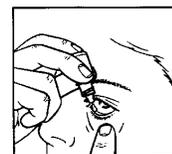
PATANOL is an eye drop. Only use it in your eye(s).

If you are using other eye drops, wait at least 5 minutes before putting in PATANOL and other eye drops. If you are using an eye ointment, you should apply it last.

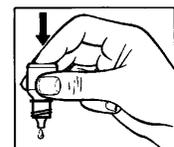
Remove your contacts before applying PATANOL and wait at least 15 minutes before putting your contacts back in.

Usual dose:

Adults and Children (3 years and older): 1 to 2 drops in each affected eye twice daily.

Instructions for use:

1



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1. Get the PATANOL bottle and a mirror.
2. Wash your hands.

3. 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. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).
6. Bring the bottle tip close to the eye. Use the mirror if it helps. **Do not touch your eye or eyelid, or any surface with the dropper.** It could contaminate the drops, cause an eye infection and damage the eyes.
7. Gently press on the base of the bottle with your forefinger to release one drop at a time. Do not squeeze the bottle: it is designed so that just a gentle press on the bottom is all that is required (picture 2).
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 think you have used too much PATANOL, contact a healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

A small number of people who use PATANOL 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.

Side effects may include:

In the eye:

- eye problems such as dry, itchy, red, irritated or crusted eyes
- eye surface inflammation with or without surface damage
- eye discharge
- eye pain
- increased tear production
- eyelid redness, spasm, swelling or dryness
- sensitivity to light
- blurred vision

- staining in your eye
- burning, stinging or gritty feeling or a feeling as if something is trapped in the eye.

Other areas of your body:

- headache
- dizziness
- fatigue or tiredness
- nasal dryness
- a dry mouth
- a change in your sense of taste
- nausea
- red or itchy skin.

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom / effect | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|--|-------------------------------------|--------------|---|
| | Only if severe | In all cases | |
| Rare Allergic reactions: swelling of the mouth and throat, shortness of breath, hives, severe itching and rash | | | ✓ |

This is not a complete list of side effects. For any unexpected effects while taking PATANOL, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature or between 4 °C - 30°C. Throw away the bottle at the end of treatment. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

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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PATANOL is a registered trademark.

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