

PART III: CONSUMER INFORMATION

PATADAY®
olopatadine hydrochloride ophthalmic solution

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

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

PATADAY is used for the treatment of itchy eyes associated with seasonal 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:

PATADAY 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:

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

Tell your doctor if you have allergies.

Do not use PATADAY in children under the age of 16 years.

What the medicinal ingredient is:

olopatadine hydrochloride

What the nonmedicinal ingredients are:

Preservative: benzalkonium chloride

Other ingredients include: dibasic sodium phosphate, edetate disodium, povidone, 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). Each mL contains 2 mg olopatadine.

WARNINGS AND PRECAUTIONS

BEFORE you use PATADAY talk to your doctor or pharmacist.

Pregnancy or breast-feeding

If you are pregnant, or planning to become pregnant, talk to your

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

Use of PATADAY and use of contact lenses

- Do not wear contact lenses if your eyes are red.
- PATADAY 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 PATADAY and wait at least 15 minutes before putting your contacts back in.

Use of PATADAY with other eye drops or ointments

- If you use other eye drops, wait at least 5 minutes between putting in PATADAY 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 PATADAY. 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 PATADAY.

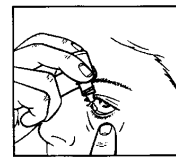
PROPER USE OF THIS MEDICATION

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

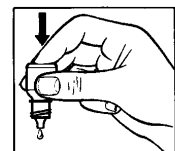
If you are using other eye drops, wait at least 5 minutes before putting in PATADAY and the other eye drops. If you are using an eye ointment, you should apply it last.

Usual dose:

Adults: 1 drop in each affected eye once daily.



1



2

Instructions for use:

1. Get the PATADAY bottle and a mirror if needed.
2. Wash your hands.
3. Twist off the cap, being careful not to touch the dropper tip.
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 there (Figure 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 the bottom of the bottle with your forefinger to release one drop (Figure 2). Do not squeeze the bottle: it is designed so that just a gentle press on the bottom is all that it needs.
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 PATADAY, 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 PATADAY, 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.

- nasal dryness
- increased heart rate
- 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 PATADAY, contact your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

A small number of people who use PATADAY 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, swelling
- 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

HOW TO STORE IT

Store at room temperature or between 4-25°C. Throw away the bottle at the end of your treatment. Keep out of the reach and sight of children.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found on the Health Canada website or 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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