READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE PATIENT MEDICATION INFORMATION

Pr PAZEO*

Olopatadine Hydrochloride Ophthalmic Solution: 0.7% w/v olopatadine (as olopatadine hydrochloride)

Read this carefully before you start taking **PAZEO**^{*} and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PAZEO**^{*}.

What is PAZEO^{*} used for?

PAZEO^{*} is used to treat itchy eyes associated with allergic conjunctivitis.

Allergic conjunctivitis is caused when you have an allergic reaction to substances like pollen, house dust or animal fur that result in:

- your eye(s) feeling itchy
- redness in your eye(s)
- swelling on the surface of your eye(s)

How does PAZEO^{*} work?

PAZEO^{*} works by treating the symptoms of your eyes that are caused by allergies.

What are the ingredients in PAZEO*?

Medicinal ingredients: olopatadine (as olopatadine hydrochloride)

Preservative: benzalkonium chloride

Non-medicinal ingredients: boric acid, hydrochloric acid and/or sodium hydroxide (to adjust pH), hydroxypropyl-gamma-cyclodextrin, hydroxypropyl methylcellulose, mannitol, polyethylene glycol 400, povidone and purified water.

PAZEO*comes in the following dosage forms:

Ophthalmic solution: 0.7% w/v

Do not use PAZEO* if:

• you are allergic to:

- o olopatadine hydrochloride
- any of the other ingredients in PAZEO* or
- the components of the container (polyethylene or polypropylene)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PAZEO^{*}. Talk about any health conditions or problems you may have, including if you are:

- pregnant or planning to become pregnant
- breast-feeding. Do not use PAZEO^{*}. It may get into your breast milk.

Other warnings you should know about:

General: PAZEO* contains benzalkonium chloride (a preservative) which may cause eye irritation and is known to change the colour of soft contact lenses. Do not use the drops while wearing contact lenses. Remove your lenses before applying PAZEO* and wait at least 15 minutes before putting your lenses back in.

Do not wear contact lenses if your eyes are red.

Using other eye drops: if you are using other eye drops, you should wait at least 5 minutes between putting in PAZEO* and the other drops. If you are using an eye ointment, you should apply it last.

Driving and using machines: You may find that your vision is blurred for a time just after you use PAZEO^{*}. Do not drive or use machines until your vision is clear.

Children less than 2 years old: PAZEO* has not been studied in children under the age of 2 years.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There are no known drugs that interact with PAZEO^{*}.

How to use PAZEO*:

PAZEO^{*} is an eye drop. Only use it in your eye(s).

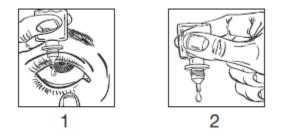
To prevent contamination of the dropper tip and solution, you should be careful not to touch your eye, eyelids or any surface with the dropper tip. Keep bottle tightly closed when you are not using it.

Remember: If you are using other eye drops, wait at least 5 minutes between putting in PAZEO* and the other drops. If you are using an eye ointment, you should apply it last.

Usual Dose:

Adults and Children (2 years and older): 1 drop in each affected eye once a day

Instructions for Use:



- Get the PAZEO^{*} bottle and a mirror.
- Wash your hands.
- Twist off the cap. Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between your eyelid and your eye. The drop will go in here (picture 1).
- 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.
- Gently squeeze the bottle to release one drop of PAZEO^{*} (picture 2).
- If you need to use the drops in both of your eyes, repeat the steps for the other eye. Put the bottle cap firmly back on immediately after you are done using it.

Overdose:

If you think you have used too much PAZEO^{*}, contact your 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 PAZEO^{*}, use it 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 you missed.

What are possible side effects from using PAZEO*?

These are not all the possible side effects you may feel when taking PAZEO^{*}. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- headache
- a dry throat
- a change in your sense of taste
- eye problems such as:
 - o dry, itchy, red, irritated or crusted eyes
 - o eye pain
 - blurred vision
 - staining in your eye
 - \circ burning, or gritty feeling or a feeling as if something is trapped in the eye

You can usually continue using the eye drops even if you experience the side effects listed above, unless the side effects become serious. If you're worried, you should talk to a doctor or pharmacist.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate
	Only if severe	In all cases	medical help
RARE			
Allergic reactions: swelling of the mouth and throat, shortness of breath, hives, severe itching			~
and rash			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program Health Canada, Postal Locator 1908C Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

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.

Storage:

- Store at room temperature or between 2-25°C
- Throw away the bottle at the end of 4 weeks
- Keep out of reach and sight of children

If you want more information about PAZEO*:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the <u>Health Canada website</u>; the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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