

PALADOPT 0.1% Eye Drops

Olopatadine hydrochloride

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you start to use PALADOPT Eye Drops.

This leaflet has been written to answer some common questions about PALADOPT. It does not contain all of the available information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. In deciding to prescribe PALADOPT for you or your child, your doctor has weighed the potential risks and benefits of using this medicine.

The information in this leaflet applies to PALADOPT only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using PALADOPT, ask your doctor or pharmacist.

Keep this leaflet with your medicines.

You may need it again.

What PALADOPT Eye Drops is used for

PALADOPT belongs to the group of medicines called antihistamines and also to the group of medicines called anti-allergics.

PALADOPT is used to treat allergic conjunctivitis, which is inflammation of the eye due to pollens that cause an allergic response to give watery, itchy and/or red eyes.

Before prescribing PALADOPT for you or your child, your doctor will have examined the eye and decided that PALADOPT is the right medicine.

Your doctor may have prescribed PALADOPT for another reason. Ask your doctor if you have any questions about why PALADOPT has been prescribed for you or your child.

PALADOPT is not addictive.

Before you use PALADOPT Eye Drops

When you must not use it

You are allergic to olopatadine or to any other of the ingredients in PALADOPT (these are listed under Product Description).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use PALADOPT if:

- **the safety seal around the closure and neck area is broken**
- **the bottle/packaging shows signs of tampering**
- **the expiry date on the bottle/carton has passed.**

If you use this medicine after the expiry date has passed, it may not work.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in PALADOPT Eye Drops (benzalkonium chloride) may be deposited in soft contact lenses.

You can put your soft contact lenses into your eyes 15 minutes after you have used PALADOPT Eye Drops.

Do not give PALADOPT to a child under 3 years.

The safety and effectiveness of PALADOPT in children under 3 years have not been established.

If you are not sure whether you should start using PALADOPT Eye Drops, talk to your doctor.

Before you start to use it

Let your doctor know if any of the following applies before you or your child start using PALADOPT:

You have:

- allergies to any other medicines or any substances such as foods, preservatives or dyes
- any other medical conditions.

If you:

- **Are pregnant or are intending to become pregnant.**
Your doctor will discuss the risks and benefits of using PALADOPT Eye Drops when pregnant.
- **Are breast feeding or intending to breast feed.**
Your doctor will discuss the risks and benefits of using PALADOPT when breast feeding.

If you have not told your doctor about any of the above, tell them before you use PALADOPT Eye Drops.

Using other medicines

Tell your doctor or pharmacist if you or your child are taking any other medicines, including medicines that

you buy at a pharmacy or health food shop without a doctor's prescription.

This is particularly important if you are currently using any other type of eye drops.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using PALADOPT with other medicines.

How to use PALADOPT Eye Drops

Carefully follow all directions given to you by your doctor and pharmacist. They may differ from the information contained in this leaflet.

If you are being changed from one medicine to another, follow your doctor's instructions carefully as to when to stop the medicine and when to start the new eye drops.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

How much to use

The usual dose of PALADOPT is one to two drops in the affected eye(s) twice each day. The dosing instructions will be printed on the label your pharmacist put on the bottle or carton.

How to use it

It is important to use PALADOPT exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and the eye problem may not improve. Using it more often than you should may not improve the eye problem any faster and may cause increased side effects.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

Follow these steps to use the eye drops:

1. Wash your hands thoroughly.

2. Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
3. Shake the bottle.
4. Remove the cap from the bottle.
5. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).



Diagram 1

6. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
7. Place the tip of the bottle close to your eye. Do not let it touch your eye.
8. Release one drop into the pouch/pocket formed between the eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (see Diagrams 2 and 3).

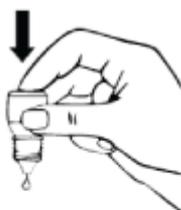


Diagram 2 and 3



9. Close your eye. Do not blink or rub your eye.
10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining

through the tear duct to the nose and throat, from where it can be absorbed into other parts of the body. This will also reduce the unpleasant taste sensation that some people experience when using these drops.

11. If necessary, repeat the above steps for the other eye.
12. Your eyelids can only hold less than one drop at a time, so it is normal for a small amount of the eye drop to spill onto your cheek. You should wipe away any spillage with a tissue.
13. Replace the cap on the bottle, closing it tightly.
14. Wash your hands again with soap and water to remove any residue.

You may feel a slight burning sensation in the eye(s) shortly after using PALADOPT Eye Drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Do not touch the tip of the dropper tip with your fingers, to the eye or any other surface.

This will help prevent the eye drops becoming dirty or contaminated.

How long to use it

Your doctor or pharmacist will tell you how long to use PALADOPT.

Do not take PALADOPT longer than your doctor tells you.

If you use PALADOPT longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are unsure about when or how to stop using PALADOPT you should talk to your doctor or pharmacist.

If you forget to use it

If you forget to use PALADOPT you should put the drops that you missed in the eye(s) as soon as you remember and then go back to using them as recommended by your doctor. If it is almost time for the next dose, skip the dose that you missed and continue using them as recommended.

Never take a double dose to make up for the one that you missed.

If you are not sure what to do, contact your doctor or pharmacist.

If you have trouble remembering to use the medicine, ask your pharmacist for some hints.

If you or your child swallow it

Immediately telephone the nearest Poisons Information Centre (in Australia call 13 11 26; in New Zealand call 0800 POISON or 0800 764 766), your doctor or go to Casualty in the nearest Hospital, if you think that you or someone else has swallowed PALADOPT. Do this even if there are no signs of discomfort or poisoning.

While using PALADOPT

Things you must do

Tell all doctors and pharmacists who are treating you or your child that PALADOPT is being used.

If you feel that PALADOPT is not helping the eye problem, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used PALADOPT exactly as prescribed.

Otherwise your doctor may think that it was not effective and change the treatment unnecessarily.

You should tell your doctor if you become pregnant while you are using PALADOPT.

Things you must not do

Do not:

- stop using PALADOPT without first asking your doctor
- give this medicine to anyone else, even if they appear to have the same condition as you or your child
- let children handle
- use PALADOPT to treat other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

You should not drive or operate any machinery if PALADOPT affects your vision.

If the itching or pain in the eye does not diminish or increases, or severe pain is experienced in the eye, contact your doctor immediately.

Ask your doctor or pharmacist if you are concerned about the length of time that you or your child have been using PALADOPT.

Side Effects

All medicines can have side effects. Sometimes they are serious, however most of the time they are not. You may need to seek medical treatment if you or your child get some of the side effects.

Tell your doctor as soon as possible if you or your child do not feel well while using PALADOPT.

PALADOPT Eye Drops is generally well tolerated. Reactions that affect the eyes have been reported including:

- Swelling of the eyelid or front part of the eye
- Eye pain
- Blurred vision
- Feeling like there is something in the eye
- Increased tearing
- Dry eye
- Red eye/eyelids
- Itching
- Crusty eyelids
- Increased sensitivity to sunlight

Occasionally some people notice unwanted effects in the rest of their body as a result of using PALADOPT Eye Drops. These effects may include:

- Headache
- Weakness
- Dizziness
- Changes to sensation of taste
- Dry nose

- Dry mouth
- Red, sore and inflamed skin rash
- Nausea

Tell your doctor immediately and stop using at PALADOPT the first sign of a skin rash or any other sign of allergy (e.g. hives).

Other side effects not listed above may also occur in some patients. Let your doctor know if you observe any unwanted effects while using PALADOPT, even if they do not appear in the list above.

Do not feel alarmed by this list of possible side effects. You may not experience any of them.

After using PALADOPT

Storage

Store PALADOPT in a cool, dry place where the temperature stays below 25°C. Do not leave PALADOPT in the car, in the bathroom or in other warm, damp places.

Heat and temperature can destroy some medicines

Do not refrigerate PALADOPT.

Keep PALADOPT, and all other medicines, in a safe place away from children.

A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

Disposal

Discard each bottle of PALADOPT 4 weeks after it has been opened.

Write the date the bottle was opened on the label to remind you when to discard the bottle.

If your doctor tells you to stop using PALADOPT or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product Description

What it looks like

PALADOPT is a colourless liquid that comes in a 5 mL dropper bottle.

Ingredients

Active drug:

Olopatadine.

Other ingredients:

Benzalkonium chloride, sodium chloride, sodium phosphate - dibasic, purified water.

Supplier

In Australia, this product is supplied by:

Aspen Pharma Pty Ltd
34-36 Chandos street
St Leonards NSW 2065

AUST R 227798

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