

PATANOL™ 0.1%

Eye Drops

Olopatadine hydrochloride

Consumer Medicine Information

What is in this leaflet

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

This leaflet answers some common questions about Patanol Eye Drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.novartis.com.au

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Patanol against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What PATANOL is used for

Patanol Eye Drops belong to the group of medicines called antihistamines.

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

Before prescribing Patanol Eye Drops for you, your doctor will have examined your eye(s) and decided that Patanol Eye Drops is the right medicine for you.

Your doctor may have prescribed Patanol Eye Drops for another reason.

Ask your doctor if you have any questions about why Patanol Eye Drops have been prescribed for you.

This medicine is only available with a doctor's prescription.

Patanol Eye Drops are not addictive.

Use in Children

Patanol Eye Drops are not recommended for use in children under 3 years of age.

The safety and effectiveness of Patanol Eye Drops in children in this age group has not been established.

Before you use PATANOL

When you must not use it

Do not use Patanol Eye Drops if:

You are allergic to olopatadine or to any of the ingredients in Patanol Eye Drops listed at the end of this leaflet 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 Patanol Eye Drops 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 Patanol Eye Drops (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used Patanol Eye Drops.

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

Before you start to use it

Tell your doctor if:

- you have allergies to any other medicines or any substances such as foods, preservatives or dyes
- **you are pregnant or are intending to become pregnant.**
Your doctor will discuss the risks and benefits of using Patanol Eye Drops when pregnant.
- **you are breastfeeding or intend to breastfeed.**
Your doctor will discuss the risks and benefits of using Patanol Eye Drops when breastfeeding.
- you have any other medical conditions.

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

Using or taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy at a pharmacy, supermarket 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 be affected by Patanol or may affect how well it works. You may need different amounts of your medicines, or you may need to take or use different medicines.

Your doctor or pharmacist will be able to tell you what to do when using Patanol Eye Drops with other medicines.

How to use PATANOL

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 Patanol Eye Drops is one to two drops in the affected eye(s) twice each day for up to 14 weeks.

The dosing instructions will be printed on the label your pharmacist puts on the bottle or carton.

How to use it

It is important to use Patanol Eye Drops 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 with soap and water.
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.

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 your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger.
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 your 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 shortly after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your eye, eyelid or anything else.

This will help prevent the drops becoming dirty or contaminated.

If you have trouble knowing whether you have placed your drops correctly, you may want to store them in the fridge. Some people

find it easier to feel the drops in the eye if they are cold.

After using Patanol Eye Drops, wait at least 5 minutes before putting any other eye drops in your eye(s).

Wait until 15 minutes before replacing your contact lenses.

When to use it

Use Patanol Eye Drops every day, at about the same time(s) each day, unless your doctor tells you otherwise. Using your eye drops at the same time(s) each day will have the best effect. It will also help you remember when to use the eye drops.

How long to use it

Patanol Eye Drops is usually given for up to 14 weeks. However, your doctor or pharmacist will tell you how long you need to use Patanol Eye Drops.

Do not use Patanol Eye Drops longer than your doctor tells you.

If you use Patanol Eye Drops 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 Patanol Eye Drops talk to your doctor or pharmacist.

If you forget to use it

If you forget to use Patanol Eye Drops, 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.

Do not use double the amount to make up for the dose that you missed.

Using multiple doses may cause unwanted side effects.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any, or all of the contents of a bottle of Patanol Eye Drops, immediately telephone your doctor or Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

While you are using PATANOL

Things you must do

Tell all doctors and pharmacists who are treating you that you are using Patanol Eye Drops.

Tell your doctor if, for any reason, you have not used or stopped using Patanol Eye Drops.

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

If you become pregnant while using Patanol Eye Drops tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Patanol Eye Drops.

Things you must not do

Do not stop using Patanol Eye Drops without first asking your doctor.

Do not give this medicine to anyone else, even if they appear to have the same condition as you.

Do not use Patanol Eye Drops to treat other complaints unless your doctor or pharmacist tells you to.

Do not let children handle Patanol Eye Drops.

If a child accidentally swallows any of the drops read the instructions under "If you use too much (overdose)".

Things to be careful of

Be careful driving or operating machinery until you know how Patanol Eye Drops affect you and your vision.

As with any eye medicine, temporary blurred vision or other visual disturbances may affect the ability to drive or use machinery in some people. If blurred vision occurs when you use your drops, wait until your vision is clear before driving or operating machinery.

Side effects

Tell your doctor as soon as possible if you do not feel well while using Patanol Eye Drops.

This medicine helps most people with allergic conjunctivitis but may have unwanted effects in a few people.

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

Do not be alarmed by the following list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following effects in the eye(s) and the eye area and they worry you:

- swelling of the eyelids 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.

These are the most common side effects of your medicine. They are usually mild and short-lived.

Occasionally, some people notice unwanted effects in the rest of the body as a result of using Patanol 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.

Stop using Patanol Eye Drops and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- skin rash
- swelling of the face, hands or feet
- wheezing, difficulty in breathing
- shortness of breath (dyspnoea, heart failure)
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

These hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After using PATANOL

Storage

Store Patanol Eye Drops in a cool, dry place where the temperature

stays below 25°C. It is not necessary to store Patanol Eye Drops in the refrigerator but it is acceptable if you prefer to instill cold drops.

Do not freeze.

Do not leave Patanol Eye Drops in the car, in the bathroom or in other warm, damp places.

Heat and humidity can destroy some medicines.

Do not leave the top off the bottle for any length of time, to avoid contaminating the eye drops.

Keep it where children cannot reach it.

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

Disposal

Discard each bottle of Patanol Eye Drops 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.

Patanol Eye Drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time, there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should then be used.

If your doctor tells you to stop using Patanol Eye Drops or they have passed the expiry date, ask your pharmacist what to do with any that is left over.

Product Description

What it looks like

Patanol Eye Drops are a colourless to pale yellow liquid that comes in a 5 mL DROP-TAINER® bottle.

Ingredients

Patanol Eye Drops contain olopatadine 0.1% (1 mg/mL) as the active ingredient.

Patanol also contains the inactive ingredients:

- benzalkonium chloride, as a preservative
- sodium chloride
- sodium phosphate-dibasic dodecahydrate
- purified water.

Supplier

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
 ABN 18 004 244 160
 54 Waterloo Road
 Macquarie Park NSW 2113
 Telephone: 1-800-671-203.
 Web site: www.novartis.com.au

Australian registration number

AUST R 82000.

Date of preparation

This leaflet was prepared in August 2017.

© Novartis Pharmaceuticals Australia Pty Limited 2017

® Registered Trademark

Internal document code:
 (pat030717c) based on PI
 (pat030717i)