Patanol® 0.1%

Eye Drops Solution
Olopatadine hydrochloride

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Patanol Eye Drops?

Patanol contains the active ingredient Olopatadine hydrochloride. Patanol is used to treat seasonal allergic conjunctivitis, an inflammation of conjunctiva (a thin membrane that lines the inside of the eyelids and covers the white portion of the eye) due to allergens such as pollens.

For more information, see Section 1. Why am I using Patanol Eye Drops? in the full CMI.

2. What should I know before I use Patanol Eye Drops?

Do not use if you have ever had an allergic reaction to Patanol or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Patanol Eye Drops? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Patanol and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Patanol Eye Drops?

- Your doctor will advise you on the appropriate dose.
- Do not use Patanol Eye Drops longer than your doctor tells you.

More instructions can be found in Section 4. How do I use Patanol Eye Drops? in the full CMI.

5. What should I know while using Patanol Eye Drops?

Things you should do	 Remind any doctor, dentist, pharmacist or specialist you visit that you are using Patanol. Tell your doctor immediately if you develop any signs of allergic reaction. Remove soft contact lenses before using Patanol.
Things you should not do	 Do not stop using this medicine suddenly. Do not give Patanol to anyone else, even if they seem to have the same condition as you. Do not use Patanol in children.
Driving or using machines	 Patanol may cause temporary blurred vision or other visual problems in some people. If blurred vision occurs, wait until the vision clears before driving or using machinery.
Looking after your medicine	 Store below 25 °C Do not freeze.

For more information, see Section 5. What should I know while using Patanol Eye Drops? in the full CMI.

6. Are there any side effects?

Common side effects include headache, eye pain, dry eye(s), itchy eye(s), blurred vision, feeling that something is in your eye(s), redness of the eye(s)

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Patanol® 1

Patanol® 0.1%

Eye Drops Solution

Active ingredient: Olopatadine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Patanol. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Patanol.

Where to find information in this leaflet:

- 1. Why am I using Patanol Eye Drops?
- 2. What should I know before I use Patanol Eye Drops?
- 3. What if I am taking other medicines?
- 4. How do I use Patanol Eye Drops?
- 5. What should I know while using Patanol Eye Drops?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

1. Why am I using Patanol Eye Drops?

Patanol contains the active ingredient Olopatadine hydrochloride. Patanol belongs to a group of medicines called Antihistamines.

Patanol is used to treat seasonal allergic conjunctivitis, an inflammation of conjunctiva (a thin membrane that lines the inside of the eyelids and covers the white portion of the eye) due to allergens such as pollens. It causes allergic symptoms such as redness of eyes, itching, swollen and watery eyes. Patanol helps to reduce the symptoms of allergy.

2. What should I know before I use Patanol Eye Drops?

Warnings

Do not use Patanol Eye Drops:

- If you are allergic to Olopatadine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- In children below 3 years of age.
- If the safety seal around the closure and neck area is broken
- If the bottle/packaging shows signs of tampering

Check with your doctor if you:

- have any medical condition
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will advise you regarding the possible risks and benefits of using Patanol during Pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Patanol may affect breast milk production. Your doctor will advise you regarding the possible risks and benefits of using Patanol during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Patanol and affect how it works. Your doctor or pharmacist will be able to tell you what to do when using Patanol Eye Drops with other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Patanol.

4. How do I use Patanol Eye Drops?

How much to use

- Your doctor will advise you on the appropriate dose.
- Follow the instructions provided and use Patanol until your doctor tells you to stop.
- Use one to two drops of Patanol in the affected eye(s) twice daily for up to 14 weeks.
- Do not use Patanol Eye Drops longer than your doctor tells you.
- If you do not understand your dose, contact your doctor or Pharmacist

When to use Patanol Eye Drops

 Patanol should be used every day, at about the same time(s) each day, unless your doctor tells you otherwise.

How to use Patanol Eye Drops

- Sitting or lying down position might make the process simpler.
- Remove contact lenses if you are wearing them before using the eye drops.
- Your doctor will advise you on the appropriate dose for Patanol.
- Shake the bottle well prior to use.
- Follow the steps below to use Patanol Eye Drops:

Patanol® 2

- Wash your hands thoroughly with soap and water.
- Before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- Remove the cap from the bottle.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Hold the bottle upside down in one hand between your thumb and middle finger (refer diagram 1).

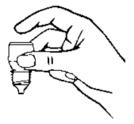


Diagram 1

- Tilt your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
- Place the tip of the bottle close to your eye. Do not touch the tip to your eye as this may cause injury to your eye.
- Do not touch the dropper tip to your eyelid or surrounding areas or any surface to avoid contamination of the dropper tip and solution.
- 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 (refer diagrams 2 and 3).



• Diagram 2



Diagram 3

- Gently close your eye(s). Do not blink or rub your eye(s).
- When 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 prevent 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 and may result in less side effects.
- This will also help to prevent the unpleasant taste sensation that some people experience while using Patanol Eye Drops.
- If necessary, repeat the above steps for the other eye.
- You may feel initial discomfort or a slight burning sensation in the eye shortly after using Patanol. If it continues, or is uncomfortable, contact your doctor or pharmacist.
- If you want to use any other eye drops wait at least 5 minutes after using Patanol.
- It is normal for a small amount of eye drops to spill onto your cheek since your eyelids can only hold less than one drop at a time. Wipe away any spillage with a tissue.
- Replace the cap on the bottle and close it tightly.
- Always keep the bottle tightly closed when not in use.
- Wash your hands again with soap and water to remove any residue.
- Wait for 15 minutes before putting your contact lenses in.
- Discard Patanol Eye Drops 28 days after opening it.

If you forget to use Patanol Eye Drops

Patanol should be used regularly at the same time each day. If you miss your dose at the usual time, 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 your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Patanol Eye Drops

If you think that you have used too much Patanol, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you accidentally use several Patanol Eye Drops in your eyes, immediately wash your eyes with warm tap water.

5. What should I know while using Patanol Eye Drops?

Things you should do

Remove soft contact lenses before using Patanol.
 Patanol contains the preservative benzalkonium

chloride which may cause eye irritation and can be deposited in or discolour soft contact lenses.

- Put your lenses back in 15 minutes after using Patanol.
- Patanol Eye Drops are for eye use only.
- Close the bottle of Patanol Eye Drops tightly when not in use.

Call your doctor straight away if you:

- develop any signs of allergic reaction.
- become pregnant, plan to become pregnant or if you are breast feeding while using Patanol
- take any medicines for any condition

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Patanol.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not touch the dropper tip to any surface, eyelids or surrounding areas.
- Do not give Patanol to anyone else, even if they seem to have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Patanol affects you.

Patanol may cause temporary blurred vision or other visual problems in some people.

If blurred vision occurs, wait until your vision clears before driving or using machinery.

Looking after your medicine

Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard Patanol Eye Drops bottle 28 days after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

ess serious side effects				
Less serious side effects	What to do			
Eye problems:	Speak to your			
 Blurred vision Burning or stinging sensation in eye(s) Cold syndrome (feet or hands turning white or blue when it is cold) Dry eye(s) Redness of the eye(s) Feeling that something is in your eye(s) Eyelid swelling Itching of eye(s) Eye pain Eye discharge Excessive secretion of tears from the eye(s) Uncomfortable feeling in eye(s) 	doctor if you have any of these less serious side effects and they worry you.			
Other problems				
 Headache Unusual weakness Feeling sick Discomfort and dryness in the throat, cough, difficulty swallowing or pain when swallowing or talking. Sneezing, stuffy or runny nose, headache. Fever, headache, cough, ear pain, tiredness. Dry nose Dry mouth 				
• Dizziness				

Serious side effects

Serious side effects	What to do
 Eye problems: Eye pain, redness, eye sensitivity to light, blurred vision. Other problems: Taste disturbance or loss of taste 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Patanol® 4

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Patanol Eye Drops contains

Active ingredient (main ingredient)	olopatadine hydrochloride (1.11 mg/mL) which is equivalent to olopatadine (1.0 mg/mL)
Other ingredients (inactive ingredients)	Sodium chloride, dibasic sodium phosphate dodecahydrate, sodium hydroxide / hydrochloric acid (for pH adjustment), benzalkonium chloride (0.1 mg/mL as preservative) and purified water.
Potential allergens	NA

Do not take this medicine if you are allergic to any of these ingredients.

What Patanol Eye Drops looks like

Patanol is a colourless to pale yellow and essentially particle free sterile isotonic solution. It is available in LPDE bottle (dispenser). Pack size: 1 x 5 mL.

Who distributes Patanol Eye Drops

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

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