

APO-Olopatadine Eye Drops

Contains the active ingredient olopatadine (as olopatadine hydrochloride)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about olopatadine. 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 last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

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

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Olopatadine eye drops. It contains the active ingredient olopatadine hydrochloride.

It 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 olopatadine for you or your child, your doctor will have examined the eye and decided that olopatadine is the right medicine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children under age 3 years.

Safety and effectiveness has not been established.

Before you use this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, olopatadine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

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

The preservative in olopatadine 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 olopatadine eye drops.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You or your child has allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You or your child have or have had any medical conditions.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop. This is particularly important if you are currently using any other type of eye drops.

How to use this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to use

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose of olopatadine is one or two drops in the affected eye(s) twice each day. The dosing instructions will be printed on the

label your pharmacist puts on the bottle or carton.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to use it

It is important to use olopatadine exactly as your doctor 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. Shake the bottle.
3. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger.
5. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
6. Place the tip of the bottle close to your eye. Do not let it touch your eye.
7. 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.
8. Close your eye. Do not blink or rub your eye.
9. 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.

10. If necessary, repeat the above steps for the other eye.
11. 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.
12. Replace the cap on the bottle, closing it tightly.
13. 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 olopatadine eye drops. If this persists, or is very uncomfortable, contact your doctor.

Do not touch the tip of the dropper tip with your fingers, to the eye or any other surface. This will prevent the eye drops becoming dirty or contaminated.

When to use it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to use it for

Continue taking your medicine for as long as your doctor tells you.

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

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

Make sure you have enough to last over weekends and holidays.

If you forget to use it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you or your child take too much (overdose)

If you think that you or your child have swallowed it or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using this medicine

Things you must do

Tell your doctor that you or your child is taking this medicine if:

- if you feel that this medicine is not helping the eye problem
- if for any reason, you have not used this medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change the treatment unnecessarily
- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- Let children handle this medicine.

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 if you are concerned about the length of time that you or your child has been using this medicine.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Possible side effects

Tell your doctor as soon as possible if you or your child does not feel well while you are taking olopatadine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Olopatadine eye drops are generally well tolerated. Reactions that affect the eyes have been reported.

Tell your doctor if you notice any of the following:

- 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

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- Headache
- Weakness
- Dizziness
- Changes to sensation of taste
- Dry nose
- Dry mouth
- Red, sore and inflamed skin rash
- Nausea

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

Allergic reactions

If you think you are having an allergic reaction to olopatadine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Do not refrigerate this medicine.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 olopatadine 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 taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Australian Registration Numbers

APO-Olopatadine 1 mg/mL (0.1%)
bottle: AUST R 241497.

Sponsor

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Product description

What APO-Olopatadine Eye Drops looks like

1 mg/mL (0.1%) Eye Drops: Clear, colourless solution.

5 mL bottle.

Ingredients

Each eye drop contains 1 mg/mL olopatadine as the active ingredient.

It also contains the following inactive ingredients:

- sodium chloride
- dibasic sodium phosphate
- benzalkonium chloride (as preservative)
- water for injections
- hydrochloric acid
- sodium hydroxide

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.