

Zaditen[®] Eye Drops 0.25 mg/mL

Ketotifen

CONSUMER MEDICINE INFORMATION

What is in this leaflet

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

This leaflet answers some common questions about Zaditen 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.medsafe.govt.nz.

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 Zaditen 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 Zaditen is used for

Zaditen contains ketotifen which is a histamine H₁-receptor antagonist. This class of medicines block histamine and other agents in the body that cause allergic reactions.

Zaditen is used to treat the short-term symptoms of seasonal allergic conjunctivitis (itchy, watery or swollen eyes and/or eyelids).

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

Your doctor or pharmacist may have given it to you for another reason.

Ask your pharmacist or doctor if you have any questions about why this medicine has been given to you.

This medicine is not addictive.

This medicine is available from a pharmacy.

Use in children

Zaditen is not for use in children under 3 years of age. The safety and effectiveness of Zaditen in this age group has not been established.

Before you use Zaditen

When you must not use it

Do not use Zaditen if you have an allergy to:

- Ketotifen or any of the ingredients 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 Zaditen Eye Drops if:

- **the bottle/packaging is torn or 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.

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

Tell your doctor or pharmacist if are pregnant or intend to become pregnant.

Zaditen is not recommended in pregnant women. Your doctor or pharmacist will discuss the risks and benefits of using Zaditen Eye Drops when pregnant.

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.

Tell your doctor or pharmacist if you are using other eye drops or ointments or taking any other medicines. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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

How to use Zaditen

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

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

How much to us

The usual dose of Zaditen in adults and children over 3 years is one

drop in the affected eye(s) twice a day (morning and night).

How to use it

It is important to use Zaditen 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 your eye problem may not improve. Using it more often than you should may not improve your eye problem any faster and may cause side effects.

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.

If you wear soft contact lenses, remove your contact lenses before using this medicine. Wait for 15 minutes after using it before reinserting your contact lenses into your eyes.

Zaditen multi-dose bottles contain the preservative, benzalkonium chloride which can discolour soft contact lenses,

Follow these steps to use Zaditen in a multi-dose bottle:

1. Wash your hands thoroughly before using the drops.
2. Open the multi-dose bottle.
3. Make sure that the tip of the dropper does not touch anything as this may contaminate the solution.
4. Hold the bottle in one hand between the thumb and forefinger.
5. With your head tilted back, use the forefinger of your other hand to pull down the lower lid of the eye to be treated.

6. Place the dropper close to your eye but without touching the eye or eyelid, and squeeze the bottle gently so that one drop falls into the pouch between your lower eyelid and your eye, and then release your lower lid. Only one drop is needed.
7. Close your eye and gently press the inner corner of your eye with your forefinger for one minute.
8. Treat your other eye in the same way if it is affected.
9. Close the bottle, and keep it stored at temperatures below 25°C and discard the remaining solution 4 weeks after opening.

Follow these steps to use Zaditen the single dose unit:

1. Wash your hands thoroughly before using the drops.
2. Open the blister pack of the single dose unit.
3. Remove the strip of the single dose unit and tear off one single dose unit from the strip. Hold the single dose unit by the tab with the nozzle pointing downwards and tap gently until all the air bubbles are above the solution.
4. Twist the tab off the single dose unit.
5. Make sure that the tip of the single dose unit does not touch anything as this may contaminate the solution.
6. Hold the single dose unit in one hand between the thumb and forefinger.
7. With your head tilted

backwards, use the forefinger of your other hand to pull down the lower lid of the eye to be treated.

8. Place the single dose unit to your eye but without touching your eye or the eye lid so that one drop falls into the pouch between your lower eyelid and your eye, and then release your lower lid. Only one drop is needed.
9. Close your eye and gently press the inner corner of your eye with your forefinger for one minute.
10. Treat your other eye in the same way if it is also affected.
11. Discard each single dose unit immediately after use. Keep the remaining single dose units at temperatures below 25°C, preferable in the outer container.

If you are using any other eye drops at the same time as Zaditen leave an interval of at least 5 minutes between each drop to stop the drops from being washed out of the eye.

How long to use it

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

Do not use Zaditen for longer than your doctor tells you.

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

If you are not sure how long to use Zaditen, talk to your doctor or pharmacist.

If you forget to use it

If you forget to use Zaditen 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 your next dose, skip the dose you missed and continue using them as recommended.

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

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

If you use too much (overdose)

It is unlikely that you will experience any symptoms if you accidentally swallow Zaditen. Similarly, do not worry if more than one drop is accidentally dropped into your eye.

If you are concerned speak to your doctor or pharmacist.

While you are using Zaditen

Things you must do

If you become pregnant while using Zaditen tell your doctor or pharmacist.

If you are about to be started on any medicine, remind your doctor and pharmacist that you are using Zaditen.

Tell any other doctors, dentists or pharmacists who treat you that you are using this medicine.

Things you must not do

Do not stop using Zaditen without first asking your doctor or pharmacist.

Do not use Zaditen to treat other complaints unless your doctor or pharmacist tells you to.

Do not give Zaditen to anyone else, even if they have the same symptoms as yours.

Do not let children handle Zaditen.

Things to be careful of

You should not drive or operate any machinery if Zaditen affects your vision (blurred vision) or you are feeling tired.

Children should be careful when riding bicycles or climbing.

Side effects

Tell your doctor as soon as possible if you do not feel well while using Zaditen.

This medicine helps most people with eye allergies but it 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 medical treatment if you get some of the side effects.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- burning, stinging or blurring of vision immediately after using the drops
- eye irritation, eye pain or feeling of having something in your eye
- swollen eyelid or other eyelid changes
- unusual sensitivity of the

- eye to light
- headache
- feeling tired or sleepy
- dry mouth
- rash, eczema or itchiness.

Tell your pharmacist or doctor as soon as possible if you notice any of the following:

- tiny breaks in the skin covering the eye
- swelling of the face
- runny or sticky discharge from the eye with itching of the eye and crusty eyelids
- pain in the eye
- bleeding under the surface of the eye
- skin rash
- worsening of pre-existing allergic conditions such as asthma i.e. wheezing or difficulty breathing.
- worsening of the symptoms of eczema
- dizziness.

The above list includes serious side effects which may require medical attention.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell while using Zaditen.

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

After using Zaditen

Storage

Multi-dose bottle

- Keep the bottle sealed until it is time to use the eye drops. If you

open the bottle, the eye drops may not keep.

Single dose units:

- Keep the inner blisters sealed until it is time to use the eye drops.
- If you open the inner blisters, the eye drops may not keep.
- After opening each inner blister, try to keep the single dose units it contains inside the outer box.
- Use the single dose units from each opened blister which have been stored in the outer box for up to three months and then start a new blister even if there are some single dose units left from the old blister.
- If the single dose units from an opened blister are left out of the box at any time, use them for four weeks and then start a new blister even if there are some single dose units left from the old blister.

Keep Zaditen Eye Drops in a cool dry place where the temperature stays below 25°C.

Do not store Zaditen or any other medicine in the bathroom or near a sink. Do not it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Zaditen in a safe place away from the sight or reach of children.

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

Put the top back on the bottle right away after use to avoid contamination.

Disposal

Multi-dose bottle

Write the date on the bottle when you open the eye drops and throw away any remaining amount after 4 weeks.

Single-dose unit

Discard the content of the unit immediately after use.

If your doctor tells you to stop using Zaditen 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

Zaditen is a clear, colourless to faintly yellow solution.

Ingredients

The active ingredient in Zaditen Eye Drops is ketotifen 0.25 mg in 1 mL.

Zaditen Multi-dose bottles also contain:

- Benzalkonium chloride as a preservative
- Glycerol
- Sodium hydroxide
- Water for injections.

Zaditen Single dose units

- Glycerol
- Sodium hydroxide
- Water for injections.

Supplier

Zaditen is supplied in New Zealand
by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335

Date of preparation

This leaflet was prepared in August
2020.

© Novartis Pharmaceuticals
Australia Pty Limited 2018.

® Registered trademark.