

ZADITEN® Eye Drops 1.0%

Ketotifen

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use Zaditen Eye Drops.

This leaflet answers some common questions about Zaditen Eye Drops. It does not contain all of 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 expected benefits of you using Zaditen Eye Drops against the risks this medicine could have for you.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What ZADITEN is used for

Zaditen contains the active ingredient, ketotifen, which is an anti-inflammatory medicine. It works by blocking the allergic response and reducing inflammation.

This medicine is used for short term treatment of the symptoms of seasonal allergic conjunctivitis (itchy, watery or swollen eyes and/or eyelids).

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

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

This medicine is not addictive.

It is available from your pharmacy.

Use in children

Zaditen is not recommended for use in children under 3 years.

The safety and effectiveness of Zaditen in this age group has not been established.

Before you use ZADITEN

Do not use Zaditen Eye Drops if you have an allergy to:

- Ketotifen
- Other ingredients in Zaditen that are 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 this medicine if the expiry date has passed, the packaging is torn or the seal around the closure of the multi-dose or single dose units and neck area is broken.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

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

Before you start to use it

Tell your doctor or pharmacist if:

- **You have an allergy to any other medicines or any other substances, such as foods, preservatives or dyes**
- **You are pregnant, or intend to become pregnant**
Your doctor will discuss the possible risks and benefits of using Zaditen during pregnancy.
- **You are breastfeeding or intend to breastfeed**
Your doctor will discuss the possible risks and benefits of using Zaditen when you are breast-feeding.

If you have not told your doctor about any of the above, tell him/ her before you use Zaditen Eye Drops.

Do not put Zaditen Eye Drops into your eye(s) while you are wearing contact lenses.

The preservative in Zaditen Eye Drops bottle, benzalkonium chloride, may be deposited in contact lenses that may cause irritation to your eyes.

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

Taking or using other medicines

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

Some medicines and Zaditen Eye Drops may interfere with each other.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How to use ZADITEN

Carefully follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

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

How much to use

The usual dose of Zaditen Eye Drops is one drop in the affected eye(s) twice a day. This will normally be in the morning and at night. After using Zaditen Eye Drops wait at least 5 minutes before putting any other eye drops in your eye(s).

If you wear soft contact lenses, remove them before using this medicine. Wait for 15 minutes after using Zaditen before reinserting the contact lenses.

The preservative in Zaditen Eye Drops bottle can affect the contact lenses.

If you are unsure about when, or how, to stop using Zaditen Eye Drops you should talk to your doctor.

How to use

Follow these steps to use the single dose units:

1. Wash your hands thoroughly with soap and water.
 2. Open the blister pack of the single dose units.
 3. Remove the strip of single dose units and tear off one 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 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 back, use the forefinger of the other hand to pull down the lower lid of the eye to be treated.
 8. Place the single dose unit tip close to your eye but without touching your eye or eyelid, and squeeze unit gently so that one drop falls into the pouch between your lower lid and your eye, and then release your lower lid.
- Only one drop is needed.**
9. Close your eyes 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 room temperature (below 25°C), preferably in the carton (See "After using Zaditen – Storage").

Follow these steps to use the multi-dose bottle:

1. Wash your hands thoroughly with soap and water.
2. Open the multi-dose bottle.
3. Make sure the tip of the bottle 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 the 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 your eye or eyelid, and squeeze the bottle gently so that one drop falls into the pouch between your lower lid and your eye, and then release your lower lid.

Only one drop is needed.

- Close your eyes and gently press the inner corner of your eye with your forefinger for one minute.
- Treat your other eye in the same way if it is also affected.
- Close the bottle and keep it at room temperature (below 25°C). Discard the multi-dose bottle and remaining solution four (4) weeks after opening.

When to use it

Use Zaditen Eye Drops at about the same time every day unless your doctor or pharmacist tells you otherwise.

Using your eye drops at the same time each day will have the best effect in treating your allergic conjunctivitis. It will also help you remember when to use the eye drops.

How long to use it

You can stop using this medicine when the itching in your eye(s) has gone.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use the drops as soon as you remember, and then go back to using your medicine as you would normally.

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 what to do, ask your pharmacist or doctor.

If you use too much (overdose)

It is unlikely that you will experience symptoms or side effects if you accidentally swallow Zaditen. Similarly, do not be concerned if more than one drop is accidentally dropped into your eye.

If you have any doubts, speak to your doctor or pharmacist for advice or contact the Poisons Information Centre on 13 11 26.

While you are using Zaditen

Things you must do

Tell your pharmacist or doctor immediately if you become pregnant while using Zaditen.

If you are about to be started on any new medicine, remind your pharmacist or doctor 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 use Zaditen to treat any other complaints unless your pharmacist or doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how Zaditen affects you.

This medicine may cause blurred vision or tiredness in some people.

If you have either of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Side effects

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

This medicine helps most people with allergic conjunctivitis but may have unwanted side effects in some people.

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

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

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 or a feeling of having something in your eye
- swollen eyelid or other eyelid changes
- unusual sensitivity of the eye to light
- headache or tiredness
- dry mouth.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- tiny breaks in the skin covering the eye
- 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
- wheezing or difficulty breathing.

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

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

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

After using Zaditen

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C. Do not freeze the eye drops.

Do not store Zaditen Eye Drops or any other medicine in the car, bathroom, the window sill or in other warm, damp places.

Heat and dampness can destroy some medicines.

Keep it out of 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.

Multi-dose Bottle:

- Keep the bottle sealed until it is time to use the eye drops.**
- After opening, write the date on the bottle.**
- Use the eye drops for four (4) weeks.** These 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.

If you need to continue treatment get a new bottle of drops, even if there is some left in the old bottle.

- Put the top back on the bottle right away after use to avoid contaminating the eye drops. Do not leave the top off the bottle for any length of time as the drops may not keep well.**

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 well.
- After opening the single dose unit, use the drops once and immediately discard any unused solution.** These eye drops contain no preservative.
- Keep the remaining single dose units at room temperature (below 25°C), preferably in the carton.**

Disposal

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

Zaditen is a sterile solution containing ketotifen that is available in a multi-dose eye drop bottle in packs of 2.5 mL and 5 mL.

It is also available as single dose units in packs of 5 (1 x 5) and 20 (4 x 5).

Ingredients

Zaditen contains the active ingredient ketotifen 250 µg in 1mL.

Zaditen also contains:

- Benzalkonium chloride (as a preservative) in the multi-dose bottles only
- Glycerol
- Sodium hydroxide
- Water for Injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Zaditen 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

Date of preparation

This leaflet was prepared in June 2017.

Australian registration numbers

Multi-dose bottles: 99979.

Single dose units: 113770.

® Registered Trademark

© Novartis Pharmaceuticals Australia Pty Limited 2017.

Internal document code:

(zad200617c) based on PI (zad200617i)