

Zaditen®

ketotifen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zaditen.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

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

All medicines have risks and benefits. Your pharmacist or doctor can weigh 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 pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

What Zaditen is used for

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

It works by blocking certain aspects of the allergic response and reducing inflammation.

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.

Before you use Zaditen

When you must not use it

Do not use Zaditen if you have an allergy to:

- any medicine containing ketotifen
- any of the ingredients listed at the end of this leaflet.

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 after the expiry date printed on the pack, if the packaging is torn or shows signs of tampering, or if the medicine does not look quite right.

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

Do not use the multidose bottle or any individual single dose unit if the seal is broken.

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

Before you start to use it

Tell your pharmacist or doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your pharmacist or doctor can discuss with you the risks and benefits involved.

Tell your pharmacist or doctor if you are using Zaditen and you wear soft contact lenses.

You should remove soft contact lenses before using Zaditen and not reinsert them until at least 15 minutes after use.

If you have not told your pharmacist or doctor about any of these things, tell him/her before you start using Zaditen.

Taking other medicines

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

Some medicines and Zaditen may interfere with each other.

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

How to use Zaditen

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

They may differ from the information contained in this leaflet.

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

How much to use

The usual dose of Zaditen is one drop in the affected eye(s) twice a day (in the morning and evening).

How to use it

This medicine is available in a multidose bottle and in single dose units.

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

The ingredients in Zaditen can affect contact lenses.

Follow these steps to use the multidose bottle (steps 1-2 and 5-11) or single dose units (steps 1-10 and 12):

1. Wash your hands before using the drops.
2. Open the multidose bottle or blister pack of single dose units.
3. Remove the strip of single dose units 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 the tip of the dropper or single dose unit does not touch anything as this may contaminate the solution.
6. Hold the bottle or single dose unit in one hand between the thumb and forefinger.
7. With your head tilted back, use the forefinger of your other hand to pull down the lower lid of the eye to be treated.
8. Place the dropper or single dose unit tip 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 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. Close the bottle and keep it at room temperature (below 25°C). Discard the multidose bottle and remaining solution four weeks after opening.
12. Discard each single dose unit immediately after use. Keep remaining single dose units at room temperature (below 25°C) and preferably in the outer carton (see After Using Zaditen Storage).

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 being washed out of the eye.

How long to use it

Stop using this medicine when the itching 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 it as soon as you remember, and then go back to using your medicine as you would normally.

If you are not sure what to do, ask your pharmacist or doctor.

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

If you use too much (overdose)

There is no danger if you accidentally swallow Zaditen. Similarly, do not worry if more than one drop is accidentally dropped into your eye.

If there is any doubt, contact your pharmacist or doctor for advice.

While you are using Zaditen

Things you must do

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

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 pharmacist or doctor as soon as possible if you do not feel well while you are using Zaditen.

This medicine may have unwanted side 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 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 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 attention.

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

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

After using Zaditen

Storage

Multidose 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 well.
- **After opening, use the bottle of eye drops for four weeks and then get a new bottle of eye drops, even if there is some left in the old bottle.**
- **Keep your eye drops in a cool dry place where the temperature stays below 25°C.**

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 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 your 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 leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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

If your pharmacist or doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Zaditen comes in a multidose bottle or in strips of 5 single dose units. Each strip of 5 single dose units is sealed in a blister to protect it from light, air and water.

Each bottle contains 2.5 or 5 mL and each single dose unit contains 0.4 mL of a clear, colourless to faintly yellow liquid.

A box of single dose units contains 1 x 5 or 4 x 5 i.e. 5 or 20 single dose units.

Ingredients

Zaditen contains 250 microgram/mL of ketotifen as the active ingredient. It also contains:

- glycerol
- sodium hydroxide
- water for injections.

The multidose bottle also contains:

- benzalkonium chloride.

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

Sponsor

Zaditen is supplied in Australia by:
Novartis Pharmaceuticals Australia
Pty Limited

ABN 18 004 244 160

54 Waterloo Road

North Ryde NSW 2113

Telephone 1-800-671-203

Web site: www.novartis.com.au

Zaditen is supplied in New Zealand
by:

Novartis New Zealand Ltd

Auckland

Telephone 0800-652-422

Web site: www.medsafe.govt.nz

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Multidose Bottle: AUST R 99979

Single Dose Units: AUST R 113770