

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

ZADOMAX RELIEF 0.025% W/V EYEDROPS

Ketotifen fumarate 0.025%w/v

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your healthcare provider.

In this leaflet:

1. What Zadomax Relief Eyedrops is and what it is used for
2. What you need to know before you use Zadomax Relief Eyedrops
3. How to use Zadomax Relief Eyedrops
4. Possible side effects
5. How to store Zadomax Relief Eyedrops
6. Contents of the pack and other information

1. WHAT ZADOMAX RELIEF EYEDROPS IS AND WHAT IT IS USED FOR

Zadomax Relief Eyedrops contains the active substance ketotifen, which is an anti-allergic substance. Zadomax Relief Eyedrops is used to treat eye symptoms of hay fever.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZADOMAX RELIEF EYEDROPS

Do not use Zadomax Relief Eyedrops

If you are allergic (hypersensitive) to ketotifen or any of the other ingredients of this medicine.

Warnings and precautions

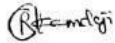



Talk to your doctor, pharmacist, or nurse before using Zadomax Relief Eyedrops.

Other medicines and Zadomax Relief Eyedrops

If you need to apply any other medicinal products to your eyes together with Zadomax Relief Eyedrops, wait at least 5 minutes between applying each product.

Zadomax Relief Eyedrops with food, drink, and alcohol

Zadomax Relief Eyedrops may increase the effect of alcohol.

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Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Zadomax Relief Eyedrops can be used during breast-feeding.

Driving and using machine

Zadomax Relief Eyedrops may cause blurred vision or drowsiness. If this happens to you, wait until this has cleared before driving or operating machinery.

3. HOW TO USE ZADOMAX RELIEF EYEDROPS

Always use this medicine exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults, elderly, and children (age 3 and older) is one drop into the affected eye(s) twice a day (in the morning and evening).

Instructions for use

- Wash your hands.
- Open the bottle. Do not touch the tip after opening the bottle.
- Lean your head back.
- Pull down your lower eyelid with your finger and hold the bottle in your other hand. Squeeze the bottle so that one drop falls into the eye.
- Close your eyes and press the tip of one finger against the corner of the eye for around 1-2 minutes. This will prevent the drop running through the tear duct into your throat and most of the drop will remain in the eye. If necessary, repeat steps 3 to 5 with your other eye.
- Close the bottle after use

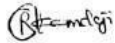


If you have any further questions on the use of this product, ask your doctor, pharmacist, or nurse.

If you use more Zadomax Relief Eyedrops than you should

There is no danger if you have accidentally taken Zadomax Relief Eyedrops by mouth or if you have used more than one drop in the eye. If you have any doubt, contact your doctor for advice.

If you forget to use Zadomax Relief Eyedrops

If you forget to use Zadomax Relief Eyedrops, you should treat your eyes as soon as you remember.

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Then continue with your normal routine. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS ZADOMAX RELIEF EYEDROPS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported.

Common (*affecting less than 1 in every 10 patients*)

- eye irritation or pain.
- inflammation in the eye.

Uncommon (*affecting less than 1 in every 100 patients*)


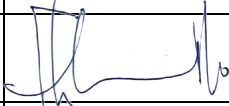

- blurred vision when putting drops on the eye.
- dry eye.
- eyelid disorder.
- conjunctivitis.
- increased sensitivity of the eyes to light.
- visible bleeding in white of eye.
- headache.
- drowsiness.
- rash (which may also itch).
- eczema (itchy, red, burning rash).
- dry mouth.
- allergic reaction (including swelling of the face and eyelids) and increase in severity of existing allergic conditions such as asthma and eczema.

5. HOW TO STORE ZADOMAX RELIEF EYEDROPS

Keep all medicines out of the reach of children.
Store below 30°C, in a dry place.

Do not take Zadomax Relief Eyedrops after the expiry date which is stated on the label after “EXP” The expiry date refers to the last day of that month.

Stop using the bottle 4 weeks after first opening. This is to prevent infections.

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Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Zadomax Relief Eyedrops contains:


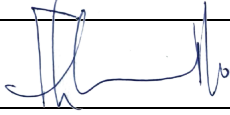

Each ml of Zadomax Relief Eyedrops contains Ketotifen fumarate 0.025% w/v.

What Zadomax Relief Eyedrops looks like and contents of the pack:

It comes in 2.5ml, 5ml and 10ml solution in an LDPE bottle, placed in an outer carton with an insert.

SUPPLIER AND MANUFACTURER

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