

Package leaflet: Information for the user

Zaditen 0.25 mg/ml, eye drops, solution in single-dose containers Ketotifen

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Zaditen is and what it is used for

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

2. What you need to know before you use Zaditen

Do not use Zaditen

If you are allergic (hypersensitive) to ketotifen or any of the other ingredients of this medicine (listed in section 6).

Other medicines and Zaditen

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is particularly important for medicines which are used to treat:

- depression
- allergy (e.g. antihistamine)

Zaditen with food, drink and alcohol

Zaditen may increase the effect of alcohol.

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.

Zaditen can be used during breast-feeding.

Driving and using machines

Zaditen 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 Zaditen

Always use this medicine exactly as your doctor or pharmacist has 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).

One single-dose container contains enough solution to treat both eyes in one application.

Instructions for use

1. Wash your hands.
2. Open the blister pack/pouch and pull out the block of single-dose containers.
3. Remove one of the single-dose containers from the strip (Fig. 1).
4. Place the remaining single-dose containers back and close the blister/pouch by folding the edge over. Place the blister pack/pouch in the carton.
5. Open the single-dose container by twisting off the tip. Do not touch the tip after opening the container (Fig 2).
6. Lean your head back (Fig. 3).
7. Pull down your lower eyelid with your finger and hold the container in your other hand. Squeeze the container so that one drop falls into the eye (Fig 4).
8. Close your eyes and press the tip of one finger against the inner 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 (Fig 5). If necessary repeat steps 6 to 8 with your other eye.
9. Discard the container after use.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5

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

If you use more Zaditen than you should

There is no danger if you have accidentally taken Zaditen 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 Zaditen

If you forget to use Zaditen you should treat your eyes as soon as you remember. Then continue with your normal routine. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system

Ireland
FREEPOST
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zaditen

Keep this medicine out of the sight and reach of children. Do not store above 25°C.
After opening a blister/pouch, any unused single-dose containers can be stored for 3 months if in the outer carton or else for 4 weeks.
The single-dose container is not sterile itself, but its contents are sterile until the container is opened. Once opened, the contents of the single dose container should be used immediately and not saved.
Do not use this medicine after the expiry date, which is stated on the carton after EXP.
The expiry date refers to the last day of that month.
Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zaditen contains

The active substance is ketotifen (as fumarate). Each ml contains 0.345 mg ketotifen fumarate corresponding to 0.25 mg ketotifen.
The other ingredients are glycerol (E422), sodium hydroxide (E524) and water for injections.

What Zaditen looks like and contents of the pack

Zaditen is a clear, colourless to faint yellow solution. One single-dose container contains 0.4 ml. Zaditen is available in packs containing 5, 10, 20, 30, 50 and 60 single-dose containers. Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Laboratoires THEA
12, rue Louis Blériot
63017 Clermont-Ferrand Cedex 2
France

Manufacturer:

Excelvision
27, rue de la Lombardière
07100 Annonay
France

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria.....	Zaditen konservierungsmittelfrei 0,025% - Augentropfen in Einzeldosisbehältnissen
Czech Republic	Zaditen SDU 0,025%
Denmark.....	Zaditen
Finland	Zaditen 0,25 mg/ml silmätipat, liuos kerta-annospakkauksessa
France	Zalerg 0.25 mg/ml eye drops, solution in single-dose container
Germany	Zaditen ophtha sine 0,25 mg/ml Augentropfen Lösung in Einzeldosisbehältnissen
Greece	Zaditor 0,25 mg/ml, οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης
Iceland	Zaditen
Ireland	Zaditen 0.25mg/ml,eye drops, solution in single-dose containers
Italy	Zaditen 0,25 mg/ml collirio soluzione (5, 10, 20, 30, 50, 60) contenitori monodose
Luxembourg	Zaditen ophtha sine 0,25 mg/ml Augentropfen Lösung in Einzeldosisbehältnissen
Norway	Zaditen
Portugal	Zaditen 0,25 mg/ml colírio, solução em unidoses
Spain.....	Zaditen colirio monodosis
Sweden	Zaditen 0,25 mg/ml, ögondroppar, lösning i endosbehållare
The Netherlands	Zaditen Unidose 0,25 mg/ml, oogdruppels, oplossing

This leaflet was last revised in 08/2014