Package Leaflet: Information for the user

23301102

ZADITEN

0.25 mg/ml, eye drops, solution
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, 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, 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. antihistamines)

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.

Zaditen contains benzalkonium chloride
Zaditen contains benzalkonium chloride and may cause eye irritation.
If you wear soft contact lenses you should remove them before using Zaditen as it can discolour your soft contact lenses. You should wait at least 15 minutes after using Zaditen before reinserting your contact lenses into your eyes.

3. How to use Zaditen
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
1. Wash your hands.
2. Open the bottle. Do not touch the tip after opening the bottle.
3. Lean your head back (Fig. 1).
4. 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 (Fig. 2).
5. 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 (Fig. 3). If necessary repeat steps 3 to 5 with your other eye.
6. Close the bottle after use.


Fig. 1


Fig. 2


Fig. 3

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
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.

The bottle is not sterile itself, but its contents are sterile until the bottle is opened.

After opening the bottle, the eye drops can only be stored for 4 weeks.

Do not use this medicine after the expiry date, which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not throw away any 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), water for injections and benzalkonium chloride.

What Zaditen looks like and contents of the pack
Zaditen is a clear, colourless to faint yellow solution. The solution is available in a pack containing one bottle of 5 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Laboratoires THEA
12, rue Louis Blériot, 63017 Clermont-Ferrand Cedex 2, France.

The manufacturer responsible for release on to the market is :
EXCELVISION, 27, rue de la Lombardière, 07100 Annonay, France.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at:
THEA Pharmaceuticals Ltd, telephone number from UK 0345 521 1290, from Ireland +44 (0)345 521 1290.

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

Austria	Zaditen 0,025% - Augentropfen
Czech Republic	Zaditen 0,025%
Denmark	Zaditen
Finland	Zaditen 0,25 mg/ml silmätipat, liuos
France	Zalergonium, 0,25 mg/ml, collyre en solution
Germany	Zaditen ophtha 0,25 mg/ml Augentropfen
Greece	Zaditor οφθαλμικές σταγόνες
Iceland	Zaditen
Ireland	Zaditen 0.25mg/ml, eye drops, solution
Italy	Zaditen 0,25 mg/ml collirio soluzione, 1 flacone da 5 ml
Luxembourg	Zaditen 0,25 mg/ml, collyre en solution
Norway	Zaditen
Portugal	Zaditen 0,25 mg/ml colírio, solução
Spain	Zaditen colirio
Sweden	Zaditen 0,25 mg/ml, ögondroppar, lösning
The Netherlands	Zaditen 0,25 mg/ml, oogdruppels, oplossing
United Kingdom	Zaditen 0.25 mg/ml, eye drops, solution

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