Package leaflet: Information for the user

ZADITEN® 1 mg/5 ml Oral Solution

Ketotifen (as Ketotifen hydrogen fumarate)

Read all of this leaflet carefully before start taking 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Zaditen is and what it is used for
2. What you need to know before you take Zaditen
3. How to take 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

The name of your medicine is Zaditen and it contains ketotifen. It belongs to a group of drugs which have anti-allergic activities and it is used to treat allergic conditions such as rhinitis.

2. What you need to know before you take Zaditen

Do not take Zaditen
- if you are allergic (hypersensitive) to ketotifen or any of the other ingredients (see section 6) of Zaditen.
- if you have epilepsy.
- if you are taking any oral medicines for diabetes.
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zaditen.

- During the first few days of treatment your reactions may be impaired (i.e. you may feel drowsy or your reactions may be slower than usual, even if you do not feel drowsy). You should not take charge of vehicles or machinery until the effect of your medicine on your reactions is known.
- Zaditen may increase the effects of sedatives, anti-histamines, medicines used to treat depression or anxiety, anticoagulants and alcohol.
- As Zaditen may lower the seizure threshold it should be used with caution in patients with a history of epilepsy. Convulsions have been reported very rarely during Zaditen therapy.
- In diabetic patients, the carbohydrate content of the oral solution (5 ml = 3 g carbohydrate) should be taken into consideration.
- Thrombocytopenia may occur in patients taking Zaditen at the same time as oral antidiabetic drugs (biguanides). The simultaneous administration of these drugs should therefore be avoided.
- Do not stop taking asthma medications unless your doctor tells you to, however well you feel

Other medicines and Zaditen
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- If you are taking any medicines for diabetes
- If you are taking any medicines for asthma
- If you are taking any sedatives, medicines to treat depression or anxiety, or anti-histamines (medicines used to treat cold and flu), or anticoagulants.

Zaditen with food, drink and alcohol

- You should not drink alcohol whilst taking Zaditen.

Pregnancy, breast-feeding and fertility
- Ask your doctor or pharmacist for advice before taking any medicine.
- It is not recommended to take Zaditen during pregnancy. If you become pregnant whilst taking Zaditen, tell your doctor.
- Ketotifen is excreted in breast milk; therefore mothers receiving Zaditen should not breast-feed.

Driving and using machines
During the first days of treatment with Zaditen reactions may be impaired. Do not to take charge of vehicles or machinery until the effect of Zaditen treatment on the individual is known.

Zaditen contains maltitol liquid
Contains maltitol liquid (hydrogenated glucose syrup). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Zaditen contains parahydroxybenzoates
This medicine contains parahydroxybenzoates as a preservative and may cause allergic reactions (possibly delayed).

Zaditen contains ethanol
This medicinal product contains 2 vol % ethanol (alcohol), i.e. up to 100 mg per dose, equivalent to 2 ml beer and 0.83 ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

3. How to take Zaditen

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will tell you how much oral solution to take and when to take it. It is important that you follow your doctor's instructions exactly and never change the dose yourself, however well you feel.
- Ask your doctor or pharmacist if you are unsure about how much solution to take or when to take it.
- You should take Zaditen with food.
- Do not stop taking Zaditen unless your doctor tells you to, however well you feel. Discontinuation of treatment should take place gradually over a 2 to 4 week period.

The usual dose is:

<u>Adults and the Elderly:</u>
1 mg (1 x 5 ml spoonful) twice daily with food. If necessary the dose may be increased to 2 mg (2 x 5 ml spoonful) twice daily.
At the higher dose, an accelerated onset of efficacy may be expected.

Use in children:
Children aged 2 to 3 years
Dosage: 0.05 mg (=0.25 ml Zaditen Oral Solution) per kilogram body weight twice daily (morning and evening).

Children over 3 years of age and adolescents:
1 mg (1 x 5 ml spoonful) twice daily with food.

Use in the elderly:
No evidence exists that elderly patients require different dosages or show different side effects from younger patients.

Patients known to be easily sedated should begin treatment with 0.5 to 1 mg (2.5 ml to 5 ml spoonful) at night for the first few days.

If you take more Zaditen than you should
All medicines can be risky if you take too much. If you accidentally take too much Zaditen, tell your doctor immediately or go to your nearest casualty department as soon as possible. Take your medicine pack with you so that people can see what you have taken.

If you forget to take Zaditen
If you miss one dose take it as soon as you remember and take your next dose at its regularly scheduled time. If you miss more than one dose do not take a double dose to make up for forgotten one, just continue with your normal schedule.

If you stop taking Zaditen
Do not stop taking Zaditen unless your doctor tells you to, however well you feel. Discontinuation of treatment should take place gradually over a 2 to 4 week period.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

<u>Some side effects can be serious</u>
Stop taking Zaditen and tell your doctor immediately if you notice any of the following very rare symptoms (likely to affect fewer than 1 of every 10,000 patients)**:**

- If you have skin rash, redness of the skin, blistering of the lips, eyes and mouth accompanied with fever, chills, headache, cough and body aches
- If you have a yellowing of the skin and eyes, coloured bowel motions, dark coloured urine (signs of jaundice, liver disorder, hepatitis)

If any of these apply to you, tell your doctor straight away.

Tell your doctor immediately if you have a fit (convulsions).

Common side effects:
Likely to affect between 1 and 10 of every 100 patients
- Agitation
- Irritability
- Inability to sleep (insomnia)
- Nervousness

Uncommon side effects:
Likely to affect fewer than 1 of every 100 patients
- Dizziness
- Burning sensation when passing urine and need to urinate frequently and urgently (cystitis)
- Dry mouth

Rare side effects:
Likely to affect less than 1 of every 1,000 patients
- Drowsiness
- Weight increased

Not known:
- Somnolence
- Headache
- Vomiting
- Nausea
- Diarrhoea

Other side effects that have been reported are feeling sick or being sick, headache, convulsions (fits), urticaria (hives) or rash.

The sleepiness, dry mouth and dizziness usually go away a few days after you have started taking Zaditen.

Symptoms of CNS stimulation, such as agitation, irritability, insomnia, and nervousness, have been observed particularly in children.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 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 out of the sight and reach of children.
Do not use Zaditen after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of the month.
Do not store above 25°C.
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 the hydrogen fumarate), Each 5 ml of oral solution contains 1 mg ketotifen.
- The other ingredients are propyl parahydroxybenzoate (E216), methyl parahydroxybenzoate (E218), strawberry flavour liquid, citric acid anyhydrous (E330), disodium hydrogen phosphate (E450), ethanol, liquid maltitol (hydrogenated glucose syrup) and purified water.

What Zaditen looks like and contents of the pack
The oral solution is a clear, colourless medicine with a strawberry odour.
Brown glass bottles with a polyethylene closure containing 300 ml.
Amber glass bottle with a child resistant, tamper evident closure containing 300 ml.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Alfasigma S.p.A.
Via Ragazzi del '99, n. 5
40133 Bologna (BO)
Italy

Manufacturer
Famar Orleans
5 avenue de Concyr
F-45071 Orléans
Cedex 2
France

Local representative
CD Pharma S.r.l.
Viale Cassiodoro, 16
20145 Milan
Italy
Tel. +39 02-43980539
info@cdpharmagroup.one

This leaflet was last revised in November 2018