Package leaflet: Information for the user

ZADITEN® 1 mg tablets

{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.

What is in this leaflet:

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 to ketotifen or any of the other ingredients of Zaditen (listed in section 6).
- if you have epilepsy.
- if you are taking any oral medicines for diabetes
- if you are breastfeeding

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.Your doctor may reduce the dose if your reactions are slowed.
- Zaditen may increase the effects of sedatives, anti-histamines, medicines used to treat depression or anxiety, anticoagulants to reduce the ability of the blood to clot 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.
- 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 oral medicines for diabetes
- If you are taking any medicines for asthma
- If you are taking any medicines to treat sleeplessness or anxiety or medicines to treat depression
- If you are taking anti-histamines to treat allergic reactions such as itching, rash or runny nose
- If you are taking any anticoagulants to reduce the ability of the blood to clot

Zaditen with food,drink and alcohol
- You should take Zaditen with food.
- You should not drink alcohol whilst taking these tablets.

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 take charge of vehicles or machinery until the effect of Zaditen treatment on the individual is known.

Zaditen contains lactose
Zaditen contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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 many tablets to take and when to take them. 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 many tablets to take or when to take them.
- You should take your tablets 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.
- Place the tablet in your mouth. Take a mouthful of water, then swallow the tablet whole. You may drink more water afterwards to wash the tablet down.

The usual dose is:

Adults and the Elderly**:**
1 mg (1 tablet) twice daily with food. If necessary the dose may be increased to 2 mg (2 tablets) twice daily. At the higher dose, an accelerated onset of efficacy may be expected.

Use in children:
For younger children, who cannot swallow tablets or where the required dose cannot be administered using tablets, Zaditen Oral Solution 1mg/5ml is available.

Dosage for children 2 to 3 years old: 0.05 mg (=0.25 ml Zaditen Oral Solution 1mg/5ml) per kilogram body weight twice daily (morning and evening).

Children over 3 years of age and adolescents: 1 mg (=5ml Zaditen Oral Solution 1mg/5ml,or 1 tablet) 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 (half a tablet to 1 tablet) 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.

Some side effects can be serious
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 (particularly children)
- 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 this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and foil after EXP. The expiry date refers to the last day of that month.
Leave the tablets in the foil. Only remove them when it is time to take your medicine.
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 protect the environment.

6. Contents of the pack and other information

What Zaditen contains
- The active substance is ketotifen (as the hydrogen fumarate). Each tablet contains 1 mg ketotifen.
- The other ingredients are magnesium stearate, maize starch, pregelatinized maize starch and lactose monohydrate.

What Zaditen looks like and contents of the pack
The tablets are flat, white or yellow-tinged white, circular, bevel-edged and scored. PVC/PVDC blister pack, containing 7, 14 or 28 or 60 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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