

## ZADITEN® Tablets 1 mg (ketotifen)

### Patient Information Leaflet

This medicine will usually be referred to as Zaditen Tablets or Zaditen in this leaflet.

### What you need to know about Zaditen Tablets

Your doctor has decided that you need this medicine to help treat your condition.

### Please read this leaflet carefully before you start to take your medicine. It contains important information. Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist. This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours. 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.

### In this leaflet:

1. What Zaditen Tablets are and what they are used for
2. Things to consider before you start to take Zaditen Tablets
3. How to take Zaditen Tablets
4. Possible side effects
5. How to store Zaditen Tablets
6. Further information

### 1. What Zaditen Tablets are and what they are used for

Zaditen Tablets contains the active ingredient: ketotifen. Ketotifen is an antihistamine with anti-allergy properties.

In allergic conditions certain substances are released in the body. These trigger inflammatory responses. Zaditen Tablets act to dampen down these responses and can therefore be used to treat various allergic conditions such as rhinitis (inflammation of the mucous membranes in the nose) and conjunctivitis (inflammation of the mucous membranes in the eye).

### 2. Things to consider before you start to take Zaditen Tablets

**Some people MUST NOT take Zaditen Tablets. Talk to your doctor if:**

- You think you may be allergic to ketotifen or to any of the other ingredients of Zaditen Tablets. (These are listed in Section 6 of the leaflet.)
- You are pregnant, or planning to become pregnant. Tell your doctor straight away if you become pregnant whilst taking Zaditen Tablets.
- You are breast-feeding.

**You should also ask yourself these questions before taking Zaditen Tablets. If the answer to any of these questions is YES, tell your doctor or pharmacist because Zaditen Tablets might not be the right medicine for you.**

- Do you have epilepsy?
- Do you have an inherited intolerance to some sugars? (The tablets contain a small amount of lactose.)

### Are you taking other medicines?

Some medicines can interfere with your treatment. Make sure your doctor knows if you are taking any of the following:

- Oral medicines for diabetes
  - Medicines to treat sleeplessness or anxiety
  - Anti-histamines to treat allergic reactions such as itching, rash or runny nose.
- Always tell your doctor about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

### Will there be any problems with driving or using machinery?

During the first few days of treatment you may feel that your reactions are slower than usual. Some people can feel drowsy or dizzy. If you are affected in any way you should not drive or do anything that requires you to be alert (such as operate tools or machinery) until any problems clear up.

### Other special warnings

The effects of alcohol may be increased by Zaditen Tablets. Do not drink alcohol when you are taking them.

### 3. How to take Zaditen Tablets

The doctor will decide what dose of Zaditen Tablets you should take. Always take the tablets exactly as your doctor has told you to. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take, and how often. If you are not sure, ask your doctor or pharmacist. Keeping taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

Swallow the tablets with a drink of water. Take them at the same time as you are eating.

### Adults

The usual dose is 1 or 2 mg (1 or 2 tablets) twice a day.

### Children (aged over 3 years)

The usual dose is 1 mg (1 tablet) twice a day.

**Zaditen Tablets should not be given to children under 3 years of age.**

The doctor may decide to start with a lower dose.

### What if you forget to take a dose?

If you forget to take a dose of Zaditen, take another one as soon as you remember, unless it is almost time for your next dose. If it is almost time for your next dose, just take the next dose as you would do normally and miss out the tablets that you have forgotten to take. Do not take a double dose of Zaditen to make up for the tablets you forgot.

### What if you take too many tablets?

All tablets can be risky if you take too many. If you take too many Zaditen Tablets, tell your doctor or hospital casualty department as soon as possible. Take your medicine pack with you so that people can see what you have taken.

### 4. Possible side effects

Zaditen Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects.

**Some side effects can be serious**  
**Stop taking the tablets and tell your doctor immediately if you notice any of the following rare symptoms:**

- A severe skin reaction with blistering or peeling. These might be the symptoms of an allergic reaction.

Tell your doctor immediately if you have a fit.

### The side effects listed below have also been reported:

**Up to 1 in 10 people have experienced:**  
Feeling hyperactive, irritable or nervous, disturbed sleep.

**Up to 1 in 100 people have experienced:**  
Cystitis (a burning or pain when passing urine), feeling dizzy or having a dry mouth

### Up to 1 in 1,000 people have experienced:

Weight gain, feeling sleepy.

### Very rare side effects (likely to affect fewer than 1 in 10,000 people):

Severe skin reactions including rashes, blistering or peeling, convulsions (fits) or problems with their liver including hepatitis or an increase in liver enzymes (this will only show in a blood test).

The sleepiness, dry mouth and dizziness usually go away a few days after you have started taking Zaditen. **If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.**

### 5. How to store Zaditen Tablets

Keep your tablets in the foil. Only remove them when it is time to take your medicine. Store below 25°C.

Keep all medicines out of the reach and sight of children.

Do not take the tablets after their expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking Zaditen Tablets, please take any unused tablets back to your pharmacist to be destroyed. Only keep the tablets if the doctor tells you to. Do not throw them away with your normal household water or waste.

This will help to protect the environment.

### 6. Further information

Zaditen Tablets 1 mg are white, flat tablets with a breakline on one side.

They contain 1 mg of the active ingredient ketotifen (as 1.38 mg of ketotifen hydrogen fumarate). The tablets also contain the inactive ingredients magnesium stearate, pre-gelatinised corn starch, lactose and maize starch.

The tablets come in blister packs of 60.

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Zaditen Tablets are made by Mipharm S.p.A., Via Bernardo Quaranta, 12, 20141 Milan (MI), Italy.

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| MATERIAL NUMBER 932707             |  | LEAFLET               | SIZE 160 x 254 mm |  |                |
| SIGMA-TAU MATERIAL NUMBER 20023853 |  |                       |                   |                                                                                     |                |
| PN 714026                          |  | ZADITEN TABLS 1 ML    |                   | U.K.                                                                                | PLANT: MIPHARM |
| NUMBER OF COLORS: 1                |  |                       |                   |                                                                                     |                |
| Version 1<br>11-11-13              |  | Version 2<br>26-11-13 |                   | Pantone<br>314 C                                                                    |                |
| NEW PN                             |  |                       |                   |                                                                                     |                |
| APPROVAL                           |  |                       |                   |                                                                                     |                |
| TEXT APPROVAL                      |  | TECHNICAL APPROVAL    |                   | SIGMA-TAU APPROVAL                                                                  |                |

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