

ZADITEN® Elixir 1 mg/5 ml (ketotifen)

Patient Information Leaflet

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

What you need to know about Zaditen Elixir

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 Elixir is, and what it's used for
2. Things to consider before you start to take Zaditen Elixir
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4. Possible side effects
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1. What Zaditen Elixir is and what it's used for

Zaditen Elixir 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 Elixir acts 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 Elixir

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

- You think you may be allergic to ketotifen or to any of the other ingredients of Zaditen Elixir. (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 Elixir.
- You are breast-feeding.

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

- Do you have epilepsy?
- Do you have an inherited intolerance to some sugars? (The Elixir contains a small amount of maltitol.)

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 where you need to be alert (such as operate tools or machinery) until any problems clear up.

Other special warnings

- Zaditen Elixir contains small amounts of the preservatives methyl and propyl hydroxybenzoate. These can sometimes cause allergic reactions which might appear some time after first taking the elixir.
- Zaditen Elixir contains ethanol (alcohol). 5 ml of the elixir contains nearly 0.1 g of ethanol. A daily dose of 20 ml (4 mg ketotifen), will contain nearly 0.4 g of ethanol. This is less than a glass of wine or a pint of beer, but will affect your blood alcohol levels.
- The effects of alcohol may be increased by Zaditen Elixir. Do not drink alcohol if you are taking Zaditen.

3. How to take Zaditen Elixir

The doctor will decide what dose of Zaditen Elixir you should take. Always take the Elixir 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 much Elixir to take, and how often. If you are not sure, ask your doctor or pharmacist. Keep taking the Elixir for as long as you have been told unless you have any problems. In that case, check with your doctor.

Take at the same time as you are eating.

Adults

The usual dose is 1 or 2 mg (One or two 5 ml spoonful) twice a day.

Children (aged over 3 years)

The usual dose is 1 mg (One 5 ml spoonful) twice a day.

Zaditen Elixir 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 dose that you have forgotten to take. Do not take a double dose of Zaditen to make up for the dose you forgot.

What if you take too much?

All medicines can be risky if you take too much. If you take too much Zaditen Elixir, 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 Elixir is suitable for most people, but, like all medicines, it can sometimes cause side effects.

Some side effects can be serious

Stop taking the Elixir 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 Elixir

Store below 25°C.

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

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

If your doctor tells you to stop taking Zaditen Elixir, please take any which you haven't used back to your pharmacist to be destroyed. Only keep it if the doctor tells you to. Do not throw it away with your normal household water or waste. This will help to protect the environment.

6. Further information

Zaditen Elixir is a clear, strawberry-flavoured liquid containing 1 mg of the active ingredient ketotifen (as 1.38 mg of ketotifen hydrogen fumarate) in each 5 ml. The Elixir also contains methyl and propyl hydroxybenzoate, citric acid, disodium phosphate, 96% v/v ethanol, maltitol liquid and purified water.

It comes in bottles of 150 or 300 ml. Some of the pack sizes may not be available.

The product licence holder is Novartis Pharmaceuticals UK Limited trading as Sandoz Pharmaceuticals, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, England. Zaditen Elixir is made by Famar France, Site Industriel d'Orleans, Avenue du Champ de Mars, F-45072 Orleans, France-

This leaflet was revised in August 2008.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at Novartis Pharmaceuticals UK Ltd, telephone number 01276 698370.

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