

Zofran[®] Zydis[®] Wafers

Ondansetron

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start taking Zofran Zydis wafers.

This leaflet answers some common questions about Zofran Zydis wafers. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zofran Zydis wafers against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Zofran Zydis wafers are used for

Zofran Zydis wafers belong to a group of medicines called antiemetics.

Zofran Zydis wafers work by helping to stop the nausea (sick feeling) and vomiting which can occur after certain

treatments. 'Wafer' used in the product name, is the word used for the special type of tablet which dissolves in a few seconds when placed on the tongue. It is easier to swallow than ordinary tablets.

Zofran Zydis wafers should only be used to treat the nausea and vomiting for which they have been prescribed.

Your doctor may have prescribed Zofran Zydis wafers for another reason.

Ask your doctor if you have any questions about why Zofran Zydis wafers have been prescribed for you.

Zofran Zydis wafers are not addictive.

Before you take Zofran Zydis wafers

When you must not take them

Do not take Zofran Zydis wafers if you have ever had an allergic reaction to ondansetron or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing,

hayfever, lumpy rash ("hives") or fainting.

- **Do not take Zofran Zydis wafers if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using Zofran Zydis wafers if you are pregnant or breastfeeding.

Do not take Zofran Zydis wafers after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take Zofran Zydis wafers if the packaging is torn or shows signs of tampering.

If you're not sure whether you should be taking Zofran Zydis wafers, talk to your doctor.

Before you start to take them

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **you have, or used to have, liver problems**

- **you suffer from severe constipation or have a blockage in your gut**
- **you have phenylketonuria, as Zofran Zydis wafers contain aspartame.**

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Zofran Zydis wafers with other medicines.

Use in children

There is limited experience in children. Zofran Zydis wafers can be taken by children over 4 years of age.

How to take Zofran Zydis wafers

The Pharmacist's label on the pack will tell you how to take Zofran Zydis wafers. If there is something you do not understand, ask your doctor or pharmacist.

How much to take

DO NOT take more Zofran Zydis wafers than your doctor or pharmacist tells you.

DO NOT take Zofran Zydis wafers MORE OFTEN than

your doctor or pharmacist tells you.

If you vomit within one hour of taking your first Zofran Zydis wafer of each course prescribed for you, you should take the same dose again. If you continue to vomit, tell your doctor.

How to take them

PEEL BACK the foil top of the blister strip and GENTLY remove the Zofran Zydis wafer. (DO NOT try to push it through the foil top as the wafer is fragile and will break up inside the foil). Place the Zofran Zydis wafer on top of your tongue. It will disappear very quickly, then swallow as normal.

When to take them

Your doctor or pharmacist will be able to tell you when you should take your Zofran Zydis wafers.

How long to take them

Your doctor or pharmacist will be able to tell you how long you should take your Zofran Zydis wafers.

If you forget to take them

If you miss your dose and you do not feel sick take your next dose when you are meant to.

If you miss your dose, and you feel sick, take the missed dose as soon as possible, then go back to taking your Zofran Zydis wafer as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Zofran Zydis wafers, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Zofran Zydis wafers

Things you must do

Tell your doctor or pharmacist that you are taking Zofran Zydis wafers if you are about to be started on any new medicines. Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking Zofran Zydys wafers, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Zofran Zydys wafers to treat any other complaints unless your doctor says to.

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking Zofran Zydys wafers, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Zofran Zydys wafers can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- headache
- a sensation of warmth or flushing
- mild stomach cramps
- constipation or diarrhoea
- dry mouth
- hiccups
- dizziness or light-headed feeling

Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor or pharmacist immediately if you notice any of the following:

- chest pain or tightness of chest
- changes in the way your heart beats eg if you notice it beating faster or slower than normal, or if it beats irregularly or if it 'throbs'
- low blood pressure
- abnormal muscular body movements or shaking
- involuntary upward movement of the eyes
- unusual muscle tone causing distortion of the body
- fits or convulsions

If you think you are having an allergic reaction to Zofran Zydys wafers, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- **wheezing**
- **swelling of the lips/mouth**
- **difficulty in breathing**
- **hay fever**
- **lumpy rash ("hives")**
- **fainting**

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

If your nausea (feeling of sickness) or vomiting does not go away, ask your doctor what to do.

In certain illnesses and treatments where Zofran has been used, blood vessel blockage has occurred.

However, it is important to note that blood vessel blockage has also occurred in these illnesses and treatments when Zofran has NOT been used. Discuss this with your doctor if you have any concerns.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking Zofran Zydys wafers

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Keep Zofran Zydys wafers in a cool, dry place where it stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your Zofran Zydys wafers in their pack until it is time to take them.

If taken out of their pack, they may not keep well.

Disposal

If your doctor tells you to stop taking Zofran Zydys wafers, or they have passed their expiry date, ask your pharmacist what to do with any wafers left over.

Product description

What Zofran Zydys wafers look like.

Zofran Zydys is a special type of tablet called a 'wafer'.

Zofran Zydys wafers are white, round wafers, with no markings on either side. They come in a foil blister pack of 4 or 10 wafers, which are contained in a box. There is a 4 mg strength and an 8 mg strength.

Ingredients

Zofran Zydys wafers contain either 4 mg or 8 mg of the active ingredient ondansetron. They also contain gelatin, mannitol, aspartame, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate and strawberry flavour.

Zofran Zydys wafers do not contain gluten or lactose.

Manufacturer

Your Zofran Zydys wafers are supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia Victoria 3155
Australia.

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 16 January 2003.

The information provided applies only to: Zofran[®] Zydys[®] wafers.

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[®]Zydys is a registered trade mark of RP Scherer Corporation.

Zofran Zydys Wafers 4 mg:
AUST R 63054

Zofran Zydys Wafers 8 mg:
AUST R 63055.

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