Consumer Medicine Information

What is in this leaflet

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

This leaflet answers some common questions about Ondaz 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 Ondaz 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 Ondaz Zydis wafers are used for

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

Ondaz 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.

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

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Before you take Ondaz Zydis wafers

When you must not take it

- Do not take this medicine if you have an allergy to ondansetron, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description.
 - 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 this medicine 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 Ondaz Zydis wafers if you are pregnant or breastfeeding.

- Do not take this medicine if you are taking apomorphine (used to treat Parkinson's disease)
- Do not take this medicine 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 this medicine if the packaging is torn or shows signs of tampering.
 If you're not sure whether you should be taking Ondaz Zydis wafers, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- you have allergies to any other medicines, foods, preservatives or dyes.
- · you have or used to have liver problems
- you suffer from severe constipation or have a blockage in your gut
- you have phenylketonuria, as Ondaz Zydis wafers contain aspartame.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect the way others work.

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

Use in children

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

How to take Ondaz Zydis wafers

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

How much to take

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

DO NOT take Ondaz Zydis wafers MORE OFTEN than your doctor or pharmacist tells you.

If you vomit within one hour of taking your first Ondaz 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 it

PEEL BACK the foil top of the blister strip and GENTLY remove the Ondaz 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 Ondaz Zydis wafer on top of your tongue. It will disappear very quickly, then swallow as normal.

When to take Ondaz Zydis

Your doctor or pharmacist will be able to tell you when you should take this medicine.

How long to take Ondaz Zydis

Your doctor or pharmacist will be able to tell you how long you should take this medicine.

If you forget to take it

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 Ondaz 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 the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Ondaz Zydis wafers. Do this 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 Ondaz Zydis wafers

Things you must do

Tell your doctor or pharmacist that you are taking Ondaz 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 your medicine or change the dose without checking with your doctor.

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

Do not take Ondaz Zydis wafers to treat any other complaints unless your doctor tells you to

Side effects

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

Like other medicines, Ondaz Zydis 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.

Do not be alarmed by this list of possible sideeffects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The most commonly reported side-effects are:

- headache
- a sensation of warmth or flushing
- · mild stomach cramps
- constipation or diarrhoea
- dry mouth
- hiccups
- burning sensation at the site of injection

Tell your doctor or pharmacist immediately if you notice any of the following:

- · chest pain or tightness of the chest
- changes in the way your heart beats e.g. 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 Ondaz Zydis 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 sideeffects. 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 Ondaz 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 Ondaz 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.

Other side effects not listed above may also occur in some people.

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

After taking Ondaz Zydis wafers

Storage

Keep it 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 your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Ondaz Zydis wafers or any other medicine in a bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep your Ondaz Zydis 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 Ondaz Zydis wafers, or they have passed their expiry date, ask your pharmacist what to do with any wafers left over.

Product description

What it looks like

Ondaz Zydis is a special type of tablet called a 'wafer'.

Ondaz Zydis comes in two types of wafers:

- Ondaz Zydis 4mg white, round wafers, with no markings on either side.
- Ondaz Zydis 8mg white, round wafers, with no markings on either side.

Available in a foil blister pack of 4 or 10 wafers, which are contained in a box.

Ingredients

Active Ingredient:

- Ondaz Zydis 4mg 4mg ondansetron
- Ondaz Zydis 8mg 8mg ondansetron.

Inactive Ingredients:

- gelatin
- mannitol
- aspartame
- sodium methyl hydroxybenzoate
- sodium propyl hydroxybenzoate
- strawberry flavour.

Ondaz Zydis wafers do not contain gluten or lactose.

Supplier

Ondaz Zydis wafers are supplied in Australia by:

Sandoz Pty Ltd ABN 60 075 449 553

19 Harris St

Pyrmont NSW 2009

Tel: 1800 634 500

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

This leaflet was revised in January 2012.

Australian Register Number(s):

4mg wafers: AUST R 116430 (blisters) 8mg wafers: AUST R 116435 (blisters)