Package Leaflet: Information for the User
Zofran® Zydis 4 mg and 8 mg Oral Lyophilisate
ondansetron

Read all of this leaflet carefully before you 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 about your illness or your medicine, ask your doctor, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Zofran Zydis is and what it is used for

Zofran Zydis contains a medicine called ondansetron. This belongs to a group of medicines called anti-emetics. Zofran Zydis is a special type of Zofran tablet that dissolves very quickly when put on top of the tongue.

Zofran Zydis is used for:

• preventing nausea and vomiting caused by chemotherapy or radiotherapy for cancer in **adults**
• preventing nausea and vomiting after surgery in **adults**
• preventing nausea and vomiting caused by chemotherapy for cancer in **children and adolescents** aged 6 months to 17 years.

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses. Zofran Zydis should start to work within one or two hours of taking a dose. You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Zofran Zydis

Do not take Zofran Zydis if:
- if you are taking apomorphine (used to treat Parkinson's Disease)
- you are allergic (hypersensitive) to ondansetron or any of the other ingredients in Zofran Zydis (listed in Section 6).

If you are not sure, talk to your doctor, nurse or pharmacist before taking Zofran Zydis.

Warnings and precautions
Check with your doctor or pharmacist before taking Zofran Zydis if:
- you have ever had heart problems
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to ondansetron, such as granisetron (known as 'Kytril')
- you have liver problems
- if you have a condition called phenylketonuria, which is an inability to break down amino acids

- you have a blockage in your gut
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before taking Zofran Zydis.

Other medicines and Zofran Zydis
Please tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Zofran can affect the way some medicines work. Also some other medicines can affect the way Zofran works.

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines:
- carbamazepine or phenytoin used to treat epilepsy, as these medicines may reduce the effect of Zofran
- rifampicin used to treat infections such as tuberculosis (TB), as this medicine may reduce the effect of Zofran
- anti-arrhythmic medicines used to treat an uneven heart beat, as these medicines may interact with Zofran and effect the rhythm of the heart
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines, as these medicines may interact with Zofran and effect the rhythm of the heart
- tramadol, a pain killer, as Zofran may reduce the effect of tramadol
- medicines that affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines), as these may interact with Zofran to cause heart arrhythmias
- medicines used to treat depression and/or anxiety:
    - o SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
    - o SNRIs (serotonin noradrenaline reuptake inhibitors) including venlafaxine, duloxetine

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having Zofran Zydis.

Tell your doctor or pharmacist immediately if you get any of these symptoms during and after the treatment with ZYDIS

- if you experience sudden chest pain or chest tightness (myocardial ischemia).

Pregnancy, breast-feeding and fertility
You should not use Zofran during the first trimester of pregnancy. This is because Zofran can slightly increase the risk of a baby being born with cleft lip and/or cleft palate (openings or splits in the upper lip and/or the roof of the mouth). If you are already pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Zofran. If you are a woman of childbearing potential you may be advised to use effective contraception.

There is insufficient information on the excretion of ondansetron/metabolites in human milk or the effects of Zofran on milk production. A risk to the newborns/infants cannot be excluded. Zofran should not be used during breast-feeding.

Driving and using machines
It is not expected that Zofran will affect your ability to drive; however if any of the side effects (listed section 4) affect you (e.g. dizziness, blurred vision) caution is advisable. **Do not drive or operate machines if you are feeling unwell.**

Zofran Zydis contains aspartame, sodium, sodium methyl para-hydroxybenzoate (E219) and sodium propyl para-hydroxybenzoate (E217) and ethanol.

Zofran Zydis 4mg Oral Lyophilisate tablet contains 0.625 mg aspartame (E951) per tablet.
Zofran Zydis 8mg Oral Lyophilisate tablet contains 1.25 mg aspartame (E951) per tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. If you have an inherited illness called phenylketonuria speak to your doctor before taking this medicine.

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

This medicine contains sodium methyl para-hydroxybenzoate (E219) and sodium propyl para-hydroxybenzoate (E217). This may cause allergic reactions (which could be delayed).

Zofran Zydis 4mg tablet contains less than 0.031mg of alcohol (ethanol) in each 4mg Oral lyophilisate tablet which is equivalent to 0.23%w/w.

Zofran Zydis 8mg tablet contains less than 0.063mg of alcohol (ethanol) in each 8mg Oral lyophilisate tablet which is equivalent to 0.23%w/w.

The amount in one tablet of this medicine is equivalent to less than 1 ml of beer or 1 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Zofran Zydis

Always take Zofran Zydis exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.
The dose you have been prescribed will depend on the treatment you are having.

To prevent nausea and vomiting from chemotherapy or radiotherapy
Adults:

On the day of chemotherapy or radiotherapy
- the usual adult dose is 8 mg taken one to two hours before treatment and another 8 mg twelve hours after**.**

On the following days
- the usual adult dose is 8 mg twice a day
- this may be given for up to 5 days.

If your chemotherapy or radiotherapy is likely to cause severe nausea and vomiting, you may be given more than the usual dose of Zofran. Your doctor will decide this.

Children and Adolescents (aged 6 months to 17 years): To prevent nausea and vomiting from chemotherapy only
The doctor will decide the dose. Look at the label for more information.
• the usual dose for a child is up to 4 mg twice a day this can be given for up to 5 days.

Infants under 6 months of age:
Zofran is not recommended in infants under 6 months of age for the prevention of nausea and vomiting from chemotherapy.

To prevent nausea and vomiting after an operation
Adults:
The usual adult dose is 16 mg given an hour before your operation

Children and Adolescents (aged 1 month to 17 years):
Children aged 2 years and over
It is recommended that Zofran is given as an injection.

Children aged under 2 years
There is little information on the correct dose of Zofran for the treatment of nausea and vomiting after an operation in children under 2 years of age. The doctor will decide the correct dose.

Patients with moderate or severe liver problems
The total daily dose should not be more than 8 mg. If you have blood tests to check how your liver is working, this medicine may affect the results.

If you are sick (vomit) within one hour of taking a dose
• tell your doctor or nurse.
If you continue to feel sick, tell your doctor or nurse.

If you take more Zofran Zydis than you should
If you or your child take more Zofran than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Zofran Zydis
If you miss a dose **and** feel sick or vomit:
• take a Zofran Zydis as soon as possible, then
• take your next tablet at the usual time (as shown on the label)
• do not take a double dose to make up for a forgotten dose.

If you miss a dose but do not feel sick
• take the next dose as shown on the label
• do not take a double dose to make up for a forgotten dose.
• Important: A minimum time interval of 12 hours must allowed between doses

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

How to remove Zofran Zydis from the blister and take the medicine

- Do not take a Zofran Zydis tablet out from its blister until you are ready to take it.
- Before you take the Zofran Zydis make sure the foil packaging has not been pierced.

Important: Do not try to push Zofran Zydis through the foil top like a usual tablet. This is because Zofran Zydis is fragile and will break.

1. **Tear off one Zofran Zydis in its blister.**
2. **Peel back the foil, as shown by the arrow**
3. **Gently push out the Zofran Zydis tablet**
4. **Place the Zofran Zydis on top of the tongue. It will dissolve very quickly. Then you can swallow as normal.**

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious

STOP taking or receiving ZYDIS and seek medical help immediately if you or your child experience any of the following:

Allergic reactions

These reactions are rare in people taking Zofran. If you have an allergic reaction, stop taking it and see a doctor straight away. The signs may include:

- sudden wheezing and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- skin rash – red spots or lumps under your skin (hives) anywhere on your body
- collapse.

Myocardial ischemia: Signs include:

- sudden chest pain or
- chest tightness

Other side effects include:

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common (affects more than 1 in 10 people)

- headache.

Common (affects less than 1 in 10 people)

- a feeling of warmth or flushing
- constipation
- changes to liver function test results (if you take Zofran Zydis with a medicine called cisplatin, otherwise this side effect is uncommon).

Uncommon (affects less than 1 in 100 people)

- hiccups

- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat
- chest pain
- slow heart rate
- fits
- unusual body movements or shaking.

Rare (affects less than 1 in 1,000 people)
- feeling dizzy or light headed during IV administration
- blurred vision.
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

Very rare (affects less than 1 in 10,000 people)
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

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, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zofran Zydis

- Keep out of the reach and sight of children.
- Do not use Zofran Zydis after the expiry date which is stated on the pack after 'Exp'. The expiry date refers to the last day of that month.
- Do not store Zofran Zydis above 30°C.
- Store in the original package in order to protect from light and moisture.
- Zofran Zydis should only be taken out of the blister immediately before taking it.
- 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 help protect the environment.

6. Contents of the pack and other information

What Zofran Zydis contains
• The active ingredient is ondansetron. Each Zofran Zydis contains ondansetron 4 mg or 8 mg.
The other ingredients are gelatin, mannitol, aspartame (E951), sodium methyl para-hydroxybenzoate (E219), sodium propyl para-hydroxybenzoate (E217), strawberry flavoring (contains ethanol)

What Zofran Zydis looks like and contents of the pack
Zofran Zydis is a white round oral lyophilisate. Each pack contains 10 Zofran Zydis units.

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