

Package leaflet : Information for the User

Zofran® Zydys 4mg 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 Zydys is and what it is used for
2. What you need to know before you take Zofran Zydys
3. How to take Zofran Zydys
4. Possible side effects
5. How to store Zofran Zydys
6. Contents of the pack and other information

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

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

Zofran Zydys 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 Zydys 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 Zydys

Do not take Zofran Zydys 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 Zydys (listed in Section 6).

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

Warnings and precautions

Check with your doctor or pharmacist before taking Zofran Zydys 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 'Kytrel')
- you have liver problems
- 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 Zydys.

Other medicines and Zofran

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 & affect 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 affect 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:
 - SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
 - 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 Zydys.

Pregnancy and breast-feeding

It is not known if Zofran is safe during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

Do not breast-feed if you are taking Zofran. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

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.**

Important information about some of the ingredients of Zofran Zydys

- This medicine contains aspartame (E951) (which is a source of phenylalanine). If you have an inherited illness called phenylketonuria speak to your doctor before taking this medicine as this may be harmful for people with phenylketonuria
- This medicine contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217). This may cause allergic reactions (which could be delayed).

3. How to take Zofran Zydys

Always take Zofran Zydys 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 & Adolescents (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 treatment 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 & 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 & 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.

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.



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 be allowed between doses

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

4. Possible side effects

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

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.

Other side effects include:

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister 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 substance is ondansetron. Each oral lyophilisate contains 4 mg ondansetron. The other ingredients are gelatin, mannitol (E421), aspartame (E951), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), strawberry flavour (The strawberry flavour has the following composition: artificial flavouring substances, natural flavouring substances and propylene glycol (E1520)).

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.

Manufacturer:

Novartis Farmaceutica, S.A., Ronda de Santa Maria, 158 – Barbera del Valles, 08210 Barcelona, Spain

Parallel Product Authorisation number: PPA 465/445/1

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Zofran is a registered trademark of the Novartis AG.

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