

Package Leaflet: Information for the User

Zofran® 4 mg film-coated tablets Zofran® 8 mg film-coated tablets 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 tablets are and what they are used for
2. What you need to know before you take Zofran tablets
3. How to take Zofran tablets
4. Possible side effects
5. How to store Zofran tablets
6. Contents of the pack and other information

1. What Zofran tablets are and what they are used for

Zofran tablets contain a medicine called ondansetron. This belongs to a group of medicines called anti-emetics. Zofran tablets are 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 tablets 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 tablets

Do not take Zofran tablets 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 tablets (listed in Section 6). If you are not sure, talk to your doctor, nurse or pharmacist before taking Zofran tablets.

Warnings and precautions

Check with your doctor or pharmacist before taking Zofran tablets 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
- you have a blockage in your gut or suffer from severe constipation
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.
- you are intolerant to some sugars (see section 2)

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

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 & 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 Ondansetron 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 tablets.

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

- 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 Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking this medicine

3. How to take Zofran tablets

Always take Zofran tablets 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 (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 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 prevention 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.

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 tablets 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 tablets

If you miss a dose **and** feel sick or vomit:

- take Zofran tablets 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.

Some side effects could be serious

STOP taking or receiving ZOFRAN 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 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 tablets 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 tablets

- 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.
- Store below 30°C.
- 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 will help protect the environment.

6. Contents of the pack and other information

What Zofran tablets contain

- The active substance is ondansetron. Each film-coated tablet contains 4 mg or 8 mg of ondansetron (as hydrochloride dihydrate).
- The other ingredients are lactose anhydrous (see section 2), microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, hypromellose, Opaspray Yellow M-1-8429.

What Zofran tablets look like and contents of the pack

- Zofran tablets are yellow, oval, film-coated tablets and come in two strengths.
- The 4 mg tablets contain 4 mg of the active ingredient ondansetron and are marked with "GXET3" on one face and plain on the other face.
- The 8 mg tablets contain 8 mg of the active ingredient ondansetron and are marked with "GXET5" on one face and plain on the other face.

Zofran tablets come in blister packs of 15 tablets.

Parallel Product Authorisation holder

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by

Novartis (Hellas) A.E.B.E., Greece or Aspen Bad Oldesloe GMBH, Germany or Novartis Pharma GmbH, Germany or Novartis Farmaceutica, S.A., Spain or LEK Pharmaceuticals d.d., Slovenia.

Repackaged by

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