

Package Leaflet: Information for the User
Zofran® 16 mg Suppositories
ondansetron

Read all of this leaflet carefully before you start using 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 suppositories are and what they are used for
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1 What Zofran Suppositories are and what they are used for

Zofran suppositories contain a medicine called ondansetron. This belongs to a group of medicines called anti-emetics. **Zofran suppositories are for use in your back passage only (rectal use). They should not be swallowed.**

Zofran suppositories are used for:

- preventing nausea and vomiting caused by chemotherapy or radiotherapy for cancer
- Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

Zofran suppositories 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 use Zofran Suppositories

Do not use Zofran suppositories 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 suppositories (listed in section 6). If you are not sure, talk to your doctor, nurse or pharmacist before using Zofran suppositories.

Warnings and precautions

Check with your doctor or pharmacist before using Zofran suppositories 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.

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

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 using Zofran suppositories.

Pregnancy, breast-feeding and fertility

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 using Zofran. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

If you are a woman of childbearing age, your doctor or healthcare provider will check if you are pregnant and perform a pregnancy test if necessary before starting treatment with Zofran. If you may become pregnant, you should use effective birth control during treatment with Zofran. Ask your doctor about options of effective birth control.

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.**

3 How to use Zofran suppositories

Always use Zofran suppositories exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

Dosage

On the day of chemotherapy or radiotherapy:

- the usual dose is one suppository (16 mg) to be inserted 1 to 2 hours before treatment.

On the following days:

- the usual dose is one suppository (16 mg) each day
- this may be repeated for up to 3 days, depending on the strength of your chemotherapy.

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

Zofran suppositories are not recommended for children.

Patients with moderate or severe liver problems

You should use Zofran as injection or tablets because the total daily dose should not be more than 8 mg. If you have any blood tests to check how liver is working, this medicine may affect the results.

Using Zofran suppositories

1. Zofran suppositories are for use in your back passage only (rectal use). They should not be swallowed.
2. Empty your bowels if you need to. Wash your hands.
3. Remove the suppository from its packaging by tearing the foil (see illustration on pack)
4. You may find that inserting the suppository is easier if you squat or bend forward
5. Gently push the pointed end of the suppository into the back passage (rectum)
6. Push the suppository in as far as possible and remain still for a little while. This allows the suppository to melt so the medicine will work
7. Wash your hands
8. Try not to empty your bowels within 1 hour of inserting the suppository.
9. If your suppository comes out of your back passage, push it back in as far as possible and remain still for a while. Wash your hands again.

If you use more Zofran suppositories than you should

If you or your child use more Zofran suppositories than you should, or accidentally swallow one, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to use Zofran suppositories

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

- use a Zofran suppository as soon as possible, then
- use your next suppository at the usual time the next day (as shown on the label)
- do not use a double dose to make up for a forgotten dose.

If you miss a dose but do not feel sick

- use the next dose as shown on the label
- do not use a double dose to make up for a forgotten dose.

Important: Only one Zofran suppository can be used per day.

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, the 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 using 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
- Local burning sensation following insertion of suppositories
- changes to liver function test results (if you use Zofran suppositories 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 suppositories

- Keep out of the reach and sight of children.
- Do not use Zofran suppositories 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 suppositories above 30°C.
- Store in the original package in order to protect from light and moisture.
- Zofran suppositories should only be taken out of the blister immediately before use.
- 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 suppositories contain

- The active ingredient is ondansetron. Each Zofran suppository contains ondansetron 16 mg.
- The other ingredient is Witespol S58, which contains hard fat, cetomacrogol 1000 and Glyceryl ricinoleate.

What Zofran suppositories look like and contents of the pack

Zofran suppository is white, smooth and torpedo shaped. Each suppository is in an individually sealed cavity enclosed in a perforated cardboard mount and packed into a carton.

Zofran suppositories are available in pack sizes of one suppository.

Marketing Authorisation Holder

Novartis Pharmaceuticals Ireland Limited, Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland.

Manufacturer

Novartis Pharma GmbH, Roonstraße 25, D-90429 Nuremberg, Germany

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