

Package Leaflet: Information for the User
Zofran® 4 mg/5 ml Syrup
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 syrup is and what it is used for
2. What you need to know before you take Zofran syrup
3. How to take Zofran syrup
4. Possible side effects
5. How to store Zofran syrup
6. Contents of the pack and other information

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

Zofran syrup contains a medicine called ondansetron. This belongs to a group of medicines called anti-emetics.

Zofran syrup 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 syrup 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 syrup

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

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

Warnings and precautions

Check with your doctor or pharmacist before taking Zofran syrup 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

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

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).

Other medicines and Zofran

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken 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 Ondansetron 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 syrup.

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.

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 syrup contains sorbitol, ethanol, sodium and sodium benzoate

Each 5ml of Zofran contains sorbitol (E420), with a calorific value of 2.6kcal/g sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Ethanol: This medicine contains alcohol (ethanol). The small amount of alcohol in this medicine will not have any noticeable effects.

Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially "sodium free"

Sodium benzoate: This medicine contains sodium benzoate.

3. How to take Zofran syrup

Always take Zofran syrup 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. Do not mix Zofran syrup with anything (not even water) before swallowing it.

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 (two 5 ml spoonfuls) 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 (one 5 ml spoonful) 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 16mg 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 (two 5 ml spoonfuls). 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 syrup 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 syrup

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

- take Zofran syrup as soon as possible, then
- take your next dose 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 syrup 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 HPRC 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 syrup

- Keep out of the sight and reach of children.
- Do not use Zofran syrup after the expiry date which is stated on the bottle and carton after 'EXP'. The expiry date refers to the last day of that month.

- Do not store Zofran syrup above 25°C.
- Do not refrigerate or freeze. Keep the bottle upright.
- Use within 28 days after opening.
- 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 syrup contains

- The active ingredient is ondansetron. Each 5 ml spoonful of Zofran syrup contains 4mg of ondansetron (as ondansetron hydrochloride dihydrate)
- The other ingredients are anhydrous citric acid (E330), sodium citrate dihydrate (E331), sodium benzoate (E211), sorbitol 70% (crystallising) (E420), strawberry flavour (ethanol) and purified water.

What Zofran syrup looks like and contents of the pack

Zofran syrup is a sugar-free, strawberry flavoured liquid. It is packed in 60 ml amber glass bottles with a child resistant cap containing 50 ml of Zofran syrup.

Parallel Product Authorisation Holder:

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

Manufacturer:

Novartis Poland Sp. z.o.o., Ul. Marynarska 15, 02-674 Warsaw, Poland.

Repackaged by:

Cast Healthcare Ltd, Unit E The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK or IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

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