

PATIENT INFORMATION LEAFLET

Zofran® 4mg Melt

(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 symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Zofran 4mg Melt but will be referred to as Zofran Melt throughout this leaflet. Also available in other strength.

What is in this leaflet:

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

1. WHAT ZOFRAN MELT IS AND WHAT IT IS USED FOR

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

Zofran Melt is used for:

- preventing nausea and vomiting caused by chemotherapy (in adults and children) or radiotherapy for cancer (adults only)
- preventing nausea and vomiting after surgery (adults only).

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOFRAN MELT

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

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

Warnings and precautions

Check with your doctor, nurse or pharmacist before taking Zofran Melt if:

- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- you have liver problems
- you have a blockage in your gut
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

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

Other medicines and Zofran

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take 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
- rifampicin used to treat infections such as tuberculosis (TB)
- antibiotics such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- tramadol, a pain killer.
- medicines that affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines and trastuzumab)
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety 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 Melt.

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 and breast-feeding

Only use during the first trimester of pregnancy after discussion with your doctor of the potential benefits and risks to you and your unborn baby of the different treatment options. 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.

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.

Important information about some of the ingredients of Zofran Melt

- Zofran Melt 4 mg contains 0.625 mg aspartame per tablet; Zofran Melt 8 mg contains 1.25 mg aspartame 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. Speak to your doctor before taking this medicine.
- This medicine contains sodium methyl para-hydroxybenzoate and sodium propyl para-hydroxybenzoate. This may cause allergic reactions (possibly delayed).

- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
- Zofran Melt 4 mg contains 0.000025 mg of benzyl alcohol per tablet; Zofran Melt 8 mg contains 0.00005 mg of benzyl alcohol per tablet. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called metabolic acidosis).
- Zofran Melt 4 mg contains less than 0.03 mg of alcohol (ethanol) per tablet which is equivalent to 0.23%w/w. Zofran Melt 8 mg contains less than 0.06 mg of alcohol (ethanol) per tablet which is equivalent to 0.23%w/w. The amount in one 4mg or 8mg tablet of this medicine is equivalent to less than 1ml of beer or 1ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. HOW TO TAKE ZOFRAN MELT

Always take Zofran Melt 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

On the day of chemotherapy or radiotherapy

- the usual adult dose is 8 mg taken one or 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.

Children aged over 6 months and adolescents:

The doctor will decide the dose depending on the child's size (body surface area) or weight. 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.

To prevent nausea and vomiting after an operation

The usual adult dose is 16 mg before your operation.

Children aged over 1 month and adolescents:

It is recommended that Zofran is given as an injection.

Patients with moderate or severe liver problems

The total daily dose should not be more than 8 mg.

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

- Do not take a Zofran Melt tablet out from its blister until you are ready to take it.
- Before you take the Zofran Melt make sure the foil packaging has not been pierced.
- **Important:** Do not try to push Zofran Melt through the foil top like a usual tablet. This is because Zofran Melt is fragile and will break.



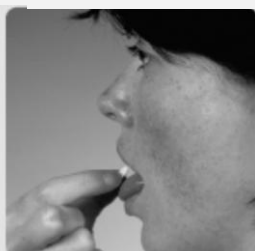
1. Tear off one Zofran Melt in its blister.



2. Peel back the foil, as shown by the arrow.



3. Gently push out the Zofran Melt tablet.



4. Place the Zofran Melt on top of the tongue. It will dissolve very quickly. Then you can swallow as normal.

Zofran Melt should start to work within one or two hours of taking a dose.

If you are sick (vomit) within one hour of taking a dose

- take the same dose again
 - otherwise, do not take more Zofran Melt than the label says.
- If you continue to feel sick, tell your doctor or nurse.

If you take more Zofran Melt 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 Melt

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

- take a Zofran Melt 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zofran Melt can cause side effects, although not everybody gets them.

Some side effects could be serious

Stop taking Zofran and seek medical help immediately if you or your child experience any of the following:

Allergic reactions

- 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:

Very common (may affect more than 1 in 10 people)

- headache.
- ##### Common (may affect up to 1 in 10 people)
- a feeling of warmth or flushing
 - constipation
 - changes to liver function test results (if you take Zofran Melt with a medicine called cisplatin, otherwise this side effect is uncommon).

Uncommon (may affect up to 1 in 100 people)

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

Rare (may affect up to 1 in 1,000 people)

- feeling dizzy or light headed
- blurred vision
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

Very rare (may affect up to 1 in 10,000 people)

- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZOFRAN MELT

Keep out of the sight and reach of children.

Do not store above 30°C.

Zofran melt should only be taken out of the blister immediately before taking it.

Do not use the Zofran Melt after the expiry date shown on the foil or carton.

If your doctor tells you to stop taking Zofran Melt, it is important to return any which are left over to your pharmacist.

If your Zofran Melt become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

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 Melt contains

Each oral lyophilisate contains 4mg ondansetron as the active ingredient.

Other ingredients: gelatin, mannitol (E421), aspartame (E951), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate and strawberry flavour (contains strawberry flavour, propylene glycol (E1520), benzyl alcohol (E1519) and sodium).

What Zofran Melt looks like and contents of the pack

Zofran Melt is a white round oral lyophilisate.

Each pack contains 10 Zofran Melt units.

MANUFACTURER AND PRODUCT LICENCE HOLDER

Manufactured by Novartis Pharma GmbH, Roonstrabe 25, D-90429 Nuremberg, Germany.
LEK Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

Procured from within the EU by Product Licence holder:
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