Package Leaflet: Information for the User

Zofran® melt 4mg

(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 melt 4mg but will be referred to as Zofran throughout this leaflet. Please note that this leaflet also contains information about the other strength Zofran melt 8mg.

What is in this leaflet:

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

1. What Zofran is and what it is used for

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

Zofran 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

Do not take Zofran 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 (listed in Section 6).

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

Warnings and precautions

Check with your doctor, nurse or pharmacist before taking Zofran 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.

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

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.

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

- Zofran 4mg contains 0.625mg aspartame per tablet; Zofran 8mg contains 1.25mg 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 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zofran

Always take Zofran 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 8mg taken one or two hours before treatment and another 8mg twelve hours after.

On the following days

- the usual adult dose is 8mg 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 4mg 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 16mg 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 8mg.

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

If you continue to feel sick, tell your doctor or nurse.

If you take more Zofran 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
If you miss a dose **and** feel sick or vomit:
- take a Zofran 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 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 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 or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zofran

Keep out of the sight and reach of children.
Do not store above 30°C.
Zofran should only be taken out of the blister immediately before taking it.
Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'.
The expiry date refers to the last day of that month.
If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zofran contains
The active ingredient in Zofran is ondansetron. Each oral lyophilisate contains 4mg ondansetron.
The other ingredients are gelatin, mannitol (E421), aspartame (E951), sodium methyl para hydroxybenzoate (E219), sodium propyl para hydroxybenzoate (E217) and strawberry flavour (contains strawberry flavour, propylene glycol (E1520), benzyl alcohol (E1519) and sodium).

What Zofran looks like and contents of the pack
Zofran is a round, white, plano-convex, fast-dispersing oral lyophilisate with no markings on either side.
Zofran is available in blister packs containing 10 oral lyophilisates.

Manufactured by: LEK Pharmaceuticals d.d., Verovškova Ulicat 57,1526 Ljubljana, Slovenia.
OR
Novartis Pharma GmbH, Roonstrasse 25, D-90429 Nuremberg, Germany.
OR
Novartis Farmaceutica, S.A., Ronda de Santa Maria, Barbera del Valles, 08210 Barcelona, Spain.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Zofran® melt 4mg; PL 18799/3153 **POM**

Leaflet date: 17.12.2025

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

Package Leaflet: Information for the User

Ondansetron 4mg oral lyophilisates

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- 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 Ondansetron 4mg oral lyophilisates but will be referred to as Ondansetron throughout this leaflet. Please note that this leaflet also contains information about the other strength Ondansetron 8mg oral lyophilisates.

What is in this leaflet:

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

1. What Ondansetron is and what it is used for

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

Ondansetron 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 Ondansetron

Do not take Ondansetron if:

- you are taking apomorphine (used to treat Parkinson's disease)
- you are allergic (hypersensitive) to ondansetron or any of the other ingredients in Ondansetron (listed in Section 6).

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

Warnings and precautions

Check with your doctor, nurse or pharmacist before taking Ondansetron 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.

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

Other medicines and Ondansetron

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 Ondansetron can affect the way some medicines work. Also some other medicines can affect the way Ondansetron 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 Ondansetron.

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

- 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 Ondansetron 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 Ondansetron. If you are a woman of childbearing potential you may be advised to use effective contraception.

Do not breast-feed if you are taking Ondansetron. 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 Ondansetron

- Ondansetron 4mg contains 0.625mg aspartame per tablet; Ondansetron 8mg contains 1.25mg 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 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Ondansetron

Always take Ondansetron 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 8mg taken one or two hours before treatment and another 8mg twelve hours after.

On the following days

- the usual adult dose is 8mg 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 4mg 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 16mg before your operation.

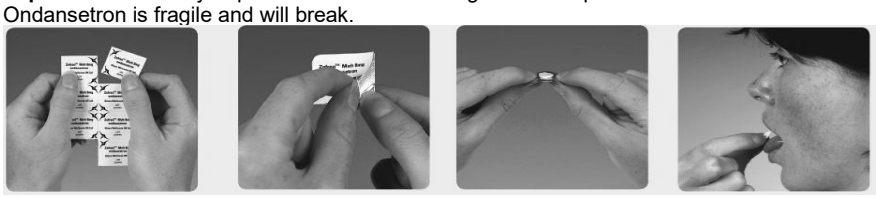
Children aged over 1 month and adolescents:
It is recommended that Ondansetron is given as an injection.

Patients with moderate or severe liver problems

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

How to remove Ondansetron from the blister and take the medicine

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



1. **Tear off one Ondansetron in its blister.**

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

3. **Gently push out the Ondansetron tablet.**

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

Ondansetron 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 Ondansetron than the label says.

If you continue to feel sick, tell your doctor or nurse.

If you take more Ondansetron than you should

If you or your child take more Ondansetron 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 Ondansetron

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

- take a Ondansetron 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, Ondansetron can cause side effects, although not everybody gets them.

Some side effects could be serious

Stop taking Ondansetron 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 Ondansetron 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 or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ondansetron

Keep out of the sight and reach of children.
Do not store above 30°C.
Ondansetron should only be taken out of the blister immediately before taking it.
Do not take the medicine after the expiry date which is stated on the carton and blister labels after 'Exp'.
The expiry date refers to the last day of that month.
If the medicine becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ondansetron contains

The active ingredient in Zofran is ondansetron. Each oral lyophilisate contains 4mg ondansetron.
The other ingredients are gelatin, mannitol (E421), aspartame (E951), sodium methyl para hydroxybenzoate (E219), sodium propyl para hydroxybenzoate (E217) and strawberry flavour (contains strawberry flavour, propylene glycol (E1520), benzyl alcohol (E1519) and sodium).

What Ondansetron looks like and contents of the pack

Ondansetron is a round, white, plano-convex, fast-dispersing oral lyophilisate with no markings on either side.
Ondansetron is available in blister packs containing 10 oral lyophilisates.

Manufactured by: LEK Pharmaceuticals d.d, Verovškova Ulica 57,1526 Ljubljana, Slovenia.
OR
Novartis Pharma GmbH, Roonstrasse 25, D-90429 Nuremberg, Germany.
OR
Novartis Farmaceutica, S.A., Ronda de Santa Maria, Barbera del Valles, 08210 Barcelona, Spain.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Ondansetron 4mg oral lyophilisates; PL 18799/3153

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