

Ondansetron ODT Lupin

Consumer Medicine Information (CMI) Summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ondansetron ODT Lupin?

Ondansetron ODT Lupin contains the active ingredient Ondansetron. Ondansetron ODT Lupin is used to treat nausea and vomiting.

For more information, see Section [1. Why am I using Ondansetron ODT Lupin?](#) in the full CMI.

2. What should I know before I use Ondansetron ODT Lupin?

Do not use if you have ever had an allergic reaction to Ondansetron or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Ondansetron ODT Lupin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ondansetron ODT Lupin and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Ondansetron ODT Lupin?

Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I use Ondansetron ODT Lupin?](#) in the full CMI.

5. What should I know while using Ondansetron ODT Lupin?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using Ondansetron ODT Lupin. If you are going to have surgery, tell the surgeon or anesthetist that you are taking this medicine. Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	Do not stop using this medicine suddenly. Do not take this medicine to treat any other complaints unless your doctor tells you to.
Driving or using machines	Be careful driving or operating machinery until you know how this medicine affects you.
Looking after your medicine	Keep your medicine in its original packaging until it is time to take it. Keep your medicine in a cool dry place where the temperature stays below 25°C. Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using Ondansetron ODT Lupin?](#) in the full CMI.

6. Are there any side effects?

Common, mild side effects of Ondansetron ODT Lupin include headache, sensation of warmth or flushing, mild stomach cramps, dry mouth, etc.

Serious side effects are chest pain or tightness of chest, low blood pressure, abnormal muscular body movements or shaking, involuntary upward movement of the eyes, fits or convulsions, etc.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Ondansetron ODT Lupin

Active ingredient(s): *Ondansetron*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ondansetron ODT Lupin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ondansetron ODT Lupin.**

Where to find information in this leaflet:

- [1. Why am I using Ondansetron ODT Lupin?](#)
- [2. What should I know before I use Ondansetron ODT Lupin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Ondansetron ODT Lupin?](#)
- [5. What should I know while using Ondansetron ODT Lupin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Ondansetron ODT Lupin?

Ondansetron ODT Lupin contains the active ingredient **Ondansetron** which belongs to a group of medicines called antiemetics.

Ondansetron ODT Lupin works by helping to stop the nausea (sick feeling) and vomiting which can occur after certain treatments. This is a special type of tablet which dissolves in a few seconds when placed on the tongue. It is easier to swallow than ordinary tablets.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Use in children

There is not enough information to recommend the use of ondansetron for children under the age of 4 years. An appropriate dosage form should be used for the child.

2. What should I know before I take Ondansetron ODT Lupin?

Warnings

Do not take Ondansetron ODT Lupin if:

- you are allergic to Ondansetron, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

you are taking apomorphine (used to treat Parkinson's disease).

- any other similar medicines (such as medicines of the same class or with a similar structure).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Tell your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have had any of the following medical conditions:
 - liver problems
 - any heart conditions
 - suffer from severe constipation or have a blockage in your gut
 - phenylketonuria, as this medicine contains aspartame.
- are planning to have surgery or an anaesthetic
- are currently receiving or are planning to receive dental treatment.

If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are on medications that affect serotonin levels, e.g. SSRIs or SNRIs (types of antidepressants), tramadol (to reduce pain).

Check with your doctor if you are on other medications that can affect your heartbeat.

Some medicines and ondansetron may interfere with each other. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ondansetron ODT Lupin.

4. How do I take Ondansetron ODT Lupin?

How much to take

Follow the instructions provided and take Ondansetron ODT Lupin.

They may differ from the information contained in this leaflet.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

If you vomit within one hour of taking your first medicine dose of each course prescribed for you, you should take the same dose again. If you continue to vomit, tell your doctor.

When to take Ondansetron ODT Lupin

Your doctor will be able to tell you when you should take this medicine.

How to take Ondansetron ODT Lupin

Peel back the foil top of the blister strip and gently remove the tablet. (DO NOT try to push it through the foil top as the tablet is fragile and may break up inside the foil).

Place the tablet on top of your tongue. It will disappear very quickly, then swallow as normal.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How long to take Ondansetron ODT Lupin

Your doctor or pharmacist will be able to tell you how long you should take your medication.

If you forget to take Ondansetron ODT Lupin

If you miss your dose and you do not feel sick take your next dose when you are meant to.

If you miss your dose, and you feel sick, take the missed dose as soon as possible, then go back to taking your medication as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much Ondansetron ODT Lupin

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice.

Symptoms of an overdose may include visual disturbances, severe constipation and hypotension.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

5. What should I know while taking Ondansetron ODT Lupin?

Things you should do

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking this one.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant or plan to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

Do not stop taking your medicine or change your dosage without first checking with your doctor.

Do not take more than your doctor tells you.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Driving or using machines

This medicine may cause dizziness, light-headedness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

If you take your medicine out of its original packaging it may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink;
- or in the car or on window sills.

Heat and dampness can destroy some medicines.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, your pharmacist can dispose of the remaining medicine safely.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

Ondansetron helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Pain related: <ul style="list-style-type: none">• Headache• Mild stomach cramps Digestion related: <ul style="list-style-type: none">• Constipation or diarrhoea Miscellaneous: <ul style="list-style-type: none">• A sensation of warmth or flushing• Dry mouth• Hiccups• Dizziness or light-headed feeling	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
Heart and blood pressure related: <ul style="list-style-type: none">• Chest pain or tightness of chest• Changes in the way your heart beats e.g. if you notice it beating faster or slower than normal, or if it beats irregularly or if it 'throbs'• Disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)• Low blood pressure Muscle related: <ul style="list-style-type: none">• Abnormal muscular body Movements or shaking• Involuntary upward movement of the eyes• Unusual muscle tone causing distortion of the body Brain related: <ul style="list-style-type: none">• Fits or convulsions Skin related: <ul style="list-style-type: none">• Severe skin reaction where the top layer of the skin detaches from the lower layers.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when ondansetron is taken in combination with other serotonergic drugs. Serotonergic drugs can include certain types of antidepressants, opioid pain medicines such as

tramadol and fentanyl, and lithium. Please note, this is not an exhaustive list. Please discuss with your pharmacist or doctor if you have any concerns.

The above list includes very serious side effects. You may need urgent medical attention or hospitalization. These side effects are very rare.

If your nausea (feeling of sickness) or vomiting does not go away, ask your doctor what to do.

In certain illnesses and treatments where Ondansetron ODT Lupin (ondansetron) orally disintegrating tablets has been used, blood vessel blockage has occurred.

However, it is important to note that blood vessel blockage has also occurred in these illnesses and treatments when ondansetron has NOT been used. Discuss this with your doctor if you have any concerns.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ondansetron ODT Lupin contains

Active ingredient (main ingredient)	Ondansetron
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Mannitol• Microcrystalline cellulose• Silicified Microcrystalline Cellulose• Crospovidone• Aspartame• Colloidal Anhydrous Silica

- | | |
|--|---|
| | <ul style="list-style-type: none">• Magnesium Stearate and• Art Strawberry FL SD 10761 |
|--|---|

What Ondansetron ODT Lupin looks like

4 mg Orally Disintegrating Tablets:

White, round shaped, flat faced bevelled edge tablets debossed with 'P' on one side and '92' on other side AUST R 292166.

Blister Pack (Aluminium-Aluminium/Peelable blister foil) of 4 or 10 orally disintegrating tablets.

8 mg Orally Disintegrating Tablets:

White, round shaped, flat faced bevelled edge tablets debossed with 'P' on one side and '91' on other side AUST R 292169.

Blister Pack (Aluminium-Aluminium/Peelable blister foil) of 4 or 10 orally disintegrating tablets.

* Not all strengths and/or pack sizes may be available.

Sponsor

Generic Health Pty Ltd
Suite 2, Level 2
19-23 Prospect Street Box Hill,
VIC, 3128 Australia

✉ ghinfo@generichealth.com.au

☎ +61 3 9809 7900

🌐 www.generichealth.com.au

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