

ONDANSETRON VIATRIS

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 being given ONDANSETRON VIATRIS?

ONDANSETRON VIATRIS contains the active ingredient ondansetron. ONDANSETRON VIATRIS is used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments and operations.

For more information, see Section [1. Why am I being given ONDANSETRON VIATRIS?](#) in the full CMI.

2. What should I know before I am given ONDANSETRON VIATRIS?

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 am given ONDANSETRON VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ONDANSETRON VIATRIS 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 is ONDANSETRON VIATRIS given?

- ONDANSETRON VIATRIS is given by injection into the muscle or by slow infusion into a vein.
- It must only be given by a doctor or nurse.

More instructions can be found in Section [4. How is ONDANSETRON VIATRIS given?](#) in the full CMI.

5. What should I know after being given ONDANSETRON VIATRIS?

Things you should do	• Remind any doctor, dentist, nurse or pharmacist you visit that you are being treated with ONDANSETRON VIATRIS.
Things you should not do	• Do not give this medicine to anyone else, even if their symptoms seem similar to yours. • Do not use this medicine to treat any other complaints unless your doctor says to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ONDANSETRON VIATRIS affects you.
Looking after your medicine	• ONDANSETRON VIATRIS is stored in the pharmacy or on the hospital ward under the correct conditions.

For more information, see Section [5. What should I know after being given ONDANSETRON VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: headache; a sensation of warmth or flushing; mild stomach cramps; constipation or diarrhoea; dry mouth; hiccups; burning sensation at the site of injection.

Serious side effects: 'wheezy' symptoms; chest pain or tightness of the 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); patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when ONDANSETRON VIATRIS is taken in combination with other serotonergic drugs; severe skin reaction where the top layer of the skin detaches from the lower layers; low blood pressure; fits or convulsions; swelling of the eyelids, face lips, mouth or throat which may cause difficulty in swallowing or breathing; skin rash, skin lumps or hives; blurred vision; dizziness.

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 VIATRIS

Active ingredient(s): ondansetron hydrochloride dihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using ONDANSETRON VIATRIS. **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 VIATRIS.**

Where to find information in this leaflet:

1. [Why am I being given ONDANSETRON VIATRIS?](#)
2. [What should I know before I am given ONDANSETRON VIATRIS?](#)
3. [What if I am taking other medicines?](#)
4. [How is ONDANSETRON VIATRIS given?](#)
5. [What should I know after I am given ONDANSETRON VIATRIS?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given ONDANSETRON VIATRIS?

ONDANSETRON VIATRIS contains the active ingredient **ondansetron**. ONDANSETRON VIATRIS belongs to a group of medicines called Serotonin receptor-3 antagonists.

ONDANSETRON VIATRIS is used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments and operations.

ONDANSETRON VIATRIS should only be used to treat the nausea and vomiting for which it has been prescribed.

Your doctor may have prescribed ONDANSETRON VIATRIS for another reason. If you want more information, ask your doctor.

ONDANSETRON VIATRIS injection is not addictive.

2. What should I know before I am given ONDANSETRON VIATRIS?

Warnings

Do not use ONDANSETRON VIATRIS if:

- you are allergic to ondansetron, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.

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

- you are taking apomorphine (used to treat Parkinson's disease)
- you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says it is safe
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering
- the injection solution is coloured, cloudy or lumpy.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition
- have or have had any of the following medical conditions:
 - o you have had to stop taking another medicine for your nausea or vomiting.
 - o you have or used to have liver problems.

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

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in ONDANSETRON VIATRIS passes into breast milk and there is a possibility that your baby may be affected.

Tell your doctor if you are pregnant or plan to become pregnant or are breast feeding. Your doctor can discuss with you the risks and benefits involved.

Use in children

The clinical safety of ondansetron injection in children under 2 years has not been studied.

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.

Some medicines may interfere with ONDANSETRON VIATRIS and affect how it works. These include:

- pain killers such as tramadol
- antibacterials such as rifampicin
- serotonergic drugs including selective serotonin reuptake inhibitors (SSRIs) and serotonin noradrenaline reuptake inhibitors (SNRIs)
- antiepileptics such as carbamazepine and phenytoin

- medicines that prolong QT interval and/or cause electrolyte abnormalities.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using ONDANSETRON VIATRIS.

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 VIATRIS.

4. How is ONDANSETRON VIATRIS given?

ONDANSETRON VIATRIS is given by injection into the muscle or by slow infusion into a vein.

It must only be given by a doctor or nurse.

Sometimes other medicines are given at the same time.

Do NOT use the injection on your own.

If you are given too much ONDANSETRON VIATRIS

This rarely happens as ONDANSETRON VIATRIS is administered under the care of highly trained doctor.

However, if you are given too much ondansetron, you may experience some of the effects listed under Section [6. Are there any side effects?](#)

If you think that you have used too much ONDANSETRON VIATRIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know after I am given ONDANSETRON VIATRIS?

Things you should do

Remind any nurse, doctor, dentist or pharmacist you visit that you are being treated with ONDANSETRON VIATRIS.

Things you should not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use this medicine to treat any other complaints unless your doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ONDANSETRON VIATRIS affects you.

Looking after your medicine

- ONDANSETRON VIATRIS will be stored in the pharmacy or the ward.
- The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

- Keep the injection ampoules in their pack until time to take.

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

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.

Keep it where young children cannot reach it, such as in a locked cupboard.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

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
Nervous system-related: • headache Gastrointestinal-related: • mild stomach cramps • constipation or diarrhoea • dry mouth Respiratory system-related: • hiccups Injection site-related: • burning sensation at the site of injection Vascular-related: • a sensation of warmth or flushing	Speak to your doctor if you have any of these less serious side effects. These are all mild side effects. There is no immediate reason to stop using your injection unless you are concerned.

Serious side effects

Serious side effects	What to do
Heart-related: • chest pain or tightness of the 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'	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness) - dizziness Blood vessel system-related: - low blood pressure Nervous system-related: - fits or convulsions Serotonin syndrome-related: - patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when ONDANSETRON VIATRIS 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. Skin-related: - severe skin reaction where the top layer of the skin detaches from the lower layers. Allergic reaction-related: - swelling of the eyelids, face lips, mouth or throat which may cause difficulty in swallowing or breathing - skin rash, skin lumps or hives 'wheezy' symptoms Eye-related: - blurred vision	notice any of these serious side effects. These serious side effects are rare.

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.

Tell your doctor as soon as possible if you do not feel well while you are being given ONDANSETRON VIATRIS or if your nausea (feeling of sickness) and vomiting does not go away.

In certain illnesses and treatments where ONDANSETRON VIATRIS is 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 VIATRIS has NOT been used. Discuss this with your doctor if you have any concerns.

If you feel unwell or have any symptoms that you do not understand, you should tell your doctor immediately.

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 VIATRIS contains

Active ingredient (main ingredient)	ondansetron (as hydrochloride)
Other ingredients (inactive ingredients)	- citric acid monohydrate - sodium citrate dihydrate - sodium chloride - water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What ONDANSETRON VIATRIS looks like

ONDANSETRON VIATRIS is a colourless clear, practically odourless, free of visible particles solution containing 2 mg/mL ondansetron (as hydrochloride):

- 4 mg/2 mL ampoule - AUST R 155842
- 8 mg/4 mL ampoule - AUST R 155843

Available in packs of five ampoules.

Who distributes ONDANSETRON VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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