

# ONDANSETRON VTRS

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## **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.

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### **1. Why am I using ONDANSETRON VTRS?**

ONDANSETRON VTRS contains the active ingredient ondansetron (as hydrochloride dihydrate). ONDANSETRON VTRS 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 using ONDANSETRON VTRS?](#) in the full CMI.

### **2. What should I know before I use ONDANSETRON VTRS?**

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 VTRS?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with ONDANSETRON VTRS 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 VTRS?**

- Take ONDANSETRON VTRS as directed by your doctor or pharmacist.
- Do NOT take MORE TABLETS than your doctor or pharmacist tells you.

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

### **5. What should I know while using ONDANSETRON VTRS?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are</li></ul>
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	<p>using ONDANSETRON VTRS.</p> <ul style="list-style-type: none"> <li>• Tell your doctor if you become pregnant or are trying to become pregnant</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine or change the dose without first checking with your doctor.</li> <li>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li> <li>• Do not use ONDANSETRON VTRS to treat any other complaints unless your doctor says to.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving, operating machinery while you are taking ONDANSETRON VTRS until you know how it affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep ONDANSETRON VTRS in a cool, dry</li> </ul>

	<p>place where it stays below 25°C.</p> <ul style="list-style-type: none"><li>• Keep ONDANSETRON VTRS in their blister pack until time to take.</li></ul>
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For more information, see Section [5. What should I know while using ONDANSETRON VTRS?](#) in the full CMI.

## 6. Are there any side effects?

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 VTRS

**Active ingredient(s):** *Ondansetron (as hydrochloride dihydrate)*

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I using ONDANSETRON VTRS?

**ONDANSETRON VTRS contains the active ingredient ondansetron (as hydrochloride dihydrate).**  
ONDANSETRON VTRS belongs to a group of

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medicines called serotonin receptor-3 antagonists.  
**ONDANSETRON VTRS is used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments and operations.**

ONDANSETRON VTRS should only be used to treat the nausea and vomiting for which they have been prescribed.

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

ONDANSETRON VTRS is not addictive.

## **2. What should I know before I use ONDANSETRON VTRS?**

### **Warnings**

#### **Do not use ONDANSETRON VTRS if:**

- you are taking apomorphine (used to treat Parkinson's disease);
- you have ever had an allergic reaction to ondansetron or any of the ingredients listed toward the end of this leaflet (see "Ingredients");

#### **Check with your doctor if you:**

- you are allergic to foods, dyes, preservatives or any other medicines;

- you have had to stop taking another medicine for your nausea or vomiting;
- you are taking any other medicines, including medicines you buy without a prescription;
- you have or used to have liver problems; or
- you are breastfeeding, pregnant or trying to become pregnant.

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 ONDANSETRON VTRS if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says it is safe;

Your doctor will discuss the risks and benefits of using ONDANSETRON VTRS if you are pregnant or breastfeeding.

### **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 affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking ONDANSETRON VTRS with other medicines.

**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 VTRS**

## **4. How do I use ONDANSETRON VTRS?**

### **How much to take**

- Take ONDANSETRON VTRS as directed by your doctor or pharmacist
- Do NOT take MORE TABLETS than your doctor or pharmacist tells you.
- Do NOT take the tablets MORE OFTEN than your doctor or pharmacist tells you.
- If you vomit within one hour taking your first ONDANSETRON VTRS tablet of each course prescribed to you, you should take the same dose again. If you continue to vomit, tell your doctor.

### **How to take ONDANSETRON VTRS**

Swallow each tablet with a drink of water. Do not crush the tablet. If you have trouble swallowing your tablet, please tell your doctor.



## **How to long to take ONDANSETRON VTRS for**

Do not stop taking ONDANSETRON VTRS, or change dose without first checking with your doctor.

## **If you forget to use ONDANSETRON VTRS**

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 ONDANSETRON VTRS 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.

## **If you use too much ONDANSETRON VTRS**

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

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 while using ONDANSETRON VTRS?**

### **Things you should do**

#### **Call your doctor straight away if you:**

- Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.
- Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

### **Things you should not do**

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use ONDANSETRON VTRS 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 VTRS affects you.**

### **Looking after your medicine**

- Keep ONDANSETRON VTRS in their blister pack until time to take.

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.**

## **When to discard your medicine**

If your doctor tells you to stop taking ONDANSETRON VTRS or it is out of date.

## **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
<ul style="list-style-type: none"><li>• Headache;</li><li>• A sensation of warmth or flushing;</li><li>• Mild stomach cramps;</li><li>• Constipation or diarrhoea;</li><li>• Dry mouth; or</li><li>• Hiccups.</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• 'Wheezy' symptoms;</li><li>• Chest pain or tightness of the chest;</li><li>• 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';</li><li>• Disturbance in heart rhythm (sometimes causing a sudden loss of consciousness);</li></ul>	<b>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.</b>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Patients may experience “serotonin syndrome” (confusion, sweating , unsteadiness, shaking, diarrhoea) when ONDANSETRON VTRS 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;</li> <li>• Severe skin reaction where the top layer of the skin detaches from the lower layers;</li> <li>• Low blood pressure;</li> <li>• Fits or convulsions;</li> <li>• Swelling of the eyelids, face, lips, mouth or throat which may cause</li> </ul>	

Serious side effects	What to do
<p>difficulty in swallowing or breathing; or</p> <ul style="list-style-type: none"> <li>• Skin rash, skin lumps or hives.</li> </ul>	

**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.

In certain illnesses and treatments where ONDANSETRON VTRS 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 VTRS 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](http://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 VTRS contains**

<b>Active ingredient (main ingredient)</b>	Ondansetron hydrochloride dihydrate
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Lactose;</li><li>• Cellulose microcrystalline;</li><li>• Magnesium stearate;</li><li>• Starch-pregelatinised maize;</li><li>• The 4 mg tablet also contains triacetin, titanium dioxide and hypromellose; and</li><li>• The 8 mg tablet also contains Opadry yellow 03K52033.</li></ul>
<b>Potential allergens</b>	This medicine contains sugars as lactose.

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

## **What ONDANSETRON VTRS looks like**

**ONDANSETRON VTRS 4mg:** White to off-white, oval shaped, film-coated tablets debossed with 'E' on one side and '01' on the other side (AUST R 422752).

**ONDANSETRON VTRS 8mg:** Yellow coloured, oval shaped, film-coated tablets debossed with 'E' on one side and '02' on the other side (AUST R 422753).

Do NOT use your tablets if they have changed colour.

## **Who distributes ONDANSETRON VTRS**

### **Sponsor**

Helix Pharmaceuticals Pty Ltd

C/-EGA Corporate Advisers Pty Ltd

Level 12, 468 St Kilda Rd

Melbourne VIC 3004

Contact: [info@helixpharmaceuticals.com.au](mailto:info@helixpharmaceuticals.com.au)

### **Distributor**

ONDANSETRON VTRS is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road



Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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