

APX-ONDANSETRON ODT 4 & 8

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 APX-ONDANSETRON ODT?

APX-ONDANSETRON ODT 4 & 8 contains the active ingredient Ondansetron. APX-ONDANSETRON ODT 4 & 8 works by helping to stop the nausea (sick feeling) and vomiting which can occur after certain treatments.

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

2. What should I know before I use APX-ONDANSETRON ODT?

Do not use if you have ever had an allergic reaction to APX-ONDANSETRON ODT 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 APX-ONDANSETRON ODT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APX-ONDANSETRON ODT 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 APX-ONDANSETRON ODT?

- The Pharmacist's label on the pack will tell you how to take APX-ONDANSETRON ODT. If there is something you do not understand, ask your doctor or pharmacist.
- **PEEL BACK the foil top of the blister strip and GENTLY remove the APX-ONDANSETRON ODT. (DO NOT try to push it through the foil top as the tablet is fragile and will break up inside the foil). Place the APX-ONDANSETRON ODT on top of your tongue. It will disappear very quickly, then swallow as normal.**

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

5. What should I know while using APX-ONDANSETRON ODT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APX-ONDANSETRON ODT.• Tell your doctor if you become pregnant or are trying to become pregnant.• Take this medicine exactly as prescribed so that it will work properly and to prevent unwanted side effects.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose without first checking with your doctor.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.• Do not use APX-ONDANSETRON ODT to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery while you are taking APX-ONDANSETRON ODT until you know how it affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep APX-ONDANSETRON ODT in a cool, dry & dark place where it stays below 25°C.• Keep your APX-ONDANSETRON ODT in their pack until it is time to take them. If taken out of their pack, they may not keep well.

For more information, see Section [5. What should I know while using APX-ONDANSETRON ODT?](#) 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.

APX-ONDANSETRON ODT 4 & 8

Active ingredient(s): *Ondansetron*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APX-ONDANSETRON ODT. **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 APX-ONDANSETRON ODT.**

Where to find information in this leaflet:

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

1. Why am I using APX-ONDANSETRON ODT?

APX-ONDANSETRON ODT contains the active ingredient **ondansetron**. APX-ONDANSETRON ODT belongs to a group of medicines called antiemetics. **APX-ONDANSETRON ODT works by helping to stop the nausea (sick feeling) and vomiting which can occur after certain treatments.**

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

Your doctor may have prescribed APX-ONDANSETRON ODT for another reason. Ask your doctor if you have any questions about why APX-ONDANSETRON ODT has been prescribed for you.

APX-ONDANSETRON ODT is not addictive.

2. What should I know before I use APX-ONDANSETRON ODT?

Warnings

Do not use APX-ONDANSETRON ODT if:

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

Check with your doctor if you:

- you are allergic to foods, dyes, preservatives or any other medicines;
- you have, or used to have, liver problems;
- you suffer from severe constipation or have a blockage in your gut; or
- you have phenylketonuria, as APX-ONDANSETRON ODT contains aspartame.

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 APX-ONDANSETRON ODT if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of using APX-ONDANSETRON ODT 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 APX-ONDANSETRON ODT 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 APX-ONDANSETRON ODT.

4. How do I use APX-ONDANSETRON ODT?

How much to take

- The Pharmacist's label on the pack will tell you how to take APX-ONDANSETRON ODT. If there is something you do not understand, ask your doctor or pharmacist.
- DO NOT take more APX-ONDANSETRON ODT than your doctor or pharmacist tells you.

- DO NOT take APX-ONDANSETRON ODT more often than your doctor or pharmacist tells you.
- If you vomit within one hour of taking your first APX-ONDANSETRON ODT of each course prescribed for you, you should take the same dose again. If you continue to vomit, tell your doctor.

How to take APX-ONDANSETRON ODT

- PEEL BACK the foil top of the blister strip and GENTLY remove the APX-ONDANSETRON ODT. (DO NOT try to push it through the foil top as the tablet is fragile and will break up inside the foil). Place the APX-ONDANSETRON ODT on top of your tongue. It will disappear very quickly, then swallow as normal.

When to use APX-ONDANSETRON ODT

- Your doctor or pharmacist will be able to tell you when you should take your APX-ONDANSETRON ODT.

If you forget to use APX-ONDANSETRON ODT

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 APX-ONDANSETRON ODT 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 APX-ONDANSETRON ODT

If you think that you have used too much APX-ONDANSETRON ODT, 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 APX-ONDANSETRON ODT?

Things you should do

Tell your doctor or pharmacist that you are taking APX-ONDANSETRON ODT if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

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.

Remind any doctor, dentist or pharmacist you visit that you are using APX-ONDANSETRON ODT.

Things you should not do

- Do not stop taking APX-ONDANSETRON ODT, or change the dose without first checking with your doctor.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use APX-ONDANSETRON ODT 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 APX-ONDANSETRON ODT affects you.

Looking after your medicine

- Keep your APX-ONDANSETRON ODT in their pack until it is time to take them.
- If taken out of their pack, they may not keep well

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.

When to discard your medicine

If your doctor tells you to stop taking APX-ONDANSETRON ODT 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"> • Headache; • A sensation of warmth or flushing; • Mild stomach cramps; • Constipation or diarrhoea; • Dry mouth; • Hiccups; or • Dizziness or light-headed feeling. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<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; • Abnormal muscular body movements or shaking; • Involuntary upward movement of the eyes; • Unusual muscle tone causing distortion of the body; • Fits or convulsions; • Patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when APX-ONDANSETRON ODT is taken in combination with other serotonergic drugs. Serotonergic drugs can include certain types of antidepressants and 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. • Severe skin reaction where the top layer of the skin detaches from the lower layers. <p>If you think you are having an allergic reaction to APX-ONDANSETRON ODT, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:</p>	<p>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.</p>

<ul style="list-style-type: none"> • Wheezing; • Swelling of the lips/mouth; • Difficulty in breathing; • Hay fever; • Lumpy rash ("hives"); or • Fainting. 	
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Others may occur in some people and there may be some side-effects not yet known.

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

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

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 APX-ONDANSETRON ODT contains

Active ingredient (main ingredient)	Ondansetron
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • mannitol; • crospovidone; • lactose monohydrate; • microcrystalline cellulose; • aspartame; • colloidal anhydrous silica; • magnesium stearate; and

	<ul style="list-style-type: none">• strawberry guarana 586997 AP0551.
Potential allergens	This medicine contains lactose and aspartame.

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

What APX-ONDANSETRON ODT looks like

APX-ONDANSETRON ODT 4: White to off-white, round tablets debossed with '5' on one side and 'E' on the other side with an embossed circular edge. (Aust R 196804).

APX-ONDANSETRON ODT 8: White to off-white, round tablets debossed with '7' on one side and 'E' on the other side with an embossed circular edge. (AUST R 196809)

Who distributes APX-ONDANSETRON ODT

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne, Victoria 3121
Australia

This leaflet was prepared in July 2024.