

APO-ONDANSETRON ODT Orally Disintegrating Tablets

Contains the active ingredient ondansetron

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

APO-ONDANSETRON ODT orally disintegrating tablets are used to treat the nausea and vomiting.

Ondansetron belongs to a group of medicines called antiemetics.

It works by helping to stop the nausea (sick feeling) and vomiting which can occur after certain treatments.

ODT refers to 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.

There is not enough information to recommend the use of ondansetron for children under the age of 4 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you are taking apomorphine (used to treat Parkinson's disease).

Do not take this medicine if you have an allergy to:

- any medicine containing ondansetron

- any of the ingredients listed at the end of this leaflet
- 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

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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

Tell your doctor if you are planning to have surgery or an anaesthetic.

Tell your doctor if you are currently receiving or are planning to receive dental treatment.

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

Taking other medicines

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

Tell your doctor if you are on medications that effect serotonin levels.

For example, some types of antidepressants such as SSRIs or SNRIs or tramadol (to reduce pain).

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

Some medicines may be affected by ondansetron or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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

They may differ from the information contained in this leaflet.

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

How much to take

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.

Do not take more than your doctor tells you.

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.

How to take it

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.

When to take it

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

How long to take it

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

If you forget to take it

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.

If you take too much (overdose)

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.

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

You may need urgent medical attention.

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

While you are taking this medicine

Things you must do

If you are about to be started on 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.

Keep all of your doctor's appointments so that your progress can be checked.

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 must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

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.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

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.

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 with nausea and vomiting, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- a sensation of warmth or flushing
- mild stomach cramps
- constipation or diarrhoea
- dry mouth

- hiccups
- dizziness or light-headed feeling

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 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

- severe skin reaction where the top layer of the skin detaches from the lower layers
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. 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 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.

Storage and disposal

Keep your medicine in its original packaging until it is time to take it.

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

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store any medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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 292170.

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 292173.

Available in blister packs of 4 or 10 orally disintegrating tablets.

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

Ingredients

Each orally disintegrating tablet contains either 4 mg or 8 mg of ondansetron as the active ingredient.

It also contains the following inactive ingredients:

- mannitol
- microcrystalline cellulose
- silicified microcrystalline cellulose
- crospovidone

- aspartame
- colloidal anhydrous silica
- magnesium stearate and
- Art Strawberry FL SD 10761

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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