

ONDANSETRON APOTEX

Ondansetron hydrochloride dihydrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about ondansetron. 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

Ondansetron is used to treat nausea (sick feeling) and vomiting. It belongs to a group of medicines called antiemetics.

This medicine works by helping to stop the nausea 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.

There is not enough information to recommend the use of this medicine 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 have an allergy to:

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

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 if you are taking apomorphine, used to treat Parkinson's disease.

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.

Ondansetron passes into breast milk and there is a possibility that your baby may be affected.

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
- severe constipation or a blockage in your gut
- phenylketonuria, as this medicine contains aspartame.

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.

Some medicines and ondansetron may interfere with each other. These include:

- certain antidepressants, such as sertraline and venlafaxine
- some opioid pain medicines, such as tramadol and fentanyl
- lithium, used for mood disorders.

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 and when you should take it. This will depend on your condition.

If you vomit within one hour of taking your first dose, 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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. 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.

If you become pregnant while taking this medicine, tell your doctor immediately.

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 change the dosage without checking with your doctor.

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 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
- 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. They are usually mild and short-lived.

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, 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
- confusion, sweating, unsteadiness, shaking, diarrhoea (signs of serotonin syndrome)
- severe skin reaction where the top layer of the skin detaches from the lower layers.

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

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

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.

Storage and disposal

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of the pack 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 Immediate Release Tablets:

Yellow coloured, oval biconvex, film coated tablets 'BL' debossed on one face and '4' debossed on the other.

Blister pack (White Opaque PVC/ Aluminium blister pack) of 4 or 10 immediate release tablets. AUST R 300710.

8 mg Immediate Release Tablets:

Yellow coloured, oval biconvex, film coated tablets 'BL' debossed on one face and '8' debossed on the other.

Blister pack (White Opaque PVC/ Aluminium blister pack) of 4 or 10 immediate release tablets. AUST R 300705.

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

Ingredients

This medicine contains either 4 mg or 8 mg of ondansetron as the active ingredient.

This medicine also contains the following:

- lactose
- microcrystalline cellulose
- pregelatinised maize starch
- magnesium stearate
- hypromellose
- titanium dioxide
- iron oxide yellow

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

Sponsor

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