

Onsetron® Tablets

contain the active ingredient ondansetron (as hydrochloride dihydrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ONSETRON.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with your medicine. You may need to read it again.

What ONSETRON is used for

ONSETRON is used to help stop the nausea and vomiting which can occur after some medical treatments.

ONSETRON belongs to a group of medicines called serotonin receptor -3 antagonists.

Your doctor may have prescribed ONSETRON for another reason. Ask your doctor if you have any questions about why ONSETRON has been prescribed for you.

ONSETRON is available only with a doctor's prescription.

There is no evidence that ONSETRON is addictive.

Before you take ONSETRON

When you must not take it

Do not take ONSETRON if

- you are taking apomorphine (a medicine used to treat Parkinson's disease)
- you are allergic to medicines containing ondansetron, any other serotonin receptor antagonists or any of the ingredients listed at the end of this leaflet.
- if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says it is safe. ONSETRON may affect your developing baby if you take it during pregnancy. It also passes into breast milk and may affect your baby.
- the expiry date (Exp.) printed on the pack has passed.
- the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if

- you are allergic to any other medicines, foods, dyes or preservatives.
- if you have had to stop taking another medicine for your nausea and vomiting.
- you plan to become pregnant or to breastfeed
- you have, or have had, any medical conditions, especially liver problems.

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

Taking other medicines

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

Some medicines may be affected by ONSETRON, or may affect how well it works. These include:

- medicines to treat epilepsy
- tramadol, a pain reliever.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take ONSETRON

How much to take

Your doctor will tell you how many tablets you need to take each day and when to take them.

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.

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

If you vomit within one hour of taking the first ONSETRON 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 ONSETRON

Swallow the tablets with a glass of water.

If you forget to take ONSETRON

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 ONSETRON 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.

How long to take ONSETRON for

Keep taking ONSETRON for as long as your doctor recommends.

If you take too much ONSETRON (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ONSETRON. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ONSETRON

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ONSETRON.

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 must not do

Do not use ONSETRON to treat any other conditions unless your doctor tells you to.

Do not give ONSETRON to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ONSETRON.

Like all other medicines, ONSETRON may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor 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

These are mild side effects. There is no immediate reason to stop taking your tablets unless you are concerned.

Tell your doctor immediately if you notice any of the following:

- wheezy symptoms
- chest pain or tightness
- changes in the way your heart beats (faster or slower than normal or if it beats irregularly or throbs)
- disturbance in heart rhythm (sometimes causing sudden loss of consciousness)
- 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, lumps or hives.

These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

If your nausea or vomiting does not go away, ask your doctor what to do.

In certain illnesses and treatments where ONSETRON 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 ONSETRON have 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, tell your doctor immediately.

After using ONSETRON

Storage

Keep ONSETRON 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.

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

Do not store ONSETRON or any other medicine in the bathroom or near a sink.

Do not leave ONSETRON in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ONSETRON, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

- maize starch
- magnesium stearate
- Opadry Y-1-7000 White.

The tablets are gluten free.

Sponsor

Medis Pharma Pty Ltd
Level 3, 5 Essex St
The Rocks NSW 2000
Australia

Distributor

Actavis Pty Ltd
Level 5, 117 Harrington St
The Rocks NSW 2000
Australia
Phone: 1800 554 414

Australian registration numbers:

ONSETRON 4 - AUST R 121359

ONSETRON 8 - AUST R 121368

Date of preparation:

16 April 2014

Product description

What it looks like

ONSETRON comes in 2 strengths of tablets:

- ONSETRON 4 - round white tablet marked "4" on one side
- ONSETRON 8 - round white tablet marked "8" on one side and a scoreline on the other.

Each pack contains 4 or 10 tablets.

Ingredients

The active ingredient in ONSETRON is ondansetron (as hydrochloride dihydrate)

- each ONSETRON 4 tablet contains 4mg of ondansetron.
- each ONSETRON 8 tablet contains 8mg of ondansetron.

The tablets also contain:

- lactose
- microcrystalline cellulose