

ONDANSETRON ODT VIATRIS

orally disintegrating tablets

ondansetron

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking ONDANSETRON ODT VIATRIS orally disintegrating tablets.

This leaflet answers some common questions about ONDANSETRON ODT VIATRIS orally disintegrating tablets. 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 risks and benefits. Your doctor has weighed the risks of you taking ONDANSETRON ODT VIATRIS

orally disintegrating tablets against the benefits this medicine is expected to 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 ONDANSETRON ODT VIATRIS orally disintegrating tablets are used for

ONDANSETRON ODT VIATRIS orally disintegrating tablets belong to a group of medicines called antiemetics.

ONDANSETRON ODT VIATRIS orally disintegrating tablets work by helping to stop the nausea (sick feeling) and vomiting which can occur after certain treatments.

'Orally disintegrating' used in the product name, is the word used for the special type of tablet which dissolves in a few seconds when placed on the tongue. It is easier to swallow than ordinary tablets.

ONDANSETRON ODT VIATRIS orally disintegrating tablets should only be used to treat the nausea and vomiting for which they have been prescribed.

Your doctor may have prescribed ONDANSETRON ODT VIATRIS orally disintegrating tablets for another reason.

Ask your doctor if you have any questions about why ONDANSETRON ODT VIATRIS orally disintegrating tablets have been prescribed for you.

ONDANSETRON ODT VIATRIS orally disintegrating tablets are not addictive.

Before you take ONDANSETRON ODT VIATRIS orally disintegrating tablets

When you must not take them

- **Do not take ONDANSETRON ODT VIATRIS orally disintegrating tablets if you are taking apomorphine (used to treat Parkinson's disease)**
- **Do not take ONDANSETRON ODT VIATRIS orally disintegrating tablets if you have ever had an allergic reaction to ondansetron or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

- **Do not take ONDANSETRON ODT VIATRIS orally disintegrating tablets 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 ONDANSETRON ODT VIATRIS orally disintegrating tablets if you are pregnant or breastfeeding.

- **Do not take ONDANSETRON ODT VIATRIS orally disintegrating tablets after the expiry date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

- **Do not take ONDANSETRON ODT VIATRIS orally disintegrating tablets if the packaging is torn or shows signs of tampering.**
- **If you're not sure whether you should be taking ONDANSETRON ODT VIATRIS orally disintegrating tablets, talk to your doctor.**

Before you start to take them

You must tell your doctor if:

- 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
- you have phenylketonuria, as ONDANSETRON ODT VIATRIS orally disintegrating tablets contain aspartame.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a 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 ODT VIATRIS orally disintegrating tablets with other medicines.

Use in children

There is limited experience in children. ONDANSETRON ODT VIATRIS orally disintegrating tablets can be taken by children over 4 years of age.

How to take ONDANSETRON ODT VIATRIS orally disintegrating tablets

The Pharmacist's label on the pack will tell you how to take ONDANSETRON ODT VIATRIS orally disintegrating tablets. If there is something you do not understand, ask your doctor or pharmacist.

How much to take

DO NOT take more ONDANSETRON ODT VIATRIS orally disintegrating tablets than your doctor or pharmacist tells you.

DO NOT take ONDANSETRON VIATRIS ODT orally disintegrating tablets MORE OFTEN than your doctor or pharmacist tells you.

If you vomit within one hour of taking your first ONDANSETRON ODT VIATRIS orally disintegrating tablet of each course prescribed for you, you should take the same dose again. If you continue to vomit, tell your doctor.

How to take them

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

When to take them

Your doctor or pharmacist will be able to tell you when you should take your ONDANSETRON ODT VIATRIS orally disintegrating tablets.

How long to take them

Your doctor or pharmacist will be able to tell you how long you should take your ONDANSETRON ODT VIATRIS orally disintegrating tablets.

If you forget to take them

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 ONDANSETRON ODT VIATRIS orally disintegrating tablet 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)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much ONDANSETRON ODT VIATRIS orally disintegrating tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking ONDANSETRON ODT VIATRIS orally disintegrating tablets

Things you must do

Tell your doctor or pharmacist that you are taking ONDANSETRON ODT VIATRIS orally disintegrating tablets 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.

Things you must not do

Do not stop taking ONDANSETRON ODT VIATRIS orally disintegrating tablets, 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 ONDANSETRON VIATRIS ODT orally disintegrating tablets to treat any other complaints unless your doctor says to.

Side effects

Check with your doctor as soon as possible if you have any problems while taking ONDANSETRON ODT VIATRIS orally disintegrating tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet. Like other medicines, ONDANSETRON ODT VIATRIS orally disintegrating tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- headache

- a sensation of warmth or flushing
- mild stomach cramps
- constipation or diarrhoea
- dry mouth
- hiccups
- dizziness or light-headed feeling

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

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

- chest pain or tightness of chest
- changes in the way your heart beats eg 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 VIATRIS ODT is taken 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.
- Severe skin reaction where the top layer of the skin detaches from the lower layers.

If you think you are having an allergic reaction to ONDANSETRON ODT VIATRIS orally disintegrating tablets, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")

- fainting

This is not a complete list of all possible side-effects. 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 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 if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking ONDANSETRON ODT VIATRIS orally disintegrating tablets

Storage

Keep this medicine where young 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 ONDANSETRON ODT VIATRIS orally disintegrating tablets in a cool, dry place where it stays below 30° C.

Do not store it, or any other medicine, in a bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Keep your ONDANSETRON VIATRIS ODT orally disintegrating tablets in their pack until it is time to take them.

If taken out of their pack, they may not keep well.

Disposal

If your doctor tells you to stop taking ONDANSETRON ODT VIATRIS orally disintegrating tablets, or they have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What ONDANSETRON ODT VIATRIS orally disintegrating tablets look like

ONDANSETRON ODT VIATRIS orally disintegrating tablets are white, round tablets, with “O” on one side and “4” or “8”

on the other side. They come in a foil blister pack of 4 or 10 tablets, which is contained in a box. There is a 4 mg strength and an 8 mg strength.

Ingredients

ONDANSETRON ODT VIATRIS orally disintegrating tablets contain either 4 mg or 8 mg of the active ingredient ondansetron. They also contain cellulose, mannitol, starch, crospovidone, silica, guar gum, aspartame, magnesium stearate, sodium lauryl sulphate and strawberry flavour.

Sponsor

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Australian registration numbers:

ONDANSETRON ODT VIATRIS 4 mg orally disintegrating
tablets: AUST R 291494

ONDANSETRON ODT VIATRIS 8 mg orally disintegrating
tablets: AUST R 291495