

ONDANSETRON VIATRIS

ondansetron hydrochloride dihydrate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use ONDANSETRON VIATRIS solution for injection.

This leaflet answers some common questions about ONDANSETRON VIATRIS. It does not contain all the available information.

It does not take the place of talking to your doctor.

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

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

Keep this leaflet.

You may need to read it again.

What ONDANSETRON VIATRIS is used for

ONDANSETRON VIATRIS contains a medicine called ondansetron. This belongs to a group of medicines called Serotonin receptor-3 antagonists.

ONDANSETRON VIATRIS is used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments and operations.

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

Your doctor may have prescribed ONDANSETRON VIATRIS for

another reason. If you want more information, ask your doctor.

ONDANSETRON VIATRIS injection is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given ONDANSETRON VIATRIS

When you must not take it

Do not take ONDANSETRON VIATRIS if you have an allergy to:

- any medicine containing (active ingredient)
- 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 pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in ONDANSETRON VIATRIS passes into breast milk and there is a possibility that your baby may be affected.

- you are taking apomorphine (used to treat Parkinson's disease) you have ever had an allergic reaction to ondansetron or any of the ingredients listed at

the end of this leaflet (see 'Product Description').

- you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says it is safe.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering
- the injection solution is coloured, cloudy or lumpy

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:

- you have had to stop taking another medicine for your nausea or vomiting.
- you have or used to have liver problems.
- you are breastfeeding, pregnant or trying to become pregnant.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using ONDANSETRON VIATRIS.

Taking other medicines

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

Some medicines and ondansetron may interfere with each other.

These include:

- pain killers such as tramadol
- antibacterials such as rifampicin
- serotonergic drugs including selective serotonin reuptake inhibitors (SSRIs) and serotonin noradrenaline reuptake inhibitors (SNRIs)
- antiepileptics such as carbamazepine and phenytoin.
- medicines that prolong QT interval and/or cause electrolyte abnormalities

Your doctor has more information on medicines to be careful with or avoid while you are receiving this medicine.

How do I take ONDANSETRON VIATRIS

ONDANSETRON VIATRIS is given by injection into the muscle or by slow infusion into a vein.

It must only be given by a doctor or nurse.

Sometimes other medicines are given at the same time.

Do NOT use the injection on your own.

The clinical safety of ondansetron injection in children under 2 years has not been studied.

While you are taking ONDANSETRON VIATRIS

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use this medicine to treat any other complaints unless your doctor says to.

If you are given too much (overdose)

This rarely happens as ONDANSETRON VIATRIS is administered under the care of highly trained doctor.

However, if you are given too much ondansetron, you may experience some of the effects listed under "Side Effects" below.

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

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

Side effects

Tell your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking ONDANSETRON VIATRIS, even if the problem is not listed below.

Like other medicines, ONDANSETRON VIATRIS injection 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
- burning sensation at the site of injection

These are all mild side effects. There is no immediate reason to

stop using your injection unless you are concerned.

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

- 'wheezy' symptoms
- chest pain or tightness of the 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)
- patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when ONDANSETRON VIATRIS is taken in combination with other serotonergic drugs.
- severe skin reaction where the top layer of the skin detaches from the lower layers.
- 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, skin lumps or hives
- blurred vision
- dizziness

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

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.

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

Tell your doctor as soon as possible if you do not feel well while you are being given ONDANSETRON VIATRIS or if your nausea (feeling of sickness) and vomiting does not go away.

In certain illnesses and treatments where ONDANSETRON VIATRIS is 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 VIATRIS has 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, you should tell your doctor immediately.

How do I store ONDANSETRON VIATRIS

ONDANSETRON VIATRIS will be stored in the pharmacy or the ward.

Keep this medicine where children cannot reach it, such as in a locked cupboard.

The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Do not leave in car, on window sill or in bathroom.

Keep the injection ampoules in their pack until time to take.

Return any unused or expired medicine to your pharmacist.

Product description

What it looks like

Each ampoule contains 2mg/mL ondansetron (as hydrochloride) in either 2 mL or 4 mL colourless clear, practically odourless, free of visible particles solution.

Available in packs of five ampoules.

Ingredients

ONDANSETRON VIATRIS contains 2mg/mL of ondansetron (as hydrochloride) as the active ingredient.

The solution for injection also contains the following inactive ingredients:

- citric acid monohydrate
- sodium citrate dihydrate
- sodium chloride
- water for injections

Supplier

ONDANSETRON VIATRIS is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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Australian registration numbers:

ONDANSETRON VIATRIS
4 mg/2 mL - AUST R 155842

ONDANSETRON VIATRIS
8 mg/4 mL - AUST R 155843

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