

ONDANSETRON ACCORD INJECTION

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ondansetron Accord Injection. 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 Ondansetron Accord Injection against the benefits this medicine is expected to have for you.

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

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

Keep this leaflet.

You may need to read it again.

What Ondansetron Accord Injection is used for

Ondansetron Accord Injection contains a medicine called ondansetron. This belongs to a group of medicines called antiemetics/ antinauseants.

Ondansetron Accord Injection is used to prevent the nausea (feeling

sick) and vomiting that may occur after surgery or after therapy with anticancer medicines (chemotherapy) or radiation.

Ondansetron Accord Injection may be used for the management of other conditions that are not mentioned above. Your doctor will be able to tell you about the specific condition for which you have been prescribed Ondansetron Accord Injection.

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

Before you are given Ondansetron Accord Injection

When you must not be given it

Do not use Ondansetron Accord Injection if:

- you have an allergy to ondansetron or any of the ingredients listed at the end of this leaflet
- you are pregnant or trying to become pregnant
- you are breastfeeding
- you are taking apomorphine (used to treat Parkinson's disease)

If you are not sure whether any of these apply to you, check with your doctor.

Before you are given it

Tell your doctor if:

1. **you have any allergies to:**
 - any other medicine
 - any other substances, such as foods, preservatives or dyes
2. **you are pregnant or intend to become pregnant**
3. **you are breastfeeding or plan to breastfeed**
4. **you have liver problems**
5. **you have an abnormal heart rhythm (QT prolongation)**
6. **you have any blood problems, including abnormal salt levels in your blood**

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your 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
- medicines that are known to lead to an abnormal heart rhythm (QT prolongation)

Your doctor will advise you about any dosage adjustments needed and continuing to take other medicines while you are receiving Ondansetron Accord Injection.

How Ondansetron Accord Injection is given

Ondansetron Accord Injection is given by injection into the muscle or by slow injection into a vein. It must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive Ondansetron Accord Injection.

The clinical safety of Ondansetron in children under 2 years has not been established.

While you are being given Ondansetron Accord Injection

If you are given too much (overdose)

This rarely happens as Ondansetron Accord Injection is administered under the care of a highly trained doctor.

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

Your doctor has information on how to recognise and treat an overdose.

Ask your doctor if you have any concerns.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Ondansetron Accord Injection or if your nausea and vomiting does not go away.

Like other medicines, Ondansetron Accord Injection can cause some side effects. If they occur, most are likely to be minor or temporary. However, some may be serious and need medical attention.

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

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

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

- headache
- a sensation of warmth or flushing
- mild stomach cramps
- constipation or diarrhoea
- dry mouth
- pain, redness or burning at place of injection
- hiccups

These are all common side effects.

Tell your doctor or nurse 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 Accord Injection is taken in combination with other 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.
- 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 serious side effects, some of which include symptoms of an allergic reaction. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some patients.

Storage

Stored below 25°C. Protect from Light.

Product description

What it looks like

Ondansetron Accord Injection is a clear, colourless to almost colourless solution in a clear or amber glass ampoule.

Pack size: Five or Ten Ampoules

Ondansetron Accord Injection can be identified by an Australian Registration Number, which is found on the packaging:

AUST R 205594 Ondansetron Accord Injection 4 mg /2 mL (sterile) Glass Ampoule (5’s, 10’s).

AUST R 205599 Ondansetron Accord Injection 8 mg /4 mL (sterile) Glass Ampoule (5’s, 10’s).

Ingredients

Ondansetron Accord Injection contains ondansetron 2 mg/mL, citric acid monohydrate, sodium citrate dihydrate and sodium chloride in water for injections.

Hydrochloric acid, concentrated and sodium hydroxide is added as necessary to adjust the pH. It does not contain a preservative.

*Name and Address of the
Sponsor*

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Date of preparation

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