ONDANSETRON ACCORD

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Ondansetron Accord?

Ondansetron Accord contains the active ingredient ondansetron. This belongs to a group of medicines called antiemetics/antinauseants. Ondansetron Accord is used to prevent the nausea (feeling sick) and vomiting that may occur after surgery or after therapy with anticancer medicines (chemotherapy) or radiation.

For more information, see Section 1. Why am I being given Ondansetron Accord? in the full CMI.

2. What should I know before I am given Ondansetron Accord?

Do not use if you have ever had an allergic reaction to an any medicine containing ondansetron or any of the ingredients listed at the end of this leaflet.

You should also not be given it if you are taking apomorphine (used to treat Parkinson's disease).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Ondansetron Accord? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ondansetron Accord and affect how it works.

See Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given Ondansetron Accord?

Ondansetron Accord is an injection and will be given to you by your doctor or nurse.

More instructions can be found in Section 4. How do I use Ondansetron Accord? in the full CMI.

5. What should I know while being given Ondansetron Accord?

Things you	Tell your doctor before you take any other medicines, whether they require a prescription or not	
should do		

For more information, see Section 5. What should I know while I am being given Ondansetron Accord? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

ONDANSETRON ACCORD

Active ingredient: ondansetron (as hydrochloride dihydrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about Ondansetron Accord. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given Ondansetron Accord.

Where to find information in this leaflet:

- 1. Why am I being given Ondansetron Accord?
- 2. What should I know before I am given Ondansetron Accord?
- 3. What if I am taking other medicines?
- 4. How will I be given Ondansetron Accord?
- 5. What should I know while being given Ondansetron Accord?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being given Ondansetron Accord?

Ondansetron Accord contains the active ingredient ondansetron. This belongs to a group of medicines called antiemetics/antinauseants.

Ondansetron Accord is used to prevent the nausea (feeling sick) and vomiting that may occur after surgery or after therapy with anticancer medicines (chemotherapy) or radiation.

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.

Ondansetron Accord 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.

2. What should I know before I am given Ondansetron Accord?

Warnings

You must not be given Ondansetron Accord 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:

- you have any allergies to:
 - any other medicine
 - any other substances, such as foods, preservatives or dyes
- you have liver problems
- you have an abnormal heart rhythm (QT prolongation)
- you have any blood problems, including abnormal salt levels in your blood.

Pregnancy and breastfeeding

Tell your doctor if:

- you are pregnant or intend to become pregnant
- you are breastfeeding or plan to breastfeed

3. What if I am 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.

4. How will I be given Ondansetron Accord?

Ondansetron Accord 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.

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

If you are given too much (overdose)

This rarely happens as Ondansetron Accord 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 "Are there any side effects?" below.

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

Ask your doctor if you have any concerns.

5. What should I know while I am being given Ondansetron Accord?

Driving or using machines

Ondansetron is unlikely to have any effect on a person's ability to drive or operate machinery.

However, you should be careful driving or operating machinery until you know how Ondansetron Accord affects you.

Looking after your medicine

The hospital will store Ondansetron Accord under the correct conditions. Any unused medicine will be disposed of appropriately by the medical staff.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Ondansetron Accord that may be left over.

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do	
 headache a sensation of warmth or flushing mild stomach cramps constipation or diarrhoea dry mouth pain, redness or burning at place of injection hiccups 	Speak to your doctor if you have any of these common side effects and they worry you	

Serious side effects

Serious side effects		What to do
•	'wheezy' symptoms	Tell your doctor
•	chest pain or tightness of the	or nurse
	chest	immediately or
•	changes in the way your heart	go to casualty
	beats, e.g. if you notice it	at your nearest
	beating faster or slower than	hospital
	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 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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Ondansetron Accord contains

Active ingredient (main ingredient)	Ondansetron (as ondansetron hydrochloride dihydrate
Other ingredients (inactive ingredients)	sodium chloride sodium citrate dihydrate citric acid monohydrate sodium hydroxide hydrochloric acid water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Ondansetron Accord looks like

Ondansetron Accord is a clear, colourless solution in a clear or amber glass ampoule in packs of 5 or 10 (4 mg/2 mL Aust R 205594, 8 mg/4 mL Aust R 205599). Or in an amber syringe in a 1 pack (4 mg/2 mL Aust R 338224, 8 mg/4 mL Aust R 338227).

Not all presentations may be marketed.

Who distributes Ondansetron Accord

Accord Healthcare Pty Ltd Level 24, 570 Bourke Street Melbourne, VIC, 3000 Australia

This leaflet was prepared in November 2021.