
Consumer Medicine Information

ONDANACCORD INJECTION

Ondansetron hydrochloride dihydrate injection 2 mg/mL, 2 ml and 4 mL

What is in this leaflet

Please read this leaflet carefully before you start using Ondanaccord.

This leaflet answers some common questions about Ondanaccord. 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 treating you with Ondanaccord against the expected benefits it will have for you.

If you have any concerns about being treated with this medicine. Ask your doctor or Pharmacist

Keep this leaflet. You may need to read it again.

What Ondanaccord are used for

Ondanaccord is used to help stop the nausea (sick feeling) and vomiting which can occur after certain treatments such as chemotherapy and radiotherapy. It is also used for prevention of nausea and vomiting, which can occur after an operation. Ondanaccord should only be used to treat the nausea and vomiting for which it has been prescribed.

Ondanaccord is not addictive.

Before you use Ondanaccord

When you must not use Ondanaccord

Do not use Ondanaccord after the expiry or "use by" date (EXP) printed on the pack. If you take it after the expiry date it may not work as well.

Do not use Ondanaccord if the packaging is torn or shows signs of tampering or if the solution in the injection looks cloudy, lumpy or discolored.

Do not give your Ondanaccord Injection to anyone else.

Do not take Ondanaccord if you have ever had an allergic reaction to ondansetron or any of the other ingredients in Ondanaccord which are listed at the end of this leaflet.

Before you take Ondanaccord

Tell your doctor if you are pregnant, trying to become pregnant or breast feeding. Your doctor can discuss the risks and benefits of using Ondanaccord with you.

If you have had to stop taking another medicine for your nausea or vomiting, tell your doctor.

If you are allergic to any foods, dyes, preservatives or any other medicine, tell your doctor.

If you have or used to have liver problems, tell your doctor.

Tell your doctor if you are constipated.

Taking other medicines

Tell your doctor the names of any medicines you are taking, including those you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:

- Carbamazepine (TegretolTM, TerilTM) – a medicine for epilepsy, bipolar disorder and some pain conditions
- Rifampicin (RifadinTM, RifanahTM) – an antibiotic used for tuberculosis and other infections
- Phenytoin (DilantinTM) – a medicine for epilepsy
- Tramadol (TramalTM, ZytramTM) – a medicine for pain

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when taking Ondanaccord with other medicines.

How to use Ondanaccord

Your Injection must only be given by a doctor or a nurse. Sometimes, other medicines are given at the same time. Do not use the injection on your own.

The injection can be given slowly:

- Into a vein
- Into a muscle

If your nausea (feeling of sickness) or vomiting does not go away, ask your doctor what to do.

Ondanaccord should not affect your ability to drive or operate machinery.

Side effects

Like all medicines, Ondanaccord may cause some side effects. Sometimes they are serious, most of the time they are not. Your doctor or pharmacist will be able to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- headache
- a sensation of warmth or flushing
- constipation
- hiccups

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

Tell your doctor immediately or go to your casualty at your nearest hospital if you notice any of the following side effects:

- 'wheezy' symptoms
- 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'
- 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
- problems with muscles or movement

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

If you feel unwell or have any symptoms that you do not understand, you should tell your doctor immediately.

After taking Ondanaccord

Keep your Ondanaccord:

In a place where children cannot reach them. A locked cupboard at least one- and-a half metres above the ground is a good place to store medicines.

In the pack until it is time to take it.

In a cool, dry place (below 25°C). Do not leave it in the car on hot days.

Away from bright sunlight.

Do not store the medicine in a bathroom or near a sink.
Humidity and heat can destroy some medicines

Instructions for use/handling

Shelf life

Ondanaccord ampoules have a shelf life of 2years.

Ondanaccord injection ampoules:-

The ampoule formulation is unpreserved and should only be used on a single occasion, injected or diluted immediately after opening; any remaining solution should be discarded.

Ondanaccord injection ampoules should not be autoclaved.

Compatibility with intravenous fluids:-

In keeping with good pharmaceutical practice intravenous solutions should be prepared at the time of infusion. However, unpreserved Ondansetron injection has been shown to be stable for seven days at room temperature (below 25°C) under fluorescent lighting or in a refrigerator with the following intravenous infusion fluids:

Sodium Chloride Intravenous Infusion BP 0.9% w/v.

Glucose Intravenous Infusion BP 5% w/v.

Mannitol Intravenous Infusion BP 10% w/v.

Ringers Intravenous Infusion.

Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v Intravenous Infusion BP.

Potassium Chloride 0.3% w/v and Glucose 5% w/v Intravenous Infusion BP.

Compatibility studies have been undertaken in polyvinyl chloride infusion bags, Polyethylene infusion bags, Glass bottles and Polypropylene syringes. It is considered that adequate stability would also be conferred by the use of polyethylene infusion bags or Type 1 glass bottles.

Dilutions of unpreserved ondansetron injection in sodium chloride 0.9% w/v or in glucose 5% w/v have been demonstrated to be stable in polypropylene syringes. It is considered that unpreserved ondansetron injection diluted with compatible infusion fluids recommended above would be stable in polypropylene syringes.

Note: Preparation must be under the appropriate aseptic conditions if extended storage periods are required.

Compatibility with other drugs:-

Ondansetron may be administered by intravenous infusion at 1mg/hour, eg. from an infusion bag or syringe pump. The following drugs may be administered via the Y-site of the ondansetron giving set for ondansetron concentrations of 16 to 160mcg/mL (eg 8mg/500mL and 8mg/50mL respectively);

- Cisplatin: - Concentrations up to 0.48mg/mL (eg. 240mg in 500mL) administered over one to eight hours.
- 5-fluorouracil: - Concentrations up to 0.8mg/mL (eg 2.4g in 3 litres or 400mg in 500mL) administered at a rate of at least 20mL per hour (500mL per 24 hours). Higher concentrations of 5-fluorouracil may cause precipitation of ondansetron. The 5-fluorouracil infusion may contain up to 0.045%w/v magnesium chloride in addition to other excipients shown to be compatible.
- Carboplatin: - Concentrations in the range 0.18mg/mL to 9.9mg/mL (eg 90mg in 500mL to 990mg in 100mL), administered over ten minutes to one hour.
- Etoposide: - Concentrations in the range 0.144mg/mL to 0.25mg/mL (eg. 72mg in 500mL to 250mg in 1 liter), administered over thirty minutes to one hour.
- Ceftazidime: - Doses in the range 250mg to 2000mg reconstituted with Water for Injections BP as recommended by the manufacturer (eg. 2.5mL for 250mg and 10mL for 2g ceftazidime) and given as an intravenous bolus injection over approximately five minutes.
- Cyclophosphamide:- Doses in the range 100mg to 1g, reconstituted with Water for Injections BP, 5mL per 100mg cyclophosphamide, as recommended by the manufacturer, and given as an intravenous bolus injection over approximately five minutes.
- Doxorubicin:- Doses in the range 10-100mg reconstituted with Water for Injections BP, 5mL per 10mg doxorubicin, as recommended by the manufacturer and given as an intravenous bolus injection over approximately five minutes.

Disposal

Return any unused medicine or medicine which has gone past its expiry date to your pharmacist.

Product description

What Ondanaccord looks like.

Your Ondanaccord Injection comes in a glass ampoule wrapped in an individual foil blister.

The ampoules contain ondansetron in 2mL or 4mL clear colourless liquid.

Pack of 5 × 2 mL ampoules, 10 × 2 mL ampoules, 5 × 4 mL ampoules, 10 × 4 mL ampoules,

Ingredients

Each solution contains either 4 or 8 milligrams of ondansetron. Your doctor will decide which strength you need.

Your injection also contains small amounts of
Citric acid,
Sodium citrate,
Sodium chloride,
Sodium hydroxide (for pH adjustment),
Hydrochloric acid, concentrated (for pH adjustment),
Water for injections

Manufacturer

Your Ondanaccord Injection *Distributed in New Zealand by:*

Arrow Pharmaceuticals (NZ) Ltd.
PO Box 128244.
Remuera, Auckland
Telephone : +64 (09) 630-4488

Further Information

Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your illness and its treatment from other sources, for example from books in public libraries.

Do not throw this leaflet away. You may want or need to read it again.

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