

Ondansetron AN tablets

Ondansetron (as hydrochloride dihydrate)

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use Ondansetron AN.

This leaflet answers some common questions about Ondansetron AN.

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 benefits and risks. Your doctor has weighed the risks of you taking Ondansetron AN against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Ondansetron AN is used for

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

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

ONDANSETRON AN should only be used to treat the nausea and vomiting for which they have been prescribed.

Your doctor may have prescribed Ondansetron AN for another reason. If you want more information, ask your doctor.

Ondansetron AN is not addictive.

Before you take Ondansetron AN

When you must not take Ondansetron AN

Do not take Ondansetron AN if:

- **You are taking apomorphine (used to treat Parkinsons disease)**
- **You have ever had an allergic reaction to ondansetron or any of the ingredients listed towards the end of this leaflet (see 'Ingredients')**
- **You are pregnant, trying to become pregnant or breastfeeding, unless your doctor says it is safe**
- **The expiry date printed n the pack has passed**
- **The packaging is torn or shows signs of tampering**

Tell your doctor if:

- **You are allergic to foods, dyes, preservatives or any other medicines.**
- **You have had to stop taking another medicine for your nausea or vomiting.**
- **You are taking any other medicines, including medicines you buy without a prescription.**
- **You have or used to have liver problems.**

- **You are breastfeeding, pregnant or trying to become pregnant.**

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

How to take Ondansetron AN

How much to take

Take Ondansetron AN as directed by your doctor or pharmacist.

Do NOT take MORE TABLETS than your doctor or pharmacist tells you.

Do NOT take the tablets MORE OFTEN than your doctor or pharmacist tells you.

If you vomit within one hour taking your first Ondansetron AN of each course prescribed to you, you should take the same dose again. If you continue to vomit, tell your doctor.

How to take it

Swallow each tablet with a drink of water. Do not crush the tablet. If you have trouble swallowing your tablet, please tell your doctor.

How long to take it

Do not stop taking Ondansetron AN, or change the dose without first checking with your doctor.

If you forget to take it

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 AN 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 the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Ondansetron AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Ondansetron AN

Things you must do

Tell your doctor, if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Things you must not do

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

Do not use Ondansetron AN to treat any other complaints unless your doctor says to.

Side Effects

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

Like other medicines, Ondansetron AN 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

These are all mild side effects. There is no immediate reason to stop taking your tablets 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 '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

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

This is not a complete list of all possible side effects. Other 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.

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 AN 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 AN 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.

After taking Ondansetron AN

Storage

Keep Ondansetron AN where 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 your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink.

Do not leave in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Ondansetron AN, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Name and Address of the Sponsor

Amneal Pharma Australia Pty Ltd,
12 River St, South Yarra
VIC - 3142
Australia

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Product description

What it looks like

- **Ondansetron AN 4 mg** (AUST R 173186)
Contains 4 mg Ondansetron (as Ondansetron hydrogen dihydrate)
White to off white, oval shaped, film-coated tablets debossed with 'E' on one side and '01' on the other side.
Available in PVC/Al blister packs of 4, 10, 30 or 90 tablets.
- **Ondansetron AN 8 mg** (AUST R 173187)
Contains 8 mg Ondansetron (as Ondansetron hydrogen dihydrate)
Yellow coated, oval shaped, film-coated tablets debossed with 'E' on one side and '02' on the other side.
Available in PVC/Al blister packs of 4, 10, 30 or 90 tablets.

Ingredients

Active Ingredient:

Ondansetron (as hydrochloride dihydrate)

Other Ingredients:

- Microcrystalline cellulose
- Lactose anhydrous
- Magnesium stearate
- Pregelatinised starch
- The 4 mg tablets also contains glycerol triacetate, hypromellose, and titanium dioxide
- The 8 mg tablet also contains Opadry Complete Film Coating System 03K52033 Yellow

Please read this leaflet carefully before you start taking Ondansetron AN. You may wish to keep it to read again.