

APO-Ondansetron

Contains the active ingredient, ondansetron (as hydrochloride dihydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about ondansetron.

It does not contain all the available information.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Ondansetron. It contains the active ingredient, ondansetron.

It is used to help stop the nausea and vomiting which can occur after some medical treatments.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed ondansetron for another reason.

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

How it works

Ondansetron belongs to a group of medicines called serotonin receptor -3 antagonists.

There is no evidence that this medicine is addictive.

Use in children

There is not enough information to recommend the use of this medicine in children four years of age and under.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You are taking apomorphine (used to treat Parkinson's disease)
- You are hypersensitive to, or have had an allergic reaction to, ondansetron or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or if it does not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. You have allergies to:

- any other serotonin receptor antagonists
- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- liver problems
- problems with your digestive system (i.e. constipation).

3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines, This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines and ondansetron may interfere with each other. These include:

- apomorphine, to treat Parkinson's Disease.
- Do not take ondansetron whilst taking this medicine.**
- medicines to treat epilepsy
 - tramadol, a pain reliever
 - rifampicin, a type of antibiotic.

These medicines may be affected by ondansetron or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor may have more information on medicines to be careful with or avoid while taking ondansetron.

Other interactions not listed above may also occur.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

Do NOT take MORE TABLETS than your doctor tells you to.

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

If you vomit within one hour of taking your first tablet 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 the tablet(s) with a glass of water. Do not crush the tablet(s).

When to take it

Take this medicine at about the same time each day. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

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

Make sure you have enough to last over weekends and holidays.

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

ondansetron 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much ondansetron, you may have problems seeing, constipation, low blood pressure, fainting or heart problems.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

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

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

Be careful while driving or operating machinery until you know how ondansetron affects you.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking ondansetron or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- headache
- a sensation of warmth or flushing
- mild stomach cramps
- constipation or diarrhoea
- dry mouth
- hiccups.

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

These may be serious side effects. You may need medical attention.

- fixed, staring eyes
- problems with your eyesight
- problems moving normally, or
- shaking or twitching
- dizziness
- low blood pressure (which would
- make you light-headed)
- liver problems.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- wheezing or difficulty breathing
- chest pain or tightness
- palpitations, or fast or slow or irregular heart beats
- fainting
- fits or convulsions
- swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse
- skin rash, lumps or hives.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

Others side effects not listed above may occur in some patients.

If your nausea or vomiting does not go away, ask your doctor what to do.

In certain medical conditions where ondansetron has been used, blood vessel blockage has occurred.

However, this has also happened in conditions when ondansetron has NOT been used. Discuss this with your doctor if you have any concerns.

Allergic reactions

If you think you are having an allergic reaction to ondansetron, do not take any more of this medicine and tell your doctor immediately or go to the Accident

and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms.

After taking this medicine

Storage

Keep your tablets in their original packaging until it is time to take them.

If you take them out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

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

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an

individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Australia

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Product description

This leaflet was prepared in January 2012

What APO-Ondansetron looks like

APO-Ondansetron 4 mg Tablets:

Round white tablets marked "4" on one side

Available in blister packs containing 4 or 10 tablets.

APO-Ondansetron 8 mg Tablets:

Round white tablets marked "8" on one side and a scoreline on the other.

Available in blister packs containing 4 or 10 tablets.

Ingredients

Each tablet contains 4 mg or 8 mg of ondansetron as the active ingredient (as hydrochloride dihydrate).

They also contain the following inactive ingredients:

- lactose
- microcrystalline cellulose
- maize starch
- magnesium stearate
- Opadry Y-1-7000 White.

This medicine is gluten-free, sucrose-free, tartrazine-free and other azo dyes-free.

Australian Registration Numbers

APO-Ondansetron 4 mg Tablets:
AUST R 152187

APO-Ondansetron 8 mg Tablets:
AUST R 152188

Distributor

Apotex Pty Ltd
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