

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

APO-ONDANSETRON

Ondansetron hydrochloride dihydrate

This leaflet is part III of a three-part “Product Monograph” published when APO-ONDANSETRON was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-ONDANSETRON. Contact your doctor or pharmacist if you have any questions about the drug.

APO-ONDANSETRON can only be obtained with a prescription from your doctor.

ABOUT THIS MEDICATION

What the medication is used for:

The name of your medicine is APO-ONDANSETRON Tablets (ondansetron hydrochloride dihydrate). This medicine is one of a group called antiemetics.

APO-ONDANSETRON is used for:

- the prevention of nausea (feeling of sickness) and vomiting during treatment for cancer (chemotherapy and radiotherapy).
- the prevention and treatment of nausea and vomiting after surgery.

What it does:

Treatments such as general anaesthesia, cancer chemotherapy and radiotherapy are thought to cause the release of a natural substance (serotonin), which can cause you to feel sick and to vomit. APO-ONDANSETRON helps to stop this from happening, thus preventing you from vomiting or feeling sick.

When it should not be used:

Do not take APO-ONDANSETRON if:

- you have a history of hypersensitivity (an allergic reaction) to any ingredient (see What the nonmedicinal ingredients are) in APO-ONDANSETRON.
- if you are taking apomorphine (used to treat Parkinson’s disease).

What the medicinal ingredient is:

Ondansetron hydrochloride dihydrate.

What the nonmedicinal ingredients are:

APO-ONDANSETRON tablets contain the following non-medicinal ingredients: croscarmellose sodium, hydroxypropylcellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, titanium dioxide and a yellow colouring agent containing yellow iron oxide.

What dosage forms it comes in:

APO-ONDANSETRON tablets are supplied in two strengths, one contains 4 milligrams of ondansetron and the other contains 8 milligrams of ondansetron. Your doctor will decide which strength you need.

WARNINGS AND PRECAUTIONS

Before you use APO-ONDANSETRON talk to your doctor or pharmacist if:

- you have a history of hypersensitivity (an allergic reaction) to any ingredient in APO-ONDANSETRON.
- If you have had an allergic reaction to medicines similar to APO-ONDANSETRON such as medicines containing *granisetron* or *palonosetron*.
- you are pregnant or likely to become pregnant.
- you are breast feeding .
- you have liver problems.
- you have signs of intestinal obstruction.
- you have a history of heart problems.

If you experience wheezing and tightness of the chest, heart throbbing, swelling of eyelids, face or lips, or develop a skin rash, skin lumps or hives, **contact your doctor immediately. Do not take anymore medicine unless your doctor tells you to do so.**

Serotonin Syndrome is a rare but potentially life-threatening reaction that may occur if you take APO-ONDANSETRON with certain other medications. It may cause serious changes in how your brain, muscles and digestive system work. Be sure to tell your healthcare professional all the medicines you are taking.

INTERACTIONS WITH THIS MEDICATION

IMPORTANT: PLEASE READ

As with most medicines, interactions with other drugs are possible. To avoid potentially life-threatening reactions tell your healthcare professional about ALL the medications you take, including those prescribed by other doctors, vitamins, minerals, natural supplements or alternative medicines. It is important that your doctor know about all your medication so that you get the best possible treatment. Tell your doctor if you are taking carbamazepine, phenytoin, or rifampicin. If you are taking any medicines containing tramadol, APO-ONDANSETRON may decrease its effectiveness.

Also, make sure you tell your doctor or pharmacist if you are taking:

- Drugs used to treat heart rhythm disorders
- Other drugs that may disturb heart rhythm
- Antipsychotics
- Antidepressants
- Antibiotics or antifungals
- Opioid analgesics (painkillers)
- Other drugs to treat nausea and vomiting
- Asthma drugs
- Cancer drugs
- Diuretics
- Other drugs that affect serotonin including SSRI*s, SNRI**s, triptans, MAOIs*** (including the antibiotic linezolid and methylene blue), drugs that contain tryptophan, or St. John's Wort.

*SSRI (Selective Serotonin-Reuptake Inhibitors) – used to treat depression or anxiety, e.g. escitalopram, citalopram, fluoxetine, paroxetine, sertraline.

**SNRI (Serotonin Noradrenalin Reuptake Inhibitors) – used to treat depression or anxiety, e.g. duloxetine, venlafaxine, desvenlafaxine.

***MAOIs (Monoamine Oxidase Inhibitors) – used to treat depression, Parkinson's disease, e.g., phenelzine, rasagiline, selegiline.

PROPER USE OF THIS MEDICATION

The label on the container of your medicine should tell you how often to take your medicine and how many doses you should take each time. If not, or if you are not sure, consult your doctor or pharmacist.

Do not take more doses, or take them more often than your doctor prescribes. If, however, you vomit within one hour of taking your medicine, you should take the same amount of medicine again. If vomiting persists, consult your doctor.

Usual dose:

Chemotherapy Induced Nausea and Vomiting

Based on how likely you are to experience nausea and/or vomiting, caused by your cancer treatment, your doctor will tell you the amount you need to take and how frequently.

Adult: You may receive APO-ONDANSETRON before and/or after chemotherapy. The dose of APO-ONDANSETRON will be between 8 and 24 mg a day (taken orally) for up to 5 days depending on the potential of your chemotherapy treatment to cause you to vomit and/or have nausea.

Children (4 to 12 years): After chemotherapy, take 4 mg orally every 8 hours for up to 5 days.

Radiotherapy Induced Nausea and Vomiting

Adult: Take 8 mg orally 1 to 2 hours before radiotherapy. After therapy, take 8 mg orally every 8 hours for up to 5 days after a course of treatment.

Prevention of Post-Operative Nausea and Vomiting

Adult: Take 16 mg orally one hour before anaesthesia.

If you have a liver problem, your dose may be altered. Please follow the instructions of your doctor.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose and do not feel sick, take the next dose when it is due.

If you forget to take your medicine and feel sick or vomit, take a dose as soon as possible.

If your doctor decides to stop the treatment, do not keep any left over medicine unless your doctor tells you to.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You may experience headaches, a feeling of warmth, flushing or constipation, while taking APO-ONDANSETRON. Although uncommon, low blood pressure and hiccups have also been reported.

IMPORTANT: PLEASE READ

There is no need to stop taking your medicine, but you should tell your doctor about these symptoms at your next visit.

If your nausea (feeling of sickness) or vomiting do not improve while taking APO-ONDANSETRON, consult your doctor for further advice.

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

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Frequency	Side Effect/ Symptom	Talk with your Doctor or Pharmacist	Stop taking drug and seek immediate emergency assistance
Uncommon	Heart problems such as fast/slow heart beat, chest pain		✓
	Seizures		✓
	Upward rolling of the eyes, abnormal muscular stiffness/body movements/shaking		✓
Rare	Eye problems such as blurred vision	✓	
	Immediate allergic reaction and symptoms such as swelling of the mouth, throat, difficulty in breathing, rash, hives, increased heart rate		✓
	Disturbance in heart rhythm (dizziness, palpitations, fainting)		✓

	Serotonin Syndrome: Symptoms of Serotonin Syndrome have been observed while taking ondansetron with certain other medications. Symptoms include: <ul style="list-style-type: none"> • agitation, confusion, restlessness, hallucinations, mood changes, unconsciousness, coma. • fast heartbeat, changes in blood pressure • Muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination • nausea, vomiting, diarrhea, fever, sweating, shivering. 		✓
Very Rare	Eye problems such as temporary blindness Signs of serious skin reactions (skin rash, redness of the skin, blistering of the lips, eyes or mouth, and skin peeling.)	✓	✓

This is not a complete list of side effects. For any unexpected effects while taking APO-ONDANSETRON, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. Your medicine may harm them.

APO-ONDANSETRON tablets should be kept at room temperature (15°C - 30°C) in a well closed container and protected from light.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Remember: This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

This leaflet does not contain the complete information about your medicine. If any questions remain unanswered or you are not sure about something, you should ask your doctor or pharmacist.

You may want to read this leaflet again. **Please Do Not Throw It Away** until you have finished your medicine.

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service, at 1-800-667-4708. This leaflet can also be found at <http://www.apotex.ca/products>

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9

Date of Revision: August 14, 2017