

PART III: CONSUMER INFORMATION

ONDANSETRON Ondansetron Oral Solution USP

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

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 ONDANSETRON Oral Solution (ondansetron hydrochloride dihydrate). This medicine is one of a group called antiemetics.

ONDANSETRON is used for:

- the prevention of nausea (feeling of sickness) and vomiting associated with emetogenic chemotherapy, and radiotherapy.
- the prevention and treatment of post-operative nausea and vomiting.

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. ONDANSETRON helps to stop this from happening, thus preventing you from vomiting or feeling sick.

When it should not be used:

Do not take ONDANSETRON if:

- you have a history of hypersensitivity (an allergic reaction) to any ingredient (see What the important non-medicinal ingredients are) in ONDANSETRON.
- you are pregnant, or likely to become pregnant, or if you are breast feeding a baby. However, there may be circumstances when your doctor advises you to use this medicine during pregnancy.

What the medicinal ingredient is:

ONDANSETRON Oral Solution contains ondansetron hydrochloride dihydrate as the medicinal ingredient.

What the important non-medicinal ingredients are:

ONDANSETRON Oral Solution contains the follow-ing non-medicinal ingredients: citric acid, hydroxyethyl cellulose, purified water, sodium benzoate, sodium citrate dihydrate, and strawberry flavour. ONDANSETRON Oral Solution is sweetened with fructose.

What dosage forms it comes in:

ONDANSETRON Oral Solution is supplied in one strength, 4 mg of ondansetron per teaspoon (5 mL), in bottles. Your

doctor will decide how many teaspoons or milliliters you need.

WARNINGS AND PRECAUTIONS

BEFORE you use ONDANSETRON Oral Solution talk to your doctor or pharmacist if:

- you have a history of hypersensitivity (an allergic reaction) to any ingredient in ONDANSETRON.
- you are pregnant or likely to become pregnant.
- you are breast feeding a baby.
- 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.**

INTERACTIONS WITH THIS MEDICATION

It is important that your doctor know about all your medication so that you get the best possible treatment. Tell your doctor about all the medicines you are taking including those you have bought yourself. If you are taking any medicines containing tramadol (such as TRAMACET), ONDANSETRON Oral Solution may decrease its effectiveness.

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

You will receive ondansetron prior to chemotherapy. 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: The dose of ONDANSETRON will be between 8 and 32 mg a day 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 the event you accidentally take more doses than prescribed, immediately contact your doctor or hospital emergency department or nearest poison control centre.

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.

Do not double dose.

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 ONDANSETRON Oral Solution. 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 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist	Stop taking the drug and call your doctor or pharmacist immediately
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		✓
Very Rare	Eye problems such as temporary blindness	✓	

This is not a complete list of side effects. For any unexpected effects while taking 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.

Your ONDANSETRON Oral Solution should be kept in its bottle, standing up at room temperature. Do not refrigerate or freeze. Do not lay the bottle on its side.

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
Address Locator: 0701D
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.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor AA Pharma Inc. at:

1-877-998-9097

This leaflet was prepared by AA Pharma Inc.

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