PART III: CONSUMER INFORMATION

Pr GRANISETRON HYDROCHLORIDE INJECTION

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

ABOUT THIS MEDICATION

What the medication is used for:

GRANISETRON HYDROCHLORIDE INJECTION is one of a group called antiemetics and it can only be obtained with a prescription from your doctor.

GRANISETRON HYDROCHLORIDE INJECTION is intended to prevent nausea (feeling sick) and vomiting which may occur after you receive cancer chemotherapy.

What it does:

Cancer chemotherapies are thought to cause the release of serotonin, a natural substance in the body. Serotonin can cause you to feel sick and to vomit. Granisetron, the active ingredient in GRANISETRON HYDROCHLORIDE INJECTION, will stop the action of serotonin and help prevent you from feeling sick and vomiting.

When it should not be used:

- Do not take this medicine if you are allergic to granisetron or any of the ingredients GRANISETRON HYDROCHLORIDE INJECTION contains.
- If you are taking apomorphine.

What the medicinal ingredient is:

Granisetron hydrochloride

What the nonmedicinal ingredients are:

Each injection contains the following inactive ingredients:
Sodium Chloride, Benzyl Alcohol, Citric Acid Monohydrate, Water for Injection and Hydrochloric Acid and/or Sodium Hydroxide for pH adjustment.

What dosage forms it comes in:

GRANISETRON HYDROCHLORIDE INJECTION is supplied in amber glass multi-use vials of 1 mL or 4 mL packaged in boxes of 1 vial. Each vial contains 1 mg/mL granisetron as hydrochloride.

WARNINGS AND PRECAUTIONS

BEFORE you use GRANISETRON HYDROCHLORIDE INJECTION talk to your doctor or pharmacist if:

• you have any allergies to similar antiemetics such as dolasetron mesylate (Anzemet®) or ondansetron (Zofran®)
• you are pregnant, plan to become pregnant or are breastfeeding
• you have liver problems
• you have a history of heart problems
• you have been told by a doctor that you have a blockage of your gut or if you have severe constipation, pain or swelling in your stomach
• your are taking other medications, including drugs you can buy without a prescription and herbal products.

As GRANISETRON HYDROCHLORIDE INJECTION may cause drowsiness, you should avoid driving a car or operating hazardous machinery until you know it does not affect you.

PROPER USE OF THIS MEDICATION

This medicine is only for you, the person for whom the prescription was written. Do not give this medication to others.

Usual adult dose:

GRANISETRON HYDROCHLORIDE INJECTION will be given to you by hospital staff before and/or after your therapy.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience an allergic reaction (e.g. shortness of breath, drop in blood pressure, skin lumps or hives), contact your doctor immediately. Do not take any more medicine unless instructed to do so by your doctor.

If you experience symptoms of heart problems such as palpitations (fast, pounding or irregular heart beat), chest pain, dizziness or fainting, tell your doctor or nurse immediately.

You may experience headaches, constipation, weakness, sleepiness, diarrhea or abdominal pain while taking GRANISETRON HYDROCHLORIDE INJECTION. You may also experience pain, anemia or fever while on GRANISETRON HYDROCHLORIDE INJECTION therapy.

There is no need to stop the medicine but you should tell your doctor about these symptoms.

This is not a complete list of side effects. For any unexpected effects while taking GRANISETRON HYDROCHLORIDE INJECTION, contact your doctor or pharmacist.

HOW TO STORE IT

GRANISETRON HYDROCHLORIDE INJECTION should be stored at controlled room temperature (15-30°C). Discard unused portion. Protect from light. The vial should be used within 30 days once opened.

The expiry date of this medicine is printed on the label. Do not use the medicine after this date. Keep your medicine in a safe place out of the reach of children.

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 0701E
    Ottawa, Ontario
    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

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Omega Laboratories Ltd, at:

Montreal:	(514) 335-0310 or 1-800-363-0584
Ontario:	(905) 629-8980 or 1-800-268-1326
Vancouver:	(604) 271-6228 or 1-877-271-6228
By mail:	Omega Laboratories Ltd. 11 177 Hamon Montreal, QC H3M 3E4

This leaflet was prepared by Omega Laboratories Limited.

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