PART III: CONSUMER INFORMATION

PrZOFRAN® Tablets and Oral Solution
(ondansetron hydrochloride dihydrate)

PrZOFRAN® ODT (Orally Disintegrating Tablets)
(ondansetron)

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

ZOFRAN 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 ZOFRAN Tablets (ondansetron hydrochloride dihydrate) or ZOFRAN Oral Solution (ondansetron hydrochloride dihydrate) or ZOFRAN ODT orally disintegrating tablets (ondansetron). This medicine is one of a group called antiemetics.

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

When it should not be used:
Do not take ZOFRAN or ZOFRAN ODT if:
- you have a history of hypersensitivity (an allergic reaction) to any ingredient in ZOFRAN or ZOFRAN ODT.
- you are taking apomorphine (used to treat Parkinson's disease).

What the medicinal ingredient is:
ZOFRAN Tablets and ZOFRAN Oral Solution contain ondansetron hydrochloride dihydrate as the medicinal ingredient.

ZOFRAN ODT orally disintegrating tablets contain ondansetron as the medicinal ingredient.

What the nonmedicinal ingredients are:
ZOFRAN Tablets contain the following nonmedicinal ingredients: lactose, magnesium stearate, methyl hydroxypropyl cellulose, microcrystalline cellulose, a small amount of a colouring agent called Opaspray or Opadry yellow, and pregelatinized starch.

ZOFRAN Oral Solution contains the following nonmedicinal ingredients: citric acid, sodium benzoate, sodium citrate dihydrate, and strawberry flavour (contains a small amount of ethanol (alcohol)). ZOFRAN Oral Solution is sucrose-free and is sweetened with sorbitol.

ZOFRAN ODT orally disintegrating tablets contain the following nonmedicinal ingredients: aspartame, gelatine, mannitol, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate and strawberry flavour (contains a small amount of ethanol (alcohol)).

What dosage forms it comes in:
ZOFRAN 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.

ZOFRAN 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.

ZOFRAN ODT orally disintegrating tablets are supplied in two strengths, one contains 4 milligrams of ondansetron and the other contains 8 milligrams of ondansetron.

WARNINGS AND PRECAUTIONS

ZOFRAN or ZOFRAN ODT are not recommended for use during pregnancy.

Breastfeeding is not recommended during treatment with ZOFRAN or ZOFRAN ODT. The ingredients can pass into your breast milk and may affect your baby.

ZOFRAN or ZOFRAN ODT may harm your unborn baby. If you are a woman of childbearing age, your doctor or healthcare provider will check if you are pregnant and perform a pregnancy test if necessary before starting treatment with ZOFRAN or ZOFRAN ODT. You should use effective birth control during treatment with ZOFRAN or ZOFRAN ODT. Ask your doctor about options of effective birth control.

BEFORE you use ZOFRAN or ZOFRAN ODT talk to your doctor or pharmacist if:
- you have a history of hypersensitivity (an allergic reaction) to any ingredient in ZOFRAN or ZOFRAN ODT.
- you have had an allergic reaction to medicines similar to ZOFRAN or ZOFRAN ODT 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.
- you have a condition called phenylketonuria and were prescribed ZOFRAN ODT, because it contains aspartame.

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 any more 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 ZOFRAN or ZOFRAN ODT 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

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, ZOFRAN 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
- Opiod 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.

For ZOFRAN ODT orally disintegrating tablets:

Do not try to push ZOFRAN ODT through the lidding foil.

Tear along the perforations of the foil to separate off one tablet within its blister unit.

Peel back the foil at the place indicated by the arrow.

Gently push the ZOFRAN ODT out of the blister pocket, and remove it with dry fingers.

Place the ZOFRAN ODT on top of the tongue. It will dissolve very quickly. Swallow as normal.

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 ZOFRAN before and/or after chemotherapy. The dose of ZOFRAN is 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 leftover medicine unless your doctor tells you to.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

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 ZOFRAN, 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

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		X
	Seizures		X
	Upward rolling of the eyes, abnormal muscular stiffness/body movements/shaking		X
Rare	Eye problems such as blurred vision	X	
	Immediate allergic reaction and symptoms such as swelling of the mouth, throat, difficulty in breathing, rash, hives, increased heart rate		X
	Disturbance in heart rhythm (dizziness, palpitations, fainting)		X
	Serotonin Syndrome: Symptoms of Serotonin Syndrome have been observed while taking ZOFRAN with certain other medications. Symptoms include: •agitation, confusion, restlessness, hallucinations, mood changes, unconsciousness, coma		X

Frequency	Side Effect/ Symptom	Talk with your Doctor or Pharmacist	Stop taking drug and seek immediate emergency assistance
	•fast heartbeat, changes in blood pressure • Muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination • nausea, vomiting, diarrhoea, 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)	X	X

This is not a complete list of side effects. For any unexpected effects while taking ZOFRAN & ZOFRAN ODT, 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 ZOFRAN Tablets and ZOFRAN ODT orally disintegrating tablets should be stored below 30°C.

Your ZOFRAN Oral Solution should be kept in its bottle, upright, between 15 and 30 °C. Do not refrigerate.

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, 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 found at:
http://www.novartis.ca or by contacting the sponsor,

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PART III: CONSUMER INFORMATION

PrZOFRAN® Injection
ondansetron (as ondansetron hydrochloride dihydrate)
2 mg/mL ondansetron for Injection

This leaflet is part III of a three-part "Product Monograph" published when ZOFRAN (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 ZOFRAN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
The name of your medicine is ZOFRAN Injection (ondansetron hydrochloride dihydrate). This medicine is one of a group called antiemetics.

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

When it should not be used:
Do not take ZOFRAN if:
- you have a history of hypersensitivity (an allergic reaction) to any ingredient in ZOFRAN.
- you are taking apomorphine (used to treat Parkinson's disease).

What the medicinal ingredient is:
ZOFRAN Injection contains ondansetron (as ondansetron hydrochloride dihydrate) as the medicinal ingredient.

What the nonmedicinal ingredients are:
ZOFRAN Injection may contain the following nonmedicinal ingredients: citric acid monohydrate, sodium chloride, and sodium citrate.

What dosage forms it comes in:
ZOFRAN Injection is available as ondansetron 2 mg/mL (as hydrochloride dihydrate) for intravenous use.

WARNINGS AND PRECAUTIONS

ZOFRAN is not recommended for use during pregnancy.

Breastfeeding is not recommended during treatment with ZOFRAN. The ingredients can pass into your breast milk and may affect your baby.

ZOFRAN may harm your unborn baby. If you are a woman of childbearing age, your doctor or healthcare provider will check if you are pregnant and perform a pregnancy test if necessary before starting treatment with ZOFRAN. You should use effective birth control during treatment with ZOFRAN. Ask your doctor about options of effective birth control.

BEFORE you use ZOFRAN talk to your doctor or pharmacist if:
- you have a history of hypersensitivity (an allergic reaction) to any ingredient in ZOFRAN.
- you have had an allergic reaction to medicines similar to ZOFRAN, 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.
- you have QT/QTc prolongation or a family history of QT/QTc prolongation
- you have low blood levels of potassium, magnesium, or calcium

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, **tell your doctor immediately.**

When given intravenously, ZOFRAN has an effect on the electrical activity of the heart known as QT/QTc prolongation. This effect can be measured as a change in the electrocardiogram (ECG). In very rare cases, drugs with this effect on the ECG can lead to disturbances in heart rhythm (arrhythmias/dysrhythmias) that could result in dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting or death. These heart rhythm disturbances are more likely in patients with risk factors, such as heart disease, or in the presence of certain interacting drugs. In general, females and people more than 65 years in age are at higher risk. It is important to follow the instructions of your doctor with regard to dosing or any special tests. If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heartbeat), or fainting, you should seek immediate medical attention.

Serotonin Syndrome is a rare but potentially life-threatening reaction that may occur if you take ZOFRAN 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

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, ZOFRAN 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
- Opiod 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

ZOFRAN Injection is not self administered by individual. It should be administered under the supervision of a health professional.

Usual dose:
Chemotherapy Induced Nausea and Vomiting
You will receive ZOFRAN by intravenous infusion. Based on how likely you are to experience nausea and /or vomiting, caused by your cancer treatment, your doctor will determine the appropriate dose regimen for you.

Adult: The single IV dose of ZOFRAN is between 8 and 16 mg before your chemotherapy. You may also receive ZOFRAN to be taken orally after your chemotherapy.

Children (4 to 12 years): The dose is 3 to 5 mg/m^2 just before chemotherapy.

Post-Operative Nausea and Vomiting
Adult: For prevention of post-operative nausea and vomiting, the dose is 4 mg at the time of surgery. For treating post-operative nausea and vomiting, the dose is 4 mg after surgery.
If you have a liver problem, your dose may be altered.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You may experience headaches, a feeling of warmness, flushing or constipation, while taking ZOFRAN. You may also experience pain, redness and burning sensation at the injection site.

Although uncommon, low blood pressure and hiccups have also been reported.

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

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Frequency	Side Effect/ Symptom	Talk with your Doctor Immediately
Uncommon	Heart problems such as fast/slow heartbeat, chest pain	X
	Seizures	X
	Upward rolling of the eyes, abnormal muscular stiffness / body movements / shaking	X
Rare	Eye problems such as blurred vision	X
	Immediate allergic reaction and symptoms such as swelling of the mouth, throat, difficulty in breathing, rash, hives, increased heart rate	X
	Disturbance in heart rhythm (dizziness, palpitations, fainting)	X
	Serotonin Syndrome: Symptoms of Serotonin Syndrome have been observed while taking ZOFRAN with certain other medications. Symptoms include: •agitation, confusion,	X

Frequency	Side Effect/ Symptom	Talk with your Doctor Immediately
	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, diarrhoea, 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)	X X

This is not a complete list of side effects. For any unexpected effects while taking ZOFRAN, contact your doctor.

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, 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

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.

This document plus the full product monograph, prepared for health professionals can be found at:
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