

CONSUMER INFORMATION

**Pr pms-DOMPERIDONE
Domperidone Tablets, House Standard
(as domperidone maleate)**

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

ABOUT THIS MEDICATION

What the medication is used for:

pms-DOMPERIDONE is used to treat symptoms of slowed stomach emptying seen in people with some gastrointestinal disorders (e.g. gastritis- inflammation of the GI tract). pms-DOMPERIDONE is also used to reduce symptoms such as nausea and vomiting caused by some drugs used to treat Parkinson's disease.

What it does:

pms-DOMPERIDONE increases the mild digestive contractions of the esophagus and stomach and helps to more effectively coordinate the emptying of food from the stomach into the intestine. It also helps to more effectively move digesting food material through the small intestine.

When it should not be used:

In should not be used in patients who are known to be allergic to domperidone or any of the non-medicinal ingredients (see *What the non-medicinal ingredients are*). It should not be used in patients who show signs of bleeding in the stomach or intestines, or who may have an obstruction or perforation of the stomach or intestines.

It should not be used in patients who have a tumour associated with the pituitary gland known as a prolactinoma.

Do not use pms-DOMPERIDONE if you have:

- moderate or severe liver problems
- heart disease including congestive heart failure or prolonged QT interval
- prolactinemia (a pituitary tumour releasing prolactin)
- electrolyte imbalance (unbalanced levels of salts) in your blood
- are taking certain drugs listed in the Interactions section of this consumer information

What the medicinal ingredient is:

Domperidone Maleate

What the important non-medicinal ingredients are:

Cornstarch, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium

docusate 85%-sodium benzoate 15% and titanium dioxide.

What dosage forms it comes in:

pms-DOMPERIDONE is available as 10 mg domperidone tablets (as domperidone maleate).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

pms-DOMPERIDONE may be associated with an increased risk of heart rhythm disorder and sudden death (cardiac arrest). This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. Domperidone should be used at the lowest possible dose for the shortest duration necessary.

- The maximum dosage is one 10 mg tablet three times daily, to help avoid adverse heart effects.
- For patients at risk for heart problems, your doctor may request an assessment of your heart function (e.g. ECG) before and/or during domperidone treatment.

BEFORE you use pms-DOMPERIDONE, talk to your doctor or pharmacist if:

- you have, or have ever had breast cancer
- you have an irregular heartbeat, or any other kind of heart disease
- you have any kind of kidney disease
- you are pregnant or plan to become pregnant
- you are breastfeeding or planning to breastfeed. Domperidone is excreted in breast milk. Discuss with your doctor.
- you experience any kind of unusual discharge of breast milk
- you are a male and have any kind of irregular growth of the breasts
- you are taking any other medications (see *Interactions* with this medication)

INTERACTIONS WITH THIS MEDICATION

Do not take pms-DOMPERIDONE with the following drugs as they are contraindicated:

- antiarrhythmics (drugs for the heart) including disopyramide, quinidine, hydroquinidine, amiodarone, dofetilide, dronedarone, sotalol)
- certain antidepressants (e.g., citalopram, escitalopram)
- certain antibiotics (e.g., erythromycin, clarithromycin, levofloxacin, moxifloxacin, spiramycin, telitromycin)
- certain antifungal agents (e.g., pentamidine)
- certain antimalarial agents (e.g., halofantrine, lumefantrine)
- certain gastrointestinal agents (e.g., cisapride, dolasetron, prucalopride)
- certain antihistamines (e.g., mequitazine, mizolastine)

- certain cancer medicines (e.g., toremifene, vandetanib, vincamine)
- some other medications (e.g., bepridil, methadone, diphemanil)
- do not take pms-DOMPERIDONE with grapefruit juice

Drugs that may interact with pms-DOMPERIDONE include:

- a drug called ketoconazole
- any kind of drug known as:
 - an “anticholinergic” drug
 - an antifungal drug
 - an antibiotic drug
 - a drug to treat AIDS
 - a drug called nefazodone

PROPER USE OF THIS MEDICATION

Usual adult dose:

For disorders involving movement of food through the stomach and intestines: one 10 mg tablet taken 3 times per day, 15 to 30 minutes before meals.

Overdose:

Symptoms of overdosage may include drowsiness, disorientation, difficulty with normal body movements, irregular heartbeat and lowered blood pressure.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Most side effects will gradually disappear with continuing administration of pms-DOMPERIDONE and are easily tolerated. The more serious or troublesome side effects are dose-related and gradually resolve after the dose is lowered or if administration of the drug is discontinued.

Common side effects include dry mouth, headache and migraine. Uncommon side effects include abdominal cramps, diarrhea, regurgitation (bring up stomach contents), nausea and rash. If these side effects become troublesome, talk to your doctor.

Contact your doctor if the more serious or troublesome side effects occur such as galactorrhea (excessive or spontaneous flow of breast milk), gynecomastia (excessive development of male mammary gland) or menstrual irregularities (spotting or delayed periods).

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	palpitations		✓	
	irregular heart beat (arrhythmia)			✓
	dizziness			✓
	fainting			✓

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

HOW TO STORE IT

Store between 15°C and 30°C. Protect from light and moisture.

Keep out of the reach and sight 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 found by contacting Pharmascience Inc at 1-888-550-6060

This leaflet was prepared by:

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