

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDOMPERIDONE-10

Domperidone maleate tablets

Read this carefully before you start taking **DOMPERIDONE-10** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DOMPERIDONE-10**.

Serious Warnings and Precautions

DOMPERIDONE-10 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-10 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 healthcare professional may request an assessment of your heart function (e.g. EEG) before and/or during DOMPERIDONE-10 treatment.

What is DOMPERIDONE-10 used for?

DOMPERIDONE-10 is used to:

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

How does DOMPERIDONE-10 work?

DOMPERIDONE-10 helps you digest food by:

- Increasing the contractions in your esophagus. This helps push food into your stomach.
- Helping your stomach empty food into the intestine.
- Helping move food through your intestine.

What are the ingredients in DOMPERIDONE-10?

Medicinal ingredients: DOMPERIDONE-10 maleate

Non-medicinal ingredients: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, fumaric acid, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose,

polyethylene glycol and titanium dioxide.

DOMPERIDONE-10 comes in the following dosage forms:

Tablets: 10 mg

Do not use DOMPERIDONE-10 if:

- you are allergic to DOMPERIDONE-10 or any of the nonmedicinal ingredients in this drug (See [What are the ingredients in DOMPERIDONE-10?](#))
- you have signs of bleeding in the stomach or intestines
- you have an obstruction or perforation of the stomach or intestines.
- you have a tumour of the pituitary gland (known as a prolactinoma).
- you have moderate or severe liver problems
- you have heart disease including congestive heart failure or prolonged QT interval
- you have prolactinemia (a pituitary tumour releasing prolactin)
- you have electrolyte imbalance (unbalanced levels of salts) in your blood
- you are taking certain drugs listed in the **“Serious Drug Interactions”** box, below.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DOMPERIDONE-10. Talk about any health conditions or problems you may have, including if you:

- have an irregular heartbeat, or any other kind of heart disease
- have, or have ever had breast cancer
- have any kind of kidney disease
- have any kind of liver disease
- are pregnant or plan to become pregnant
- are breastfeeding or planning to breastfeed. DOMPERIDONE-10 is excreted in breast milk. Discuss with your healthcare professional.

Other warnings you should know about:

Serious heart problems: Taking DOMPERIDONE-10 may cause serious heart problems, such as:

- worsening of the health of your heart,
- heart rhythm disorders (QT prolongation),
- cardiac arrest and sudden death.

If you have any of the following symptoms while you are taking DOMPERIDONE-10, stop taking DOMPERIDONE-10 and get immediate medical help:

- dizziness
- heart palpitations (feeling of rapid pounding or skipped heartbeat or “fluttering”)

- fainting

See the [Serious side effects and what to do about them](#) table, below for information on this and other serious side effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take DOMPERIDONE-10 with medicines/foods that can affect:

- your heart rhythm or
- increase your blood levels of DOMPERIDONE-10

This may cause:

- worsening of the health of your heart
- heart rhythm disorders (QT prolongation)
- cardiac arrest (your heart stops beating)
- death

Examples of these medications/foods include, but are not limited to:

- antiarrhythmics (drugs for the heart) - amiodarone, disopyramide, dofetilide, dronedarone, hydroquinidine, ibutilide, quinidine, sotalol)
- Certain antipsychotics (used to treat mental health problems) - haloperidol, pimozide, sentindole
- certain antidepressants - such as citalopram, escitalopram, nefazodone
- certain antibiotics - clarithromycin, erythromycin, levofloxacin, moxifloxacin, spiramycin, telitromycin
- certain antifungal agents - pentamidine, ketoconazole
- certain antimalarial agents - halofantrine, lumefantrine
- certain antihistamines - mequitazine, mizolastine
- certain cancer medicines - toremifene, vandetanib, vincamine
- certain gastrointestinal agents - cisapride, dolasetron, prucalopride
- other medications - bepridil, diltiazem, diphemanil, methadone, verapamil
- medicines used to treat HIV
- grapefruit, grapefruit juice and grapefruit-containing products

The following may also interact with DOMPERIDONE-10:

- MAO Inhibitors used to treat depression
- Antacids used to treat or indigestion and heartburn
- H₂-receptor blockers used to treat stomach ulcers

How to take DOMPERIDONE-10:

- Take DOMPERIDONE-10 exactly as your healthcare professional tells you to take it.

- Take DOMPERIDONE-10 by mouth, 15 to 30 minutes before meals.
- Your healthcare professional will ensure the lowest effective dose of DOMPERIDONE-10 is used for the shortest amount of time.

Usual adult dose:

One 10 mg tablet taken 3 times per day. The maximum daily dose is 30 mg per day.

Overdose:

Symptoms of overdosage may include:

- drowsiness,
- disorientation,
- difficulty with normal body movements,
- irregular heartbeat and
- lowered blood pressure.

If you think you, or a person you are caring for, have taken too much DOMPERIDONE-10, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of this medication, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take two doses at the same time.

What are possible side effects from using DOMPERIDONE-10?

These are not all the possible side effects you may have when taking DOMPERIDONE-10. If you experience any side effects not listed here, tell your healthcare professional.

Most side effects will gradually disappear with continuing administration of DOMPERIDONE-10 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
- hot flashes
- migraine
- pink eye (conjunctivitis)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Galactorrhea (excessive or spontaneous flow of breast milk),		✓	
Gynecomastia (excessive development of male mammary gland)		✓	
Menstrual irregularities (spotting or delayed periods).		✓	
UNCOMMON			
Palpitations (skipped beats)		✓	
Arrhythmia (irregular heartbeat)			✓
Dizziness			✓
Fainting (feeling dizzy or passing out)			✓
Abdominal cramps, diarrhea, regurgitation (bring up stomach contents), nausea and rash.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature 15°C to 30°C. Protect from light and moisture.

Keep out of the reach and sight of children.

If you want more information about DOMPERIDONE-10:

- Talk to your healthcare professional
 - Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>);. or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca

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