

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDOMPERIDONE

Domperidone Tablets

Read this carefully before you start taking **DOMPERIDONE** 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**.

Serious Warnings and Precautions

DOMPERIDONE may be associated with a higher risk of serious heart rhythm disorder or sudden death (cardiac arrest). This risk may be more likely in patients 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 needed.

Based on the above risk, Domperidone should not be used:

- In patients with heart problems, which cause prolongation of conduction intervals (particularly the QT interval)
- In patients with heart diseases, for example heart failure
- With medicines used to prolong QT intervals
- In patients with serious electrolyte imbalances (unbalanced levels of salts in your blood)
- With potent CYP3A4 inhibitors. These medicines may increase the level of domperidone in the body.

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 treatment.

What is **DOMPERIDONE** used for?

DOMPERIDONE is used in adults to:

- Treat symptoms of slowed stomach emptying associated with chronic and subacute gastritis (inflammation of the gastrointestinal tract) and diabetic gastroparesis (slowed stomach emptying caused by diabetes).
- Reduce symptoms such as nausea and vomiting caused by some drugs used to treat Parkinson's disease.

How does **DOMPERIDONE** work?

DOMPERIDONE stimulates the muscles of the gastrointestinal tract. This helps to move food from the stomach into the intestines. It also helps to move digesting food material through the

small intestine.

What are the ingredients in DOMPERIDONE?

Medicinal ingredients: Domperidone Maleate

Non-medicinal ingredients: Cornstarch, croscarmellose sodium, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium docusate 85%-sodium benzoate 15% and, titanium dioxide, triacetin.

DOMPERIDONE comes in the following dosage forms:

Tablets: 10 mg

Do not use DOMPERIDONE if:

- You are allergic to domperidone or any of the nonmedicinal ingredients (See **What are the ingredients in DOMPERIDONE?**).
- you have problems with your gastrointestinal tract, which may make stimulating the gastrointestinal tract dangerous such as;
 - you have signs of bleeding in the stomach or intestines,
 - you have an obstruction (blockage) or perforation (a hole in the wall) of the stomach or intestines
- you have a tumour associated with the pituitary gland known as a prolactinoma.
- you have moderate or severe liver problems
- you have heart disease including congestive heart failure
- you have heart problems, which cause prolongation of conduction intervals (particularly the QT interval)
- you have serious electrolyte imbalance (unbalanced levels of salts) in your blood
- you are taking drugs to prolong the QT interval
- you are taking potent CYP3A4 inhibitors

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

- you have an irregular heartbeat
- you have kidney problems
- you have liver problems
- you are pregnant or plan to become pregnant
- you are breastfeeding or planning to breastfeed. Domperidone is excreted in breast milk. Discuss with your healthcare professional
- you have, or have ever had breast cancer
- 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 **The following may also interact with**

DOMPERIDONE)

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 if you are taking the following:

- potent CYP3A4 inhibitors
- medications that prolong the QT interval

DOMPERIDONE should not be taken with:

- Medicines that prolong the QT intervals. Examples include, but are not limited to:
 - Bepridil, used to treat angina pectoris (heart pain caused by heart disease)
 - Diphepanil
 - Methadone, used to treat pain and drug addiction
 - Medicines used to treat abnormal heart rhythms such as; amiodarone, disopyramide, dofetilide, dronedarone, hydroquinidine, ibutilide, quinidine, sotalol
 - Certain medicines used to treat depression such as; citalopram, escitalopram
 - Certain medicines used to treat mental health problems such as; haloperidol, pimozide, sentindole
 - Certain medicines used to treat bacterial infections (antibiotics) such as; erythromycin, levofloxacin, moxifloxacin, spiramycin
 - Certain medicines used to treat fungal infections (antifungals) such as; pentamidine
 - Certain medicines used to treat and prevent malaria (antimalarial agents) such as; halofantrine, lumefantrine
 - Certain medicines used to treat gastrointestinal disorders such as; cisapride, dolasetron, prucalopride
 - Certain antihistamines such as; mequitazine, mizolastine
 - Certain medicines used in the treatment of cancer such as; toremifene, vandetanib, vincamine
- Potent CYP3A4 inhibitors. Examples include, but are not limited to:
 - Systemic azole antifungals (used to treat fungal infections) such as; clotrimazole, ketoconazole, miconazole
 - Macrolide antibiotics (used to treat various bacterial infections) such as; azithromycin, clarithromycin, erythromycin
 - HIV protease inhibitors (used to treat HIV) such as; ritonavir
 - Serotonin modulators such as: Nefazadone
 - Grapefruit juice

If you are unsure, talk to your healthcare professional.

The following may also interact with DOMPERIDONE:

- moderate CYP3A4 inhibitors such as; diltiazem and verapamil
- Monoamine oxidase (MAO) inhibitors such as; selegiline hydrochloride
- any kind of drug known as an 'anticholinergic' drug such as; atropine sulfate

How to take DOMPERIDONE:

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

Usual adult dose

One 10 mg tablet taken 3 times per day, 15 to 30 minutes before meals. The maximum daily dose is 30 mg.

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, 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?

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

Most side effects will gradually disappear with continuing administration of 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,
- migraine.

Uncommon side effects include

- Insomnia, tiredness,
- Nervousness and irritability,
- abdominal cramps,
- diarrhea,
- regurgitation (bring up stomach contents),
- heartburn
- nausea,
- constipation,
- changes in appetite,
- pain when urinating,
- inflammation of the mouth or eyes,
- rash, itchiness and hives.

Serious side effects and what to do about them			
Symptom/effect	Talk with 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			
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat			√
dizziness			√
fainting			√
palpitations		√	

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

Storage:

Keep out of the reach and sight of children.
Store between 15-30°C. Protect from light.

If you want more information about DOMPERIDONE:

- 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>); the manufacturer's website www.sivem.ca, or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

Last revised: OCT 22, 2024