

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MAR-DOMPERIDONE**

Domperidone Tablets

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

Serious Warnings and Precautions

MAR-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.

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.
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- 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. ECG) before and/or during domperidone treatment.

What is MAR-DOMPERIDONE used for?

MAR-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) 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 MAR-DOMPERIDONE work?

MAR-DOMPERIDONE 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 MAR-DOMPERIDONE?

Medicinal ingredients: domperidone maleate

Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, fumaric acid, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose and Opadry White (contains polyethylene glycol, titanium dioxide and hypromellose).

MAR-DOMPERIDONE comes in the following dosage forms:

Tablets: 10 mg domperidone (as domperidone maleate)

Do not use MAR-DOMPERIDONE if:

- you are allergic to domperidone or any of the nonmedicinal ingredients in this drug (See [What are the ingredients in MAR-DOMPERIDONE?](#))
- 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 potent CYP3A4 inhibitors
- 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 MAR-DOMPERIDONE. 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 is excreted in breast milk. Discuss with your healthcare professional.

Other warnings you should know about:

Serious heart problems: Taking MAR-DOMPERIDONE 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 MAR-DOMPERIDONE, stop taking MAR-DOMPERIDONE 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 MAR-DOMPERIDONE with medicines/foods that can affect:

- potent CYP3A4 inhibitors
- medications that prolong the QT interval
- your heart rhythm or
- increase your blood levels of MAR-DOMPERIDONE

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 MAR-DOMPERIDONE:

- Moderate CYP3A4 inhibitors such as; diltiazem and verapamil
- MAO Inhibitors used to treat depression
- Antacids used to treat or indigestion and heartburn
- H₂-receptor blockers used to treat stomach ulcers
- Any kind of drug known as an 'anticholinergic' drug such as; atropine sulfate

How to take MAR-DOMPERIDONE :

- Take MAR-DOMPERIDONE exactly as your healthcare professional tells you to take it.
- Take MAR-DOMPERIDONE by mouth, 15 to 30 minutes before meals.
- Your healthcare professional will ensure the lowest effective dose of MAR-DOMPERIDONE is used for the shortest amount of time.

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 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 MAR-DOMPERIDONE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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 MAR-DOMPERIDONE?

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

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

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 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			✓

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	
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 (canada.ca/drug-device-reporting) 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 reach and sight of children.

If you want more information about MAR-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 Drug Product Database website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.marcanpharma.com), or by calling 1-855-627-2261.

This leaflet was prepared by Marcan Pharmaceuticals Inc.

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