

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MAR- RANOLAZINE XR** **Ranolazine Extended-Release Tablets**

This Patient Medication Information is written for the person who will be taking **MAR- RANOLAZINE XR**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

The Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **MAR- RANOLAZINE XR**, talk to a healthcare professional.

Serious warnings and precautions box

- **MAR- RANOLAZINE XR** can change the electrical activity (prolong the QT interval) of your heart. You should not take more than 1000 mg of ranolazine extended-release tablet twice a day.

What is **MAR- RANOLAZINE XR** used for:

MAR- RANOLAZINE XR is a medicine used to treat chest pain (stable angina) in adults. It is used along with other medicines in patients:

- who cannot tolerate other antianginal therapies or
- for whom other antianginal therapies do not work to control their chest pain (this includes beta-blockers and calcium channel blockers)

How **MAR- RANOLAZINE XR** works:

How **MAR- RANOLAZINE XR** works to treat your symptoms of angina is not exactly known.

The ingredients in **MAR- RANOLAZINE XR** are:

Medicinal ingredient(s): Ranolazine

Non-medicinal ingredients: Ethylacrylate copolymer, Hydroxy propyl methyl cellulose, Microcrystalline Cellulose, Methacrylic acid, Magnesium stearate, Purified water, Sodium Hydroxide, Opadry® II beige (85F570087)

Composition of Opadry® II beige (85F570087): Iron oxide red, Iron oxide yellow, Macrogel/PEG, Polyvinyl alcohol-part hydrolyzed, Titanium dioxide, Talc

MAR- RANOLAZINE XR comes in the following dosage form(s):

Extended-release Tablets: 500 mg

Do not use **MAR- RANOLAZINE XR** if you:

- Are allergic to ranolazine or to any of the other ingredients in **MAR- RANOLAZINE XR** (see list of non-medicinal ingredients above)
- Have severe kidney disease
- Have moderate to severe liver disease

- Take any of the following medicines. These can have serious interactions with MAR- RANOLAZINE XR.
 - for arrhythmias: quinidine, procainamide, disopyramide, sotalol, ibutilide, amiodarone, dronedarone
 - for a fungal infection: ketoconazole, itraconazole, voriconazole, posaconazole
 - for an infection: clarithromycin
 - for depression: nefazodone
 - for HIV: nelfinavir, ritonavir, indinavir, lopinavir, saquinavir
 - for tuberculosis (TB): rifampicin, rifabutin, rifapentine
 - for seizures: phenobarbital, phenytoin, carbamazepine
 - St. John's wort
- Eat grapefruit, drink grapefruit juice or take products that contain grapefruit

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

- take medicines (prescription, over-the-counter (OTC) and natural health products)
- have or have a family history of a heart problem, called 'QT prolongation' or 'long QT syndrome'
- have low electrolyte levels (such as low potassium, magnesium or calcium), conditions that can cause low electrolyte levels (such as persistent vomiting and eating disorders) or are taking medicines that can affect your electrolyte levels such as:
 - diuretics
 - laxatives
 - enemas
 - high dose corticosteroids
 - medicines for acid reflux or gastroesophageal reflux disease (GERD)
- have liver problems
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if MAR- RANOLAZINE XR will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if MAR- RANOLAZINE XR passes into your breast milk. Your doctor will decide if you should breastfeed or if you should stop treatment with MAR- RANOLAZINE XR

Other warnings you should know about:

- **Patients over 75 years of age:** You may be more sensitive to experiencing side effects.
- **Monitoring and Laboratory tests:** Before you start treatment with MAR- RANOLAZINE XR and periodically during treatment your doctor should:
 - perform electrocardiograms (ECGs) to monitor your heart
 - do blood tests to check your electrolyte levels
 - check your kidney and liver function
- **Driving and using machinery:** You should avoid driving a car, using machinery or doing tasks that require you to be alert until you know how MAR- RANOLAZINE XR affects you. MAR- RANOLAZINE XR may cause:
 - dizziness
 - blurred vision
 - you to feel confused
 - hallucinations: hearing, seeing or sensing things that are not there

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

Serious drug interactions

Serious drug interactions with MAR-RANOLAZINE XR include:

- strong CYP 3A4 inhibitors: (e.g. ketoconazole, itraconazole, voriconazole, posaconazole, HIV protease inhibitors, clarithromycin, telithromycin, nelfinavir, ritonavir, indinavir, saquinavir and grapefruit juice) are contraindicated.
- CYP 3A4 inducers (e.g., rifampin, rifabutin, rifapentine, phenobarbital, phenytoin, carbamazepine, and St. John's wort) are contraindicated, and
- Class IA (e.g. procainamide, disopyramide) and Class III antiarrhythmics (e.g.: sotalol, ibutilide, amiodarone, dronedarone) are contraindicated.

The following may also interact with MAR-RANOLAZINE XR:

- medicines for heart problems including arrhythmias: such as digoxin, propafenone, flecainide
- medicines for bacterial, viral or fungal infection: such as erythromycin, rifampicin, rifabutin, rifapentine, fluconazole
- medicines to prevent organ rejection after a transplant: such as cyclosporine, sirolimus, everolimus
- medicines used to lower your cholesterol: such as simvastatin, lovastatin, atorvastatin
- medicines for high blood pressure: such as metoprolol, diltiazem, verapamil
- medicines for depression: such as imipramine, doxepin, amitriptyline
- metformin – used to treat high blood sugar (diabetes)
- tacrolimus – used to treat eczema

How to take MAR-RANOLAZINE XR:

Take

- MAR- RANOLAZINE XR exactly as your doctor tells you
- **Do not** crush, break or chew the tablet. Swallow it whole.
- **Do not** take more than 1000 mg twice a day
 - Do not take more than 500 mg twice a day if you also take medicines such as diltiazem, verapamil, erythromycin, and fluconazole (moderate *CYP 3A4 inhibitors*)

Usual adult dose: 1000 mg twice a day.

Overdose:

Signs of an overdose include:

- low blood pressure
- slow heart rate
- muscle twitches
- shaking
- feeling unsteady or confused

- dizziness
- nausea and vomiting
- trouble speaking / understanding
- hallucinations

If you think you, or a person you are caring for, have taken too much MAR-RANOLAZINE XR, 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, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

Possible side effects from using MAR-RANOLAZINE XR?

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

Side effects may include:

- Dizziness
- Headache
- Constipation
- Nausea

Serious side effects and what to do about them

Frequency/Side Effects/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Uncommon			
QT prolongation (changes in the electrical activity of your heart): dizziness, feeling faint or lightheaded, heart beating irregularly or fast, seizures			✓
Kidney failure in people who already have severe kidney problems		✓	

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 between (15°C – 30°C). Any unused product or waste material should be disposed of as biohazardous waste. Keep out of reach and sight of children.

If you want more information about MAR- RANOLAZINE XR:

- 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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