100.00 mm

400.00 mm

Patient Information

Ranolazine (ra noe′ la zeen) Extended-Release Tablets

Dosing Strengths:

500 mg tablets

1000 mg tablets

Read this Patient Information before you start taking ranolazine extended-release tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

What is ranolazine extended-release tablets?

Ranolazine extended-release tablets is a prescription medicine used to treat angina that keeps coming back (chronic angina).

Ranolazine extended-release tablets may be used with other medicines that are used for heart problems and blood pressure control.

It is not known if ranolazine extended-release tablets is safe and effective in children.

Who should not take ranolazine extended-release tablets?

Do not take ranolazine extended-release tablets if:

- you take any of the following medicines:
  - for fungus infection: ketoconazole (Nizoral®), itraconazole (Sporanox®, Onmel™)
  - for infection: clarithromycin (Biaxin®)
  - for depression: nefazodone
  - for HIV: nelfinavir (Viracept®), ritonavir (Norvir®), lopinavir and ritonavir (Kaletra®), indinavir (Crixivan®), saquinavir (Invirase®)
  - for tuberculosis (TB): rifampin (Rifadin®), rifabutin (Mycobutin®), rifapentine (Priftin®)
  - for seizures: phenobarbital, phenytoin (Phenytek®, Dilantin®, Dilantin- 125®), carbamazepine (Tegretol®)
  - St. John's wort (Hypericum perforatum)
- you have scarring (cirrhosis) of your liver

What should I tell my doctor before taking ranolazine extended-release tablets?

Before you take ranolazine extended-release tablets, tell your doctor if you:

- have or have a family history of a heart problem, called 'QT prolongation' or 'long QT syndrome'.
- have liver problems.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if ranolazine extended-release tablets will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if ranolazine extended-release tablets passes into your breast milk. You and your doctor should decide if you will breast-feed.

Tell your doctor about all the medicines you take, including all prescription and nonprescription medicines, vitamins, and herbal supplements. Ranolazine extended-release tablets may affect the way other medicines work and other medicines may affect how ranolazine extended-release tablets works.

Tell your doctor if you take medicines:

- for your heart
- for cholesterol
- for diabetes
- for infection
- for fungus
- for transplant
- for nausea and vomiting because of cancer treatments
- for mental problems

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

How should I take ranolazine extended-release tablets?

- Take ranolazine extended-release tablets exactly as your doctor tells you.
- Your doctor will tell you how much ranolazine extended-release tablets to take and when to take it.
- Do not change your dose unless your doctor tells you to.
- Tell your doctor if you still have symptoms of angina after starting ranolazine extended-release tablets.
- Take ranolazine extended-release tablets by mouth, with or without food.
- Swallow the ranolazine extended-release tablets whole. Do not crush, break, or chew ranolazine extended-release tablets before swallowing.
- If you miss a dose of ranolazine extended-release tablets, wait to take the next dose of ranolazine extended-release tablets at your regular time. Do not make up for the missed dose. Do not take more than 1 dose at a time.
- If you take too much ranolazine extended-release tablets, call your doctor, or go to the nearest emergency room right away.

What should I avoid while taking ranolazine extended-release tablets?

- Grapefruit and grapefruit juice. Limit products that have grapefruit in them. They can cause your blood levels of ranolazine extended-release tablets to increase.
- Ranolazine can cause dizziness, lightheadedness, or fainting. If you have these symptoms, do not drive a car, use machinery, or do anything that needs you to be alert.

What are the possible side effects of ranolazine extended-release tablets?

Ranolazine extended-release tablets may cause serious side effects, including:

- changes in the electrical activity of your heart called QT prolongation. Your doctor may check the electrical activity of your heart with an ECG. Tell your doctor right away if you feel faint, lightheaded, or feel your heart beating irregularly or fast while taking ranolazine extended-release tablets. These may be symptoms related to QT prolongation.
- Kidney failure in people who already have severe kidney problems. Your doctor may need to do tests to check how your kidneys are working.

The most common side effects of ranolazine extended-release tablets include:

- dizziness
- headache
- constipation
- nausea

Tell your doctor if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of ranolazine extended-release tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 and Zameer Pharmaceuticals LLC at 1-888-851-7033.

How should I store ranolazine extended-release tablets?

Store ranolazine extended-release tablets at room temperature between 59° to 86°F (15° to 30°C).

Keep ranolazine extended-release tablets and all medicines out of the reach of children.

General information about ranolazine extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information. Do not use ranolazine extended-release tablets for a condition for which it was not prescribed. Do not give ranolazine extended-release tablets to other people, even if they have the same condition you have. It may harm them.

The Patient Information summarizes the most important information about ranolazine extended-release tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about ranolazine extended-release tablets that is written for health professionals.

For more information, go to www.zameerpharma.com or call at 1-888-851-7033.

What is chronic angina?

Chronic angina means pain or discomfort in the chest, jaw, shoulder, back, or arm that keeps coming back. There are other possible signs and symptoms of angina including shortness of breath. Angina usually comes on when you are active or under stress. Chronic angina is a symptom of a heart problem called coronary heart disease (CHD), also known as coronary artery disease (CAD). When you have CHD, the blood vessels in your heart become stiff and narrow. Oxygen-rich blood cannot reach your heart muscle easily. Angina comes on when too little oxygen reaches your heart muscle.

What are the ingredients in ranolazine extended-release tablets?

Active ingredient: ranolazine

Inactive ingredients:

500 mg tablet: microcrystalline cellulose, lactose monohydrate, methacrylic acid–ethyl acrylate copolymer, sodium hydroxide pellets, hydroxypropyl methylcellulose, magnesium stearate, hypromellose, titanium dioxide, macrogol, triacetin, iron oxide yellow.

Methacrylic acid–ethyl acrylate copolymer (contains 0.7%, Sodium Lauryl sulfate Ph. Eur./NF and 2.3% Polysorbate 80 Ph. Eur./NF on solid substance.

1000 mg tablet: microcrystalline cellulose, lactose monohydrate, methacrylic acid–ethyl acrylate copolymer, sodium hydroxide pellets, hydroxypropyl methylcellulose, magnesium stearate, hypromellose, titanium dioxide, macrogol, triacetin, iron oxide yellow.

Methacrylic acid–ethyl acrylate copolymer contains 0.7%, Sodium Lauryl sulfate Ph. Eur./NF and 2.3% Polysorbate 80 Ph. Eur. / NF on solid substance.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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