



Patient Information Leaflet (PIL) or Package Insert

Ranolazine Extended-Release Tablets 500 mg

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What are Ranolazine extended-release tablets?
2. Who should not take Ranolazine extended-release tablets?
3. What should I tell my doctor before taking Ranolazine extended-release tablets?
4. How should I take Ranolazine extended-release tablets?
5. What should I avoid while taking Ranolazine extended-release tablets?
6. What are the possible side effects of Ranolazine extended-release tablets?
7. How should I store Ranolazine extended-release tablets?
8. Further information

1. What are Ranolazine extended-release tablets?

Ranolazine extended-release tablets are 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 are safe and effective in children.

2 Who should not take Ranolazine extended-release tablets?

Do not take Ranolazine extended-release tablets if:

- you take any of the following medicines:

**Module-1- Administrative Information and Product Information**

- 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 (Raiding®), 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

3 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 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

4. 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 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.

5. 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 extended-release tablets 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.

6. 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.

7. How should I store Ranolazine extended-release tablets?

Store Ranolazine extended-release tablets at room temperature between 20° to 25°C (68° to 77°F).

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.

8. Further information

NIZACARD 500 (Ranolazine Extended Release Tablets 500 mg)

Blue colored, Oblong shaped film coated tablets debossed with 'R18' on one side and 'H' on the other side.

NIZACARD 500 (Ranolazine Extended-Release Tablets 500 mg)



Module-1- Administrative Information and Product Information

NIZACARD 1000 (Ranolazine Extended Release Tablets 1000 mg)

Blue colored, Oblong shaped film coated tablets debossed with 'R19' on one side and 'H' on the other side.

Blister pack: 3 x 10's Clear PVC/PVdC Blister Pack.

Marketing Authorisation Holder and Manufacturer

Supplier

Hetero Labs Limited,
Hetero Corporate,
7-2-A2, Industrial Estates,
Sanath Nagar,
Hyderabad - 500 018
Telangana,
India

Manufacturer

M/s. Hetero Labs Limited, Unit - III
Plot No. 22-110,
Phase - IV, IDA,
Jeedimetla,
Hyderabad- 500055,
Telangana
India