

Package leaflet: Information for the patient

Ranolazine

375 mg Prolonged-release Tablets

Ranolazine

500 mg Prolonged-release Tablets

Ranolazine

750 mg Prolonged-release Tablets

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, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ranolazine is and what it is used for
2. What you need to know before you take Ranolazine
3. How to take Ranolazine
4. Possible side effects
5. How to store Ranolazine
6. Contents of the pack and other information

1. What Ranolazine is and what it is used for

Ranolazine is a medicine used in combination with other medicines to treat angina pectoris, which is a chest pain or discomfort that you feel anywhere along the upper part of your body between your neck and upper abdomen, often brought on by exercise or too much activity.

You must talk to your doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Ranolazine

Do not take Ranolazine if you:

- are allergic to ranolazine or any of the other ingredients of this medicine listed in section 6 of this leaflet
- have severe kidney problems
- have moderate or severe liver problems
- are using certain medicines to treat bacterial infections (clarithromycin, telithromycin), fungal infections (itraconazole, ketoconazole, voriconazole, posaconazole), HIV infection (protease inhibitors), depression (nefazodone) or heart rhythm disorders (e.g. quinidine, dofetilide, or sotalol).

Warnings and precautions

Talk to your doctor before taking Ranolazine if you:

- have mild or moderate kidney problems
- have mild liver problems
- have ever had an abnormal electrocardiogram (ECG)
- are elderly
- have low weight (60 kg or less)
- have heart failure.

Your doctor may decide to give you a lower dose or take other precautions if any of these apply to you.

Using other medicines and Ranolazine

Do not use the following medicines if you take Ranolazine:

- certain medicines to treat bacterial infections (clarithromycin, telithromycin), fungal infections (itraconazole, ketoconazole, voriconazole, posaconazole), HIV infection (protease inhibitors), depression (nefazodone), or heart rhythm disorders (e.g. quinidine, dofetilide, or sotalol).

Tell your doctor or pharmacist before you take Ranolazine if you use:

- certain medicines to treat a bacterial infection (erythromycin), or a fungal infection (fluconazole), a medicine used to prevent rejection of a transplanted organ (ciclosporin), or if you are taking some heart tablets such as diltiazem or verapamil. These medicines may cause an increase in the number of side effects, such as dizziness, nausea, or vomiting, which are possible side effects of Ranolazine (see section 4). Your doctor may decide to give you a lower dose

- medicines to treat epilepsy or another neurologic disorder (e.g. phenytoin, carbamazepine, or phenobarbital); or taking rifampicin for an infection (e.g. tuberculosis); or taking the herbal remedy St John's Wort, as these medicines may cause Ranolazine to be less effective
- heart medicines containing digoxin or metoprolol, as your doctor may want to change the dose of this medicine whilst you are taking Ranolazine
- certain medicines to treat allergies (e.g. terfenadine, astemizole, mizolastine), heart rhythm disorders (e.g. disopyramide, procainamide), and depression (e.g. imipramine, doxepin, amitriptyline), as these medicines may affect your ECG
- certain medicines to treat depression (bupropion), psychosis, HIV infection (efavirenz), or cancer (cyclophosphamide)
- certain medicines to treat high levels of cholesterol in the blood (e.g. simvastatin, lovastatin, atorvastatin). These medicines may cause muscle pain and muscle injury. Your doctor may decide to change the dose of this medicine while you are taking Ranolazine
- certain medicines used to prevent transplanted organ rejection (e.g. tacrolimus, ciclosporin, sirolimus, everolimus) as your doctor may decide to change the dose of this medicine while you are taking Ranolazine.

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Ranolazine with food and drink

Ranolazine can be taken with or without food. While being treated with Ranolazine, you should not drink grapefruit juice.

Pregnancy

You should not take Ranolazine if you are pregnant unless your doctor has advised you to do so.

Breast-feeding

You should not take Ranolazine if you are breast-feeding. Ask your doctor for advice if you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

No studies on the effects of Ranolazine on the ability to drive and use machines have been performed. Ask your doctor for advice about driving or using machines.

Ranolazine may cause side effects such as dizziness (common), blurred vision (uncommon), confusional state (uncommon), hallucination (uncommon), double vision (uncommon), coordination problems (rare), that may affect your ability to drive or use machines. If you experience these symptoms, do not drive or operate machinery until they have resolved completely.

Important information about some of the ingredients of Ranolazine

This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release tablet, that is to say essentially 'sodium-free'.

3. How to take Ranolazine

Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

Always swallow the tablets whole with water. Do not crush, suck, or chew the tablets or break them in half, as this might affect the way the medicine is released from the tablets into your body.

The starting dose for adults is one 375 mg tablet twice a day. After 2–4 weeks, your doctor may increase the dose to get the right effect. The maximum dose of Ranolazine is 750 mg twice a day.

It is important that you tell your doctor if you get side effects such as dizziness or feeling or being sick. Your doctor may lower your dose or, if this is not sufficient, stop treatment with Ranolazine.

Use in children and adolescents

Children and adolescents under 18 years old should not take Ranolazine.

If you take more Ranolazine than you should

If you accidentally take too many Ranolazine tablets or take a higher dose than recommended by your doctor, it is important that you tell your doctor at once. If you cannot contact your doctor, go to the nearest accident and emergency department. Take along any tablets that are left, including the container and the carton, so that the hospital staff can easily tell what you have taken.

If you forget to take Ranolazine

If you forget to take a dose, take it as soon as you remember unless it is nearly time (less than 6 hours) to take your next dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should stop taking Ranolazine and see your doctor immediately if you experience the following symptoms of angioedema, which is a rare condition but can be severe:

- swollen face, tongue, or throat
- difficulty swallowing
- hives or difficulty breathing.

Tell your doctor if you experience common side effects such as dizziness or feeling sick or vomiting. Your doctor may lower your dose or stop treatment with Ranolazine .

Other side effects you may experience include the following:

Common side effects (occur in 1 to 10 users in 100):

- constipation
- dizziness
- headache
- feeling sick, vomiting
- feeling weak.

Uncommon side effects (occur in 1 to 10 users in 1,000):

- altered sensation
- anxiety, difficulty sleeping, confusional state, hallucination
- blurred vision, visual disturbance
- changes in sensation (touch or taste), tremor, feeling tired or sluggish, sleepiness or drowsiness, faint or fainting, dizziness upon standing
- dark urine, blood in urine, difficulty urinating
- dehydration
- difficulty breathing, cough, nose bleed
- double vision
- excessive sweating, itching
- feeling swollen or bloated
- hot flushes, low blood pressure
- increases in a substance called creatinine or increases in urea in your blood, increase in blood platelets or white blood cells, changes in ECG heart tracing
- joint swelling, pain in extremity
- loss of appetite and/or weight loss
- muscle cramp, muscle weakness
- ringing in the ears and/or feeling a spinning sensation
- stomach pain or discomfort, indigestion, dry mouth, or wind.

Rare side effects (occur in 1 to 10 users in 10,000):

- a lack of ability to urinate
- abnormal laboratory values for liver
- acute kidney failure
- change in sense of smell, numbness in mouth or lips, impaired hearing
- cold sweat, rash
- coordination problems
- decrease in blood pressure upon standing Decreased or loss of consciousness Disorientation
- feeling of coldness in hands and legs
- hives, allergic skin reaction
- impotence
- inability to walk due to imbalance
- inflammation of pancreas or intestine
- loss of memory
- throat tightness
- low level of sodium in the blood (hyponatremia) which can cause tiredness and confusion, muscle twitching, cramps, and coma.

Not known side effects (frequency cannot be estimated from the available data):

- myoclonus.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this

leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ranolazine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on each blister strip of tablets and on the outside of the carton and bottle after EXP.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ranolazine contains

The active substance is ranolazine. Each tablet contains either 375 mg or 500 mg or 750 mg of ranolazine.

The other ingredients are: microcrystalline cellulose, hypromellose, methacrylic acid ethyl acrylate copolymer, sodium hydroxide, magnesium stearate.

The film-coating (375 mg) contains: polyvinyl alcohol-part hydrolysed, titanium dioxide, macrogol 4000, talc and indigo carmine aluminium lake (E132).

The film-coating (500 mg) contains: polyvinyl alcohol-part hydrolysed, titanium dioxide, macrogol 4000, talc, iron oxide yellow (E172) and iron oxide red (E172).

The film-coating (750 mg) contains: polyvinyl alcohol-part hydrolysed, titanium dioxide, macrogol, talc.

What Ranolazine looks like and contents of the pack

Ranolazine 375 mg prolonged-release tablets are light blue, oval shaped, film-coated tablets with "375" on one side and plain on the other. The tablet is approximately 14.9 mm x 7.1 mm.

Ranolazine 500 mg prolonged-release tablets are light orange, oval shaped, film-coated tablets with "500" on one side and plain on the other. The tablet is approximately 16.5 mm x 8.0 mm.

Ranolazine 750 mg prolonged-release tablets are white to off white, oval shaped, film-coated tablets with "750" on one side and plain on the other. The tablet is approximately 18.8 mm x 9.1 mm.

Ranolazine is supplied in blisters containing 30, 60, or 100 tablets.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer: PLIVA Hrvatska d.o.o., Prilaz baruna Filipovića 25, 10000 Zagreb, Croatia

This leaflet was last revised in January 2023.

PL 00289/2521, PL 00289/2522 and PL 00289/2523

Other sources of information

To request a copy of this leaflet in braille, large print or audio please contact: Email: medinfo@tevauk.com, Telephone: +44 (0)207 540 7117 Please provide the following information: Product name: Ranolazine 375 mg, 500 mg and 750 mg Prolonged-release Tablets Reference: PL 00289/2521, 2522 and 2523