

Package leaflet: Information for the patient

Ranolazine Celix 375 mg Prolonged-release Tablets
Ranolazine Celix 500 mg Prolonged-release Tablets
Ranolazine Celix 750 mg Prolonged-release Tablets

ranolazine

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ranolazine Celix is and what it is used for

Ranolazine Celix 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 a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Ranolazine Celix

Do not take Ranolazine Celix

- if you are allergic to ranolazine or any of the other ingredients of this medicine listed in section 6 of this leaflet
- if you have severe kidney problems
- if you have moderate or severe liver problems
- if you 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 Celix:

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

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

Other medicines and Ranolazine Celix

Do not use the following medicines if you take this medicine:

- 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 this medicine 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 Celix (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); are taking rifampicin for an infection (e.g. tuberculosis); or are taking the herbal remedy St. John's Wort, as these medicines may cause Ranolazine Celix 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 Celix.
- 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 Celix.
- 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 Celix.

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

Ranolazine Celix with food and drink

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

Pregnancy and breast-feeding

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

You should not take this medicine 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 this medicine on the ability to drive and use machines have been performed. Ask your doctor for advice about driving or using machines.

This medicine 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.

Ranolazine Celix contains lactose and sodium.

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 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 Celix

Always take this medicine exactly as your doctor has told you. 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 this medicine is 750 mg twice a day.

