Package leaflet: Information for the patient

Ranolazine 375 mg Prolonged-release tablet
Ranolazine 500 mg Prolonged-release tablet
Ranolazine 750 mg Prolonged-release tablet
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. 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

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 a 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.
- 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, voriconazol, posaconazol), HIV infection (protease inhibitors), depression (nefazodone) or heart rhythm disorders (e.g. quinidine, dofetilide, or sotalol).

Warning and precautions

Talk to your doctor before taking Ranolazine:

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

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); 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 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.

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 and 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.

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 breastfeeding.

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.

Ranolazine contains less than 1 mmol sodium (23 mg) per 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 (may affect up to 1 in 10 people) are:
Constipation
Dizziness
Headache
Feeling sick, vomiting

Feeling weak

Uncommon side effects (may affect up to 1 in 100 people) are:
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 (may affect up to 1 in 1 000) are:
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) are:
Myoclonus

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. This include any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system
HPRA Pharmacovigilance
Website: www.hpra.ie .

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 the package after "EXP".
The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 in Ranolazine is ranolazine. Each tablet contains 375 mg, 500 mg, or 750 mg ranolazine.

The other ingredients are:
Tablet core: microcrystalline cellulose (E460), methacrylic acid-ethyl acrylate copolymer (1:1), sodium hydroxide (E524), hypromellose (E464), magnesium stearate (E470b).

Film-coating system AquaPolish P white: hypromellose (E464), hydroxypropylcellulose (E463), macrogol 8000 (E1521), titanum dioxide (E171).

What Ranolazine looks like and contents of the pack
The 375 mg tablets are white, oblong, convex, film-coated tablet of dimensions 15 mm x 7.2 mm, with "375" embossed on one side.
The 500 mg tablets are white, oblong, convex, film-coated tablet of dimensions 16.5 mm x 8.0 mm, with "500" embossed on one side.
The 750 mg tablets are white, oblong, convex, film-coated tablet of dimensions 19 mm x 9.2 mm, with "750" embossed on one side.

Ranolazine is supplied in cardboard boxes containing 30, 60 or 100 tablets in PVC/PVDC/Aluminium blisters.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
ELC GROUP s.r.o.
Pobřežní 394/12, Karlin,
186 00 Prague 8
Czech Republic

Manufacturer
Adamed Pharma S.A.
ul. Marszałka Józefa Piłsudskiego 5
95-200 Pabianice, Poland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Netherland	Ranolazine ELC 375 mg tabletten met verlengde afgifte
	Ranolazine ELC 500 mg tabletten met verlengde afgifte

	Ranolazine ELC 750 mg tabletten met verlengde afgifte
Austria	Ranolazin Genericon 375 mg Retardtabletten
	Ranolazin Genericon 500 mg Retardtabletten
	Ranolazin Genericon 750 mg Retardtabletten
Bulgaria	Ranolazine ELC 375 mg Таблетка с удължено освобождаване
	Ranolazine ELC 500 mg Таблетка с удължено освобождаване
	Ranolazine ELC 750 mg Таблетка с удължено освобождаване
Cyprus	Ranolazine ELC 375 mg Δισκία παρατεταμένης αποδέσμευσης
	Ranolazine ELC 500 mg Δισκία παρατεταμένης αποδέσμευσης
	Ranolazine ELC 750 mg Δισκία παρατεταμένης αποδέσμευσης
Estonia	Ranolazine ELC
Croatia	Ranolazin ELC 375 mg tablete s produljenim oslobađanjem
	Ranolazin ELC 500 mg tablete s produljenim oslobađanjem
	Ranolazin ELC 750 mg tablete s produljenim oslobađanjem
Ireland	Ranolazine 375 mg Prolonged-release tablet
	Ranolazine 500 mg Prolonged-release tablet
	Ranolazine 750 mg Prolonged-release tablet
Lithuania	Ranolazine ELC 375 mg pailginto atpalaidavimo tabletės
	Ranolazine ELC 500 mg pailginto atpalaidavimo tabletės
	Ranolazine ELC 750 mg pailginto atpalaidavimo tabletės
Portugal	Ranolazina ELC
Romania	Ranolazină Atb 375 mg comprimate cu eliberare prelungită
	Ranolazină Atb 500 mg comprimate cu eliberare prelungită
	Ranolazină Atb 750 mg comprimate cu eliberare prelungită
Slovenia	Ranolazin ELC Group 375 mg tablete s podaljšanim sproščanjem
	Ranolazin ELC Group 500 mg tablete s podaljšanim sproščanjem
	Ranolazin ELC Group 750 mg tablete s podaljšanim sproščanjem
Italy	RANOLAZINA Bruno Farmaceutici
Spain	Ranolazina Cinfa 375 mg Comprimidos de liberación prolongada EFG
	Ranolazina Cinfa 500 mg Comprimidos de liberación prolongada EFG
	Ranolazina Cinfa 750 mg Comprimidos de liberación prolongada EFG
Greece	RANOLAZINE/GENEPHARM

This leaflet was last revised in December 2023.