

accord

Package leaflet: Information for the patient

Ranolazine Accord 375 mg, 500 mg, 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Ranolazine Accord 375 mg, 500 mg, 750 mg prolonged-release tablets but within this leaflet it will be referred to as Ranolazine.

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 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
- 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 (60kg 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); 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 these medicines 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 these medicines 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 these medicines 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 and breast-feeding

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

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) and 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 E102

Ranolazine 750 mg prolonged-release tablets contain the azo colouring agent E102. This colouring agent may cause allergic reactions.

Ranolazine contains lactose

Ranolazine prolonged-release tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Ranolazine contains sodium

This medicine 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. Check with your doctor 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) are:

- Constipation
- Dizziness
- Headache
- Feeling sick, vomiting
- Feeling weak.

Uncommon side effects (occur in 1 to 10 users in 1,000) 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, nosebleed
- 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.

Front Side

Rare side effects (occur in 1 to 10 users in 10,000) 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 (hyponatraemia) 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 the cardboard wallet and outer carton after EXP. The expiry date refers to the last day of that month.

This medicine 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: microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1), hypromellose, sodium hydroxide, magnesium stearate.

Depending on the tablet strength, the tablet coatings also contain:

375 mg tablet: hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol, triacetin, FD&C blue

#2/indigo carmine aluminium lake (E132)

500 mg tablet: hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol, triacetin, iron oxide yellow (E172), iron oxide red (E172)

750 mg tablet: hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, FD&C blue #1/brilliant blue FCF

aluminium lake (E133) and FD&C yellow #5/tartrazine aluminium lake (E102).

What Ranolazine looks like and contents of the pack

The 375 mg tablets are pale blue coloured, oval shaped, approximately 15.0 x 7.5 mm tablets debossed with "H13" on one side and plain on the other side.

The 500 mg tablets are light orange coloured, oval shaped, approximately 16.5 x 8.1 mm tablets debossed with "H11" on one side and plain on the other side.

The 750 mg tablets are pale green coloured, oval shaped, approximately 19.1 x 9.3 mm tablets debossed with "H14" on one side and plain on the other side.

Ranolazine prolonged-release tablets are packed in opaque white PVC/PVDC/Aluminium blisters containing 28, 30, 42, 56, 60 or 100 tablets in a carton.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

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