

Package leaflet: Information for the patient

Ranolazine Umedica 375 mg prolonged-release tablets
Ranolazine Umedica 500 mg prolonged-release tablets
Ranolazine Umedica 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 Umedica is and what it is used for
2. What you need to know before you take Ranolazine Umedica
3. How to take Ranolazine Umedica
4. Possible side effects
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6. Contents of the pack and other information

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

Ranolazine Umedica 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 Umedica**Do not take Ranolazine Umedica**

- 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).

Warnings and precautions

Talk to your doctor before taking Ranolazine Umedica:

- 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.

Using other medicines and Ranolazine Umedica

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 Ranolazine Umedica 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 (cyclosporin), 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 Umedica (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 Umedica 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 Umedica.
- 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 Umedica.
- certain medicines used to prevent transplanted organ rejection (e.g. tacrolimus, cyclosporin, sirolimus, everolimus) as your doctor may decide to change the dose of this medicine while you are taking Ranolazine Umedica.

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

Ranolazine Umedica with food and drink

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

Pregnancy

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

Breast-feeding

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

Ranolazine Umedica 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.

This medicine 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.

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 Umedica

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 Umedica 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 Umedica.

Use in children and adolescents

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

If you take more Ranolazine Umedica than you should

If you accidentally take too many Ranolazine Umedica 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 Umedica

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 Umedica 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 Umedica.

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, 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) 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 includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Ranolazine Umedica

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.

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 to protect the environment.

6. Contents of the pack and other information

What Ranolazine Umedica contains

The active substance in Ranolazine Umedica is ranolazine. Each tablet contains 375 mg, 500 mg and 750 mg ranolazine.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, methacrylic acid-ethyl acrylate copolymer, sodium hydroxide pellets, hydroxypropyl methylcellulose, magnesium stearate.

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

375mg tablet: hypromellose, titanium dioxide, lactose monohydrate, macrogol, triacetin, Indigo carmine Aluminium Lake (E132)

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

750 mg tablet: hypromellose, titanium dioxide, lactose monohydrate, macrogol, triacetin, Brilliant Blue FCF Aluminium Lake (E133)

What ranolazine tablets looks like and contents of the pack

Ranolazine prolonged-release tablets are oblong shaped tablets.

The 375 mg tablets are pale blue approx. 15.00mm x 7.20mm and are debossed with RAN375 on one side.

The 500 mg tablets are yellow approx. 16.50mm x 8.00mm and are debossed with RAN500 on one side.

The 750 mg tablets are light blue approx. 19.00mm x 9.20mm and are debossed with RAN750 on one side.

Ranolazine Umedica is supplied in cartons containing 28, 30, 56, 60 or 100 tablets in blister strip. Not all pack-sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder:

Umedica Laboratories UK Ltd

Office No. G42, The Panorama Park Street
Ashford
England
TN24 8DF

Manufacturer:

Elara Pharmservices Limited

5 Garden court, Lockington hall,
Main street, Lockington,
Derby, DE74 2RH, United Kingdom

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

Ranolazine Umedica 375 mg prolonged release tablets - PL 60528/0010

Ranolazine Umedica 500 mg prolonged release tablets - PL 60528/0011

Ranolazine Umedica 750 mg prolonged release tablets - PL 60528/0012

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