



**Package leaflet: Information for the user**

**Ranolazine USV 375 mg prolonged-release tablets**  
**Ranolazine USV 500 mg prolonged-release tablets**  
**Ranolazine USV 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. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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

**1. What RANOLAZINE USV is and what is used for**

Ranolazine USV 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 USV**

**Do not take RANOLAZINE USV**

- 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).

**Warning and precautions**

Talk to your doctor before taking Ranolazine USV:

- 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 USV**

Do not use the following medicines if you take Ranolazine USV:

- 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 USV 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 USV (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 USV 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 USV .
- 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 USV .
- 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 USV.

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

**Ranolazine USV with food and drink**

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

**Pregnancy**

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

**Breast-feeding**

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

Ranolazine USV 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 USV 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.

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 USV**

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 USV 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 USV.

**Use in children and adolescents**

Children and adolescents under 18 years old should not take

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USV Private Limited		
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SAP Code : 3019171	Item type : Packinsert	Version: CC 2025
Date: 02/05/2026	Artist Name : Ajay	
Product Name : Ranolazine USV 375 - 500 -750 mg prolonged-release tablets		
Actual Size : 160 mm x 320 mm (L x H) Front & Back	Reference SAP Code : 3019091	
Pharmacode : 9171	Layout No. ---	
CMYK/Pantone : ■ Black	Font type: Swis721 Cn BT	
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Ranolazine USV.

**If you take more Ranolazine USV than you should**

If you accidentally take too many Ranolazine USV 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 USV**

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 USV 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 USV.

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 via Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 USV**

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 protect the environment.

**6. Contents of the pack and other information**

**What Ranolazine USV contains**

The active substance in Ranolazine USV prolonged-release tablets 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) (E1207), Hypromellose (E464), Sodium Carbonate Anhydrous (E500), Silica Colloidal Anhydrous (E551), Magnesium Stearate (E572)

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

**375 mg tablet:** Hypromellose (E464), Lactose monohydrate, Glycerol triacetate (Triacetin) (E1518), Titanium dioxide (E171), Fd&C Blue #2/Indigo Carmine Aluminum Lake JP (E132)

**500 mg tablet:** Hypromellose (E464), Lactose monohydrate, Titanium dioxide (E171), Glycerol triacetate (Triacetin) (E1518), Iron oxide yellow (E172), Iron oxide red (E172)

**750 mg tablet:** Hypromellose (E464), Lactose monohydrate, Titanium dioxide (E171), Glycerol triacetate (Triacetin) (E1518), Iron oxide yellow (E172), Fd&C Blue #1/Brilliant Blue Fcf Aluminum Lake (E133)

**What Ranolazine USV looks like and contents of the pack**

Ranolazine USV prolonged-release tablets are oval shaped tablets.

The 375 mg tablets are pale blue, engraved with "L 38" one side and other side plain.

The 500 mg tablets are light orange, engraved with "L 39" one side and other side plain.

The 750 mg tablets are pale green, engraved with "L 40" one side and other side plain.

Ranolazine USV is supplied in cartons containing 10, 14, 20, 28, 30, 40, 56, 60, 84, 98, 100 tablets in blister strips.

Not all pack-sizes may be marketed.

**Marketing Authorisation Holder**

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**If you are blind or partially sighted and require this leaflet in a different format, call 0800 669 6825 or contact [medinfo@celixpharma.com](mailto:medinfo@celixpharma.com).**

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