

**PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

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

### **1. What Ranolazine Krka is and what it is used for**

Ranolazine Krka 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 Krka**

#### **Do not take Ranolazine Krka**

- if you are allergic to ranolazine or any of the other ingredients of this medicine (listed in section 6).
- 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 or pharmacist before taking Ranolazine Krka .

- 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 Krka**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- 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 Krka 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 Krka (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 Krka 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 Krka .
- 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 Krka .
- 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 Krka .

### **Ranolazine Krka with food and drink**

Ranolazine Krka can be taken with or without food. While being treated with Ranolazine Krka , 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 or pharmacist for advice before taking this medicine.

#### **Pregnancy**

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

#### **Breast-feeding**

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

Ranolazine Krka 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 Krka 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 Krka**

Always take this medicine exactly as your doctor or pharmacist 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 Ranolazine Krka 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 Krka.

#### **Use in children and adolescents**

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

#### **If you take more Ranolazine Krka than you should**

If you accidentally take too many Ranolazine Krka 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 Krka**

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 Krka 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 Krka .

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 people) 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Ranolazine Krka

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

Store below 25 °C.

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 Krka contains

- The active substance is ranolazine. Each prolonged-release tablet contains 375 mg, 500 mg or 750 mg ranolazine.
  - The other ingredients (excipients) are:
    - Ranolazine Krka 375 mg prolonged-release tablets: microcrystalline cellulose, methacrylic acid – ethyl acrylate copolymer (1:1), hypromellose (5 mPa·s), sodium hydroxide and magnesium stearate (E470b) in the tablet core and poly(vinyl alcohol), macrogol 3350, titanium dioxide (E171) and talc in the film coating.
    - Ranolazine Krka 500 mg prolonged-release tablets: microcrystalline cellulose, methacrylic acid – ethyl acrylate copolymer (1:1), hypromellose (5 mPa·s), sodium hydroxide and magnesium stearate (E470b) in the tablet core and poly(vinyl alcohol), macrogol 3350, titanium dioxide (E171), talc and yellow iron oxide (E172) in the film coating.
    - Ranolazine Krka 750 mg prolonged-release tablets: microcrystalline cellulose, methacrylic acid – ethyl acrylate copolymer (1:1), hypromellose (5 mPa·s), sodium hydroxide and magnesium stearate (E470b) in the tablet core and poly(vinyl alcohol), macrogol 3350, titanium dioxide (E171), talc and red iron oxide (E172) in the film coating.
- See section 2 "Ranolazine Krka contains sodium".

### What Ranolazine Krka looks like and contents of the pack

Ranolazine Krka 375 mg prolonged-release tablets: Prolonged-release tablets are white, oval, biconvex, film-coated, marked with 375 on one side of the tablet. Tablet dimensions: approximately 15 × 7 mm.

Ranolazine Krka 500 mg prolonged-release tablets: Prolonged-release tablets are pale brownish yellow, oval, biconvex, film-coated, marked with 500 on one side of the tablet. Tablet dimensions: approximately 17 × 8 mm.

Ranolazine Krka 750 mg prolonged-release tablets: Prolonged-release tablets are pink, oval, biconvex, film-coated, marked with 750 on one side of the tablet. Tablet dimensions: approximately 19 × 9 mm.

Ranolazine Krka is available in packs containing 30, 60 and 100 prolonged-release tablets in blisters.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**


**This leaflet was last revised in**