

# RANEXA Prolonged Release Tablets

**RANOLAZINE (375 mg , 500 mg, 750 mg)**

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### 1. What Ranexa is used for

Ranexa is a medicine used in combination with other medicines to treat stable 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 physical activity.

You must talk to a doctor if you do not feel better or if you feel worse.

### 2. How Ranexa works

The mechanism of action of ranolazine is largely unknown. Ranolazine may have some antianginal effects by inhibition of the late sodium current in heart cells.

### 3. Before you use Ranexa

#### - When you must not use it

- 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).

#### - Before you start to use it

Talk to your doctor before taking Ranexa:

- 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. (More than 75 years of age)
- if you have low weight (60 kg or less)
- if you have heart failure (NYHA Class III–IV).

Your doctor may decide to give you a lower dose or take other precautions if any of these apply to you.

#### - Taking other medicines

Do not use the following medicine if you take Ranexa:

- 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 Ranexa 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 Ranexa (see section 4). Your doctor may decide to give you a lower dose if you are taking.

- 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 Ranexa 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 Ranexa.
- 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 Ranexa.
- 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 Ranexa.

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

#### 4. How to use Ranexa

##### - How much to use

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. They may be taken with or without food.

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 Ranexa is 750 mg twice a day.

##### - When to use it

Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand.

##### - How long to use it

Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

##### - If you forget to use it

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 use too much (overdose)

If you accidentally take too many Ranexa 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.

#### 5. While you are using it

##### - Things you must do

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 Ranexa

##### - Things you must not do

While being treated with Ranexa, you should not drink grapefruit juice.

##### - Things to be careful of Children and adolescent

Children and adolescents under 18 years old should not take Ranexa.

##### Pregnancy and breast-feeding

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

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

#### 6. Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should stop taking Ranexa 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 Ranexa

Other side effects you may experience include the following:

##### Overall list of possible side effects:

**Common** (may affect up to 1 in 10 people):

- Constipation
- Dizziness
- Headache
- Feeling Sick,
- Vomiting

**Uncommon** (may affect up to 1 in 100 people):

- Altered sensation
- Anxiety, difficulty sleeping, confusional state, hallucination
- Blurred vision, visual disturbance, Double vision
- 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
- 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
- Ringing in the ears and/or feeling a spinning sensation
- Stomach pain or discomfort, indigestion, dry mouth, or wind

**Rare** (may affect up to 1 in 1,000 people):

- Inability 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
- Muscle weakness.
- Involuntary muscle jerk

If you get any any side effects talk to your doctor or pharmacist. This include any possible side effects not listed in this leaflet.

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

Ranexa 750 mg 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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## 7. Storage and Disposal of Ranexa

### - Storage

- 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 after EXP.
- This medicinal product does not require any special storage conditions.
- Store below 30°C

### - Disposal

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.

## 8. Product Description

### - What it looks like

Ranexa prolonged-release tablets are oval shaped tablets.

- The 375 mg tablets are pale blue and are engraved with 375 on one side.
- The 500 mg tablets are light orange and are engraved with 500 on one side.
- The 750 mg tablets are pale green and are engraved with 750 on one side

### - Ingredients

- Active ingredient(s): Ranolazine.

- Inactive ingredients  
hypromellose, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, microcrystalline

cellulose, sodium hydroxide, titanium dioxide and carnauba wax.

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

- 375 mg tablet: macrogol, polysorbate 80, Blue #2/Indigo Carmine Aluminium Lake (E132)
- 500 mg tablet: macrogol, talc, polyvinyl alcohol-part hydrolyzed, iron oxide yellow (E172), iron oxide red (E172)
- 750 mg tablet: glycerol triacetate, lactose monohydrate, Blue #1/Brilliant Blue FCF Aluminium Lake (E133) and Yellow#5/Tartrazine Aluminium Lake (E102)

### - MAL number:

Ranexa 375 mg prolonged-release tablets: MAL16035014AZ

Ranexa 500 mg prolonged-release tablets: MAL16035012AZ

Ranexa 750 mg prolonged-release tablets: MAL16035015AZ

## 9. Manufacturer

Menarini - Von Heyden GmbH  
Leipziger Straße 7-13  
01097 Dresden Germany

## Product Registration Holder

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## 10. Date of revision

23/12/2020

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