Package leaflet: Information for the patient

Ranexa 375 mg prolonged-release tablets
Ranexa 500 mg prolonged-release tablets
Ranexa 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 RANEXA is and what it is used for

Ranexa 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 RANEXA

Do not take Ranexa
- 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).

Warning and precautions
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.
- 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 Ranexa
Do not use the following medicines 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.
- 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.

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

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

Breast-feeding
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.

Ranexa 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.

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.

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 RANEXA

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 Ranexa 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 Ranexa.

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

If you take more Ranexa than you should
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.

If you forget to take Ranexa
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 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:

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.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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 RANEXA

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 Ranexa contains
The active substance in Ranexa is ranolazine. Each tablet contains 375 mg, 500 mg, or 750 mg ranolazine.

The other ingredients are: 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)

What Ranexa looks like and contents of the pack
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.

Ranexa is supplied in cartons containing 30, 60, or 100 tablets in blister strips or 60 tablets in plastic bottles. Not all pack-sizes may be marketed.

Marketing Authorisation Holder
Menarini International Operations Luxembourg S.A.
1, Avenue de la Gare L-1611 Luxembourg, Luxembourg

Manufacturer
Menarini - Von Heyden GmbH
Leipziger Straβe 7-13
01097 Dresden
Germany

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

Ireland
A. Menarini Pharmaceuticals Ltd
Tel: +353 1 284 6744

Malta
Menarini International Operations Luxembourg S.A.
Tel: +352 264976

United Kingdom (Northern Ireland)
A. Menarini Farmaceutica Internazionale S.R.L.
Tel: +44 (0)1628 856400

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Detailed information on this medicine is available on the European Medicines Agency web site http://www.ema.europa.eu.