PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

RANEXA 375 mg prolonged-release tablets

Sugar free.

RANEXA 500 mg prolonged-release tablets

Sugar free.

RANEXA 750 mg prolonged-release tablets

Contains sugar (12 mg lactose monohydrate per RANEXA 750 mg tablet).

Ranolazine

Read all of this leaflet carefully before you start taking RANEXA.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- RANEXA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What RANEXA is and what it is used for

2. What you need to know before you take RANEXA

3. How to take RANEXA

4. Possible side effects

5. How to store RANEXA

6. Contents of the pack and other information

1. What RANEXA is and what it is used for

RANEXA is 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 hypersensitive (allergic) to ranolazine or any of the other ingredients of RANEXA 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).
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with 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.

Other medicines and RANEXA:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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.

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 and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacsit or other health care provider for advice before taking RANEXA.

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 breastfeeding. Ask your doctor for advice if you are breastfeeding.

Driving and using machines:

No studies on the effects of RANEXA on the ability to drive a vehicle and use machines have been performed. Ask your doctor for advice about driving a vehicle or using machines.
RANEXA may cause side effects such as dizziness (common), blurred vision (uncommon), confusional state (uncommon), hallucinations (uncommon), double vision (uncommon), coordination problems (rare), that may affect your ability to drive a vehicle or use machines. If you experience these symptoms, do not drive a vehicle or operate machinery until they have resolved completely.

RANEXA 750 mg contains lactose and tartrazine:

RANEXA 375 mg tablets are sugar free.

RANEXA 500 mg tablets are sugar free.

Lactose: RANEXA 750 mg tablets contain sugar (lactose monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RANEXA 750 mg tablets.

Tartrazine: RANEXA 750 mg tablets contain TARTRAZINE (FD&C Yellow No. 5 Lake). This colouring agent may cause allergic reactions.

3. How to take RANEXA

Do not share medicines prescribed for you with any other person.

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

Your doctor will tell you how long your treatment with RANEXA will last.

If you have the impression that the effect of RANEXA is too strong or too weak, tell your doctor or pharmacist.

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 RANEXA 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:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the

nearest hospital or poison centre. Take along any tablets that are left, including 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

RANEXA can have side effects.

Not all side effects reported for RANEXA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RANEXA, please consult your health care provider for advice.

If any of the following happens, stop taking RANEXA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to RANEXA. You may need urgent medical attention or hospitalisation.

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:

Frequent side effects:

- constipation

- dizziness
- headache
- feeling sick, vomiting
- feeling weak

Less frequent side effects:

- feeling anxious, sleeping problems, feeling confused, hallucinations (seeing or hearing things that do not exist)
- blurred vision, visual disturbances, 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, loss of appetite and/or weight loss
- difficulty breathing, cough, nose bleed
- excessive sweating, itching
- stomach pain/discomfort, dry mouth, heartburn, 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, muscle cramps/weakness
- ringing in the ears and/or feeling a spinning sensation

Side effects with a frequency unknown:

- acute kidney failure, a lack of ability to urinate
- abnormal laboratory values for liver
- change in sense of smell, numbness in mouth or lips
- cold sweat, rash
- coordination problems
- decrease in blood pressure upon standing
- decreased or loss of consciousness

- disorientation
- impaired hearing
- feeling of coldness in hands and legs
- impotence
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SHAPRA website. By reporting side effects, you can help provide more information on the safety of RANEXA.

5. How to store RANEXA

- Store at or below 30 °C. Protect from light.
- Keep blister strips in outer carton.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

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 respectively.

Excipients for all RANEXA prolonged-release tablets:

Hypromellose

Magnesium stearate

Methacrylic acid-ethyl acrylate copolymer (1:1)

Microcrystalline cellulose

Sodium hydroxide.

Film coating for RANEXA 375 mg:

Opadry Light Blue containing:

Carnauba wax

FD&C Blue No. 2 Lake (E132)

Hypromellose

Polyethylene glycol

Polysorbate

Titanium dioxide.

Film coating for RANEXA 500 mg:

Opadry II Orange containing:

Carnauba wax

Iron oxide red (E172)

Iron oxide yellow (E172)

Polyethylene glycol

Polyvinyl alcohol

Talc

Titanium dioxide.

Film coating for RANEXA 750 mg:

Opadry II Blue containing:

Carnauba wax

FD&C Blue No. 1 Lake (E133)

FD&C Yellow No. 5 Lake (E102)

Glycerol triacetate

Hypromellose

Lactose monohydrate

Titanium dioxide.

What RANEXA looks like and contents of the pack:

RANEXA 375 mg: Pale blue, film coated, biconvex, ovoid shaped tablet debossed with '375' on one side and plain on the other side.

RANEXA 500 mg: Light orange, film coated, biconvex, ovoid shaped tablet debossed with '500' on one side and plain on the other side.

RANEXA 750 mg: Pale green, film coated, biconvex, ovoid shaped tablet debossed with '750' on one side and plain on the other side.

White, PVC/PVDC/Aluminium blister strip. Three (3) blister strips, containing 20 tablets each, packed into an outer carton.

Pack size: 60 tablets.

Holder of Certificate of Registration:

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RANEXA 375 mg: 52/7.1.4/0337

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RANEXA 750 mg: 52/7.1.4/0339

Access to corresponding Professional Information

Request via the email address: info@menarini.co.za