

RANOPRIL TABLETS

Lisinopril Tablets USP (5mg, 10mg & 20mg)

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What **RANOPRIL TABLETS** is used for

RANOPRIL TABLETS contain a medicine called lisinopril. This belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitor. It is used:

- To treat high blood pressure
- To treat heart failure along with other medicines
- If you have recently had a heart attack
- To treat kidney problems caused by Type 1 diabetes in patients with normal blood pressure and Type 2 diabetes in patients with high blood pressure.

How **RANOPRIL TABLETS** works

RANOPRIL TABLETS work by making your blood vessels widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Before you use **RANOPRIL TABLETS**

When you must not use it

Do not take **RANOPRIL TABLETS**

- If you have an allergy to lisinopril or any of the inactive ingredients of this tablet, listed at the end of this leaflet (see "Product description").
- If you have ever had an allergic reaction to another ACE inhibitor medicine.
- If a member of your family has had severe allergic reactions to an ACE inhibitor or you have had severe allergic reactions without a known cause.
- If you are more than 3 months pregnant (it is also better to avoid lisinopril in early pregnancy)

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- You have narrowing of the kidney blood vessels.
- You have recently had diarrhoea or vomiting.
- You have narrowing of the blood vessels in your heart or narrowing of the heart valves
- You have an increase in the thickness of the heart muscle
- You have kidney problems or you are having kidney dialysis
- You have high levels of cholesterol and you are having a treatment called 'LDL apheresis'
- You have problems with your blood vessels (collagen vascular disease)
- You have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up

- Your doctor has told you to control the amount of salt in your diet
- You have liver problems
- You have diabetes
- You are of black origin as lisinopril may be less effective. You may also more readily get the side effect 'angioedema' (a severe allergic reaction)
- You are having or are going to have treatment to lower the effects of an allergy such as insect stings (desensitisation treatment). If you take lisinopril while you are having this treatment, it may cause a severe allergic reaction

If you have not told your doctor about any of the above, tell him before you start taking **RANOPRIL TABLETS**.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **RANOPRIL TABLETS** may interfere with each other. These include:

- Water tablets (diuretic medicines)
- Potassium tablets or salt substitutes that have potassium in them
- Medicines for depression and for mental problems, including lithium
- Non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and arthritis
- Aspirin if you are taking more than 3 grams each day
- Medicines that contain gold, such as sodium urothiomalate, which may be given to you as an injection.
- Other medicines used to treat blood pressure and heart problems such as aliskiren, valsartan, losartan, telmisartan, atenolol,
- Nitrate medicines (for heart problems).
- Insulin or medicines that you take by mouth for diabetes
- Medicines to break up blood clots
- Medicines used to treat asthma, congestion of nose or sinus or other cold remedies

- Medicines to suppress the body's immune response (immunosuppressants)
- Allopurinol (for gout)
- Procainamide (for heart beat problems)

These medicines may be affected by **RANOPRIL TABLETS**, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

How to use RANOPRIL TABLETS

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to use

Your doctor will tell you how many tablets you need to take each day.

Taking your first dose

- Take special care when you have your first dose of lisinopril or if your dose is increased. It may cause a greater fall in blood pressure than later doses
- This may make you feel dizzy or light-headed. If this happens, it may help to lie down. If you are concerned, please talk to your doctor as soon as possible

Adults

Your dose depends on your medical condition and whether you are taking any other medicines.

For high blood pressure

- The usual starting dose is 10 mg once a day.
- The usual long-term dose is 20 mg once a day.

For heart failure

- The usual starting dose is 2.5 mg once a day.
- Increase in dose should not be greater than 10 mg at once at intervals not less than 2 weeks
- The long-term dose is up to 35 mg once a day.

After a heart attack

- The usual starting dose is 5 mg if your condition is stable after attack and 5 mg one day later. This is then followed 48 hours later by a 10 mg dose

- The usual long-term dose is 10 mg once a day.

For kidney problems in patients with diabetes

- The usual dose is either 10 mg or 20 mg once a day.

Children

Use in children is not recommended.

Kidney transplant patients

Use in kidney transplant patients is not recommended.

If you are elderly, have kidney problems or are taking diuretic medicines your doctor may give you a lower dose than the usual dose.

RANOPRIL TABLETS should be taken once a day as advised by your doctor.

How to take it

Swallow whole tablet with a glass of water.

When to use it

Your doctor will advise you on the best time of the day to take your tablet. Take **RANOPRIL TABLETS** at the same time each day with or without food.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to use it

Continue taking **RANOPRIL TABLETS** for as long as your doctor tells you.

RANOPRIL TABLETS helps control your condition but does not cure it; therefore **RANOPRIL TABLETS** must be taken every day.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much **RANOPRIL TABLETS**.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using RANOPRIL TABLETS

Things you must do

Continue taking **RANOPRIL TABLETS** every day as directed by your doctor, even if you have no symptoms of disease or if you feel normal.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking **RANOPRIL TABLETS**.

Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding.

If you are going to have surgery (even at the dentist), tell surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Tell your doctor immediately if you feel any light-headedness or dizziness after you take your first dose of **RANOPRIL TABLETS** or if your dose is increased.

If you feel light-headed, dizzy or faint, especially if you are taking a diuretic (fluid tablet), get up slowly when getting out of bed or standing up. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. **If this problem gets worse or continues, talk to your doctor.**

Make sure you drink enough water during exercise and hot weather when you are taking **RANOPRIL**

TABLETS, especially if you sweat a lot.

If you do not drink enough water while taking **RANOPRIL TABLETS**, you may faint or feel light-headed or sick.

If you have excessive vomiting and/or diarrhoea while taking **RANOPRIL TABLETS**, tell your doctor. This can result in you losing too much water and may drop your blood pressure too much.

Your doctor may occasionally do a blood test to check your potassium level in the blood and see how your kidneys are working.

Things you must not do

Do not take **RANOPRIL TABLETS** to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage because you are feeling better, unless advised by your doctor.

Things to be careful of

RANOPRIL TABLETS may cause dizziness (lightheadedness) or tiredness in some patients, especially after the first dose or if the dose is increased. Make sure you know how you react to **RANOPRIL TABLETS** before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking **RANOPRIL TABLETS**.

Like all medicines, **RANOPRIL TABLETS** can have side effects, although not everybody gets them.

Do not be alarmed by the following list of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Very serious side effects

If any of the following happens, stop taking **RANOPRIL TABLETS** and tell your doctor immediately or go to the casualty/ emergency department at your nearest hospital immediately.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- severe skin condition with blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose and genitals

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

Serious side effects

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- feeling dizzy or light headed while sitting or standing up from a lying down position
- kidney problems. The symptoms include fever, accelerated heart rate, painful urination, abdominal pain radiating to the back, kidney failure
- heart attack, stroke, abnormal heart beats or rhythm, chest pain, low heart rate
- cough
- tremor
- numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold (Raynaud's phenomenon)
- shortness of breath
- breathing problems including painful respiration, coughing of blood, pus, and build-up of fluid in lungs.
- decreased blood cell production and abnormal blood cell counts. Symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale, bleeding or bruising more easily than normal, frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- severe abdominal pain, vomiting, nausea.
- yellowing of the skin or the whites of the eyes
- inflammation of the liver. Symptoms include loss of appetite, yellowing of the skin and eyes, and dark coloured urine, weakness, weight loss; liver failure

The above list includes serious side effects that may require medical attention.

Other side effects

Tell your doctor if you notice any of the following:

- being sick, diarrhoea, feeling sick, stomach pain or indigestion.
- dizziness, headache
- mood changes
- fainting
- skin scales and plaques (psoriasis), hives
- hair loss
- painful and swollen joints
- memory impairment, abnormal sensation
- passing less urine than is normal; painful urination
- runny nose
- fever, chills, malaise, cough, chest tightness, breathlessness, and headache
- narrowing or blockage of blood vessels
- increased sensitivity of the skin to sun or other skin reactions.

Laboratory Abnormalities

- abnormal blood cell counts
- increase in blood urea, serum creatinine, serum bilirubin, liver enzymes and potassium levels
- decrease in sodium levels
- abnormal blood sugar levels
- increase in non-protein nitrogen, presence of nitrogen in blood
- decreases in heamatocrit

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→ Reporting)

Storage and Disposal of RANOPRIL TABLETS

Storage

Store below 25°C, protected from light and moisture.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN

Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product Description

What RANOPRIL TABLETS looks like

RANOPRIL TABLETS 5 mg

Light yellow coloured, uncoated, round tablets debossed with '5' on one side and scored on the other side.

RANOPRIL TABLETS 10 mg

Light yellow coloured, uncoated, round tablets debossed with '10' on one side and scored on the other side.

RANOPRIL TABLETS 20 mg

Light peach coloured, uncoated, round tablets debossed with '20' on one side and scored on the other side.

Ingredients

Active ingredient:

RANOPRIL 5 mg

Each uncoated tablet contains Lisinopril Dihydrate Ph.Eur equivalent to Lisinopril Anhydrous.....5 mg

RANOPRIL 10 mg

Each uncoated tablet contains Lisinopril Dihydrate Ph.Eur equivalent to Lisinopril Anhydrous.....10 mg

RANOPRIL 20 mg

Each uncoated tablet contains Lisinopril Dihydrate Ph.Eur equivalent to Lisinopril Anhydrous 20 mg

Inactive ingredients:

Mannitol, calcium hydrogen phosphate anhydrous, purified water, pregelatinised maize starch, magnesium stearate, ferric oxide yellow, ferric oxide red, starch maize

MAL Number:

Ranopril Tablets 5mg

MAL20040206A

Ranopril Tablets 10mg

MAL20040207A

Ranopril Tablets 20mg

MAL20040208A

Manufacturer

Ranbaxy Laboratories Limited
PAONTA SAHIB, DIST SIRMOUR,
HIMACHAL PRADESH –173 025

Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

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