

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

RAN-PERINDOPRIL 4 Tablets

Perindopril tert-butylamine

Contains sugar: Lactose monohydrate 29,192 mg

Read all of this leaflet carefully before you start taking RAN-PERINDOPRIL 4

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RAN-PERINDOPRIL 4 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 RAN-PERINDOPRIL 4 is and what it is used for
2. What you need to know before you take RAN-PERINDOPRIL 4
3. How to take RAN-PERINDOPRIL 4
4. Possible side effects
5. How to store RAN-PERINDOPRIL 4
6. Contents of the pack and other information

1. What RAN-PERINDOPRIL 4 is and what it is used for

Perindopril belongs to a class of medicines called ACE inhibitors used to treat high blood pressure. Perindopril lowers blood pressure by widening the blood vessels, which makes it easier for your heart to pump blood through them.

RAN-PERINDOPRIL 4 is used to:

- Treat high blood pressure (hypertension).
- Treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs).

- Reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who does not have heart failure.

2. What you need to know before you take RAN-PERINDOPRIL 4

Do not take RAN-PERINDOPRIL 4

- If you are hypersensitive (allergic) to perindopril or ~~to~~ any of the other ingredients of RAN-PERINDOPRIL 4 (listed in section 6).
- If you have previously been treated with a medication in the same group of medicines as RAN-PERINDOPRIL 4 (ACE inhibitors) or with a medication in the group of medicines known as angiotensin receptor blockers and have had allergic reactions with swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing.
- If you suffer from inherited or of unknown cause or spontaneous angioedema (swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing).
- If you have hypertrophic obstructive cardiomyopathy (obstruction of the left ventricle outflow).
- If you have severe kidney disease.
- If you have narrowing of the blood vessel of the kidney on both sides.
- If you have narrowing of the blood vessels in the kidney if you only have one kidney.
- If you have narrowing of the aortic valve.
- If you are taking potassium sparing diuretics such as spironolactone, triamterene, amiloride.
- If you are taking aliskiren-containing products.
- If you have a hereditary condition called porphyria.
- If you are taking lithium together with RAN-PERINDOPRIL 4 as this may lead to toxic blood concentrations of lithium.
- If you have taken or are currently taking sacubutril/valsartan, a medicine for heart failure, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.
- If you have moderate or severe kidney disease you should not take fluoroquinolones (antibiotics) together with RAN-PERINDOPRIL 4.
- Pregnancy and breastfeeding (see **Pregnancy and breastfeeding**).

Should you become pregnant while taking RAN-PERINDOPRIL 4, the treatment with RAN-PERINDOPRIL 4 must be stopped immediately. Contact your doctor to change your treatment to a different class of antihypertensive medicine.

Warnings and precautions

Take special care with RAN-PERINDOPRIL 4:

- If you have any other heart problems.
- If you have a liver problem.
- If you have kidney problems or if you are receiving dialysis.
- If you have diabetes.
- If you have been told to limit the salt in your diet or to use a salt-substitute containing potassium.
- If you are to undergo anaesthesia and/or major surgery.
- If you are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine).
- If you are going to have desensitisation treatment to reduce the effect of an allergy to bee or wasp stings.
- If you have recently suffered from diarrhoea or vomiting or are dehydrated.
- You have a blood problem such as low or lack of white blood cells (neutropenia/agranulocytosis), low blood platelet count (thrombocytopenia) or a decreased number of red cells (anaemia).
- If you have collagen vascular disease (e.g. lupus erythematosus, rheumatoid arthritis or scleroderma), are on therapy that suppresses your immune system, are taking the medicines allopurinol or procainamide, or any combinations of these.
- If you are taking fluoroquinolones together with RAN-PERINDOPRIL 4 as this may lead to severe kidney damage, especially if you are elderly or have kidney problems. Your doctor must check your kidney function before starting treatment and at regular intervals during treatment with fluoroquinolones and RAN-PERINDOPRIL 4.
- If you are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (used to treat diarrhoea)
 - sirolimus, everolimus, temsirolimus and other medicines belonging to a class of so-called mTor inhibitors (used to avoid rejection of transplanted organs).
 - sacubitril (available as fixed dose combination with valsartan), used to treat long term heart failure.

Other medicines and RAN-PERINDOPRIL 4

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

Care is needed if you are taking the following medicines along with RAN-PERINDOPRIL 4:

- Medicines for high blood pressure including diuretics (medicines which increase the amount of urine produced by the kidneys).
- Aliskiren (used to treat high blood pressure).
- Potassium-sparing medicines (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes.
- Lithium for mania or depression.
- Non-steroidal anti-inflammatory medicines (e.g. ibuprofen) for pain relief or high dose aspirin.
- Medicines to treat diabetes (such as insulin or metformin).
- Baclofen (used to treat muscle stiffness in disease such as multiple sclerosis).
- Medicines to treat mental disorder such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressant, antipsychotics).
- Immunosuppressant (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorder or following transplant surgery (e.g. ciclosporin, tacrolimus).
- Trimethoprim (for the treatment of infections).
- Estramustine (used in cancer therapy).
- Allopurinol (for the treatment of gout).
- Procainamide (for the treatment of an irregular heart beat).
- Vasodilators including nitrates (products that make the blood vessels become wider).
- Heparin (medicines used to thin blood).
- Medicines used for treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).
- Gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- Sacubitril/valsartan used to treat long-term heart failure.
- Fluoroquinolones such as moxifloxacin, sparfloxacin (antibiotics) as this may lead to severe kidney

damage.

- Medicines used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors.
- Other medicines used to treat high blood pressure, including angiotensin II receptor blockers.
- Potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone.

Ask your doctor if you are not sure what these medicines are.

Tell the doctor if you have taken any of the medicines listed above in the past but have now stopped.

RAN-PERINDOPRIL 4 with food or drink

Take RAN-PERINDOPRIL 4 in the morning before a meal.

Drinking alcohol with RAN-PERINDOPRIL 4 may make you feel dizzy. Check with your doctor whether you can drink alcohol when taking RAN-PERINDOPRIL 4.

Pregnancy and breastfeeding

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

Pregnancy:

If you are a woman of childbearing age, ensure that you take adequate contraceptive measures.

You must tell your doctor if you think you are (or might become) pregnant. RAN-PERINDOPRIL 4 should not be taken during pregnancy as it may cause serious harm to your baby if used at that stage.

Breastfeeding:

Tell your doctor if you are breastfeeding or about to start breastfeeding. RAN-PERINDOPRIL 4 is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed your baby.

Driving and using machines

Caution is necessary when driving or performing tasks requiring alertness, as some people may feel dizzy during treatment with RAN-PERINDOPRIL 4. Do not drive or operate any tools or machines until you know how RAN-PERINDOPRIL 4 affects you because your concentration may be affected.

RAN-PERINDOPRIL 4 contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take RAN-PERINDOPRIL 4

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

Always take RAN-PERINDOPRIL 4 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Mild to moderate hypertension:

Adults: The initial dose is 4 mg taken in the morning before breakfast which can be increased to a single dose of 8 mg according to the blood pressure response. The full therapeutic effect may take several weeks. Therefore, if the desired effect has not been achieved within a month of treatment, the dose may be increased.

Congestive heart failure

The treatment should be initiated under close medical supervision. The initial dose is 2 mg orally as a single dose in the morning which may, in most cases, be increased to 4 mg (once blood pressure acceptability has been demonstrated).

Your doctor will tell you how long your treatment with RAN-PERINDOPRIL 4 will last. If you have the impression that the effect of RAN-PERINDOPRIL 4 is too strong or too weak, talk to your doctor or pharmacist.

Your dose may be adjusted depending upon your kidney functioning in case you have kidney problems.

Take your tablet(s) with a glass of water, preferably at the same time each day, in the morning, before a meal.

RAN-PERINDOPRIL 4 is not recommended for use in children.

To help yourself remember to take your medicine, try to get into the habit of taking it at the same time each day. Take your tablets as directed and for as long as directed; do not stop them, even if you feel better, as the symptoms may return.

If you have taken more RAN-PERINDOPRIL 4 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take RAN-PERINDOPRIL 4

If you forget to take RAN-PERINDOPRIL 4 at the right time, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking RAN-PERINDOPRIL 4

Do not stop taking RAN-PERINDOPRIL 4 without talking to your doctor. Medicines for high blood pressure or heart failure will normally have to be taken for the rest of your life. If you stop taking RAN-PERINDOPRIL 4, your condition may get worse.

If you have any further questions on the use of RAN-PERINDOPRIL 4, ask your doctor or pharmacist.

4. Possible side effects

RAN-PERINDOPRIL 4 can have side effects.

Not all side effects reported for RAN-PERINDOPRIL 4 are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking RAN-PERINDOPRIL 4, please consult your-health care provider for advice.

If any of the following happens, stop taking RAN-PERINDOPRIL 4 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to RAN-PERINDOPRIL 4. You may need urgent medical attention or hospitalisation.

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

- Changes in the way your heart beats, for example if you notice it beating faster or more irregular.
- Yellowing of the skin and eyes, also called jaundice.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache, dizziness, vertigo, pins and needles.
- Vision disturbance, tinnitus (sensation of noise in the ears).
- Light-headedness due to low blood pressure.
- Cough, shortness of breath.
- Gastrointestinal disorder (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation).
- Allergic reaction (such as skin rashes, itching).
- Muscle cramps, feeling of tiredness.

Less frequent side effects:

- Mood swings, sleep disturbances.
- Bronchospasm (tightening of the chest, wheezing and shortness of breath).
- Dry mouth.
- Intense itching or severe skin rashes, formation of blister clusters over the skin.
- Kidney problems.
- Impotence.
- Sweating.
- An excess of eosinophils (a type of white blood cell).
- Somnolence, fasting.
- Palpitations, tachycardia.
- Vasculitis (inflammation of blood vessels).
- Photosensitivity reaction (increased sensitivity of skin to sun).
- Arthralgia (joint pain), myalgia (muscle pain).
- Malaise, oedema peripheral, fever.
- Fall.
- Confusion.
- Cardiovascular disorder (irregular heartbeat, heart attack and stroke).
- Eosinophilic pneumonia (a rare type of pneumonia).

- Rhinitis (blocked up or runny nose).
- Erythema multiforme (severe skin reactions).
- Acute renal failure.
- Change in blood value such as lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.
- Inflammation of the pancreas (which causes severe pain in the abdomen and the back), hepatitis.
- Change in laboratory parameters:
- High blood level of potassium, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients, increased blood urea and increased blood creatinine.
- Increased level of liver enzymes, high level of serum bilirubin.

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 to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of RAN-PERINDOPRIL 4.

5. How to store RAN-PERINDOPRIL 4

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package.
- Keep the blister in the outer carton.
- Protected from light/moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What RAN-PERINDOPRIL 4 contains

The active substance is perindopril.

Each tablet contains perindopril tert-butylamine 4 mg.

The other ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

What RAN-PERINDOPRIL 4 looks like and contents of the pack

White to off-white, capsule shaped tablets debossed with 'P' & '5' on either side of the score line on one side and a deep break line on the other side.

Cartons contain 30 tablets packed in cold form blister strips of 10 tablets each. Cold form blister strips comprise of cold form blister laminate composed of aluminium foil (one side bright, soft tempered, plain; dull side lacquer laminated to oriented polyamide film; bright side lacquer laminated to PVC film), PVC and polyamide with a backing of aluminium foil coated with heat seal lacquer on the inner side.

Alternatively, 10 tablets are packed in PVC blister strips in triple laminated aluminium pouch comprised of clear PVC film with the backing of aluminium foil coated with heat sealed lacquer on inner side. Three such PVC blisters are further packed in a triple laminated aluminium pouch with desiccant and sealed.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

a Sun Pharma company

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South Africa

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Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: <https://sunpharma.com/south-africa-products/>

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