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 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 erythematous, 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 floroquinolones 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 others 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.

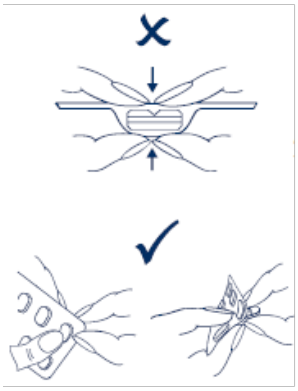
Take your tablet(s) with a glass of water, preferably at the same time each day, in the morning, before a meal.

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.

To remove the tablet intact from the blister, gently push down the tablet from the top to the bottom foil and peel off the aluminium foil.

See below picture for guidance:



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

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This leaflet was last revised in

25 February 2022

Registration number

42/7.1.3/0107

Botswana: S2 Reg. no.: BOT0801268

Namibia: NS2 Reg. no.: 20/7.1.3/0348

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

RAN-PERINDOPRIL 4 Tablette

Perindopril tert-butielamien

Bevat suiker: 29,192 mg Laktosemonohidraat

Lees die hele inligtingstuk noukeurig deur voordat jy begin om RAN-PERINDOPRIL 4 te neem

- Hou hierdie inligtingstuk. Jy sal dit moontlik weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgvoorsiener as jy verdere vrae het.
- RAN-PERINDOPRIL 4 is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met enige ander persone te deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat is RAN-PERINDOPRIL 4 en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy RAN-PERINDOPRIL 4 neem
3. Hoe om RAN-PERINDOPRIL 4 te neem
4. Moontlike newe-effekte
5. Hoe om RAN-PERINDOPRIL 4 te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat is RAN-PERINDOPRIL 4 en waarvoor word dit gebruik

Perindopril behoort aan ‘n klas van medisyne wat AOE-remmers genoem word wat gebruik word om hoë bloeddruk te behandel. Perindopril verlaag die bloeddruk deur die bloedvate te verwyd wat dit makliker maak vir jou hart om bloed daardeur te pomp.

RAN-PERINDOPRIL 4 word gebruik om:

- Hoë bloeddruk te behandel (hipertensie).
- Hartversaking te behandel (‘n toestand waar die hart nie in staat is om genoeg bloed te pomp om

aan die liggaam se behoeftes te voldoen nie).

- Die risiko van kardiale voorvalle, soos hartaanval, te verminder by pasiënte met stabiele koronêre arteriële siekte ('n toestand waar die bloedvoorsiening na die hart verminder of geblokkeer is) en wat nie hartversaking het nie.

2. Wat jy moet weet voordat jy RAN-PERINDOPRIL 4 neem

Moenie RAN-PERINDOPRIL 4 neem nie

- As jy hipersensitief (allergies) is vir perindopril of vir enige van die ander bestanddele van RAN-PERINDOPRIL 4 (gelys in afdeling 6).
- As jy voorheen behandel is met 'n middel in dieselfde groep van medisyne soos RAN-PERINDOPRIL 4 (AOE-remmers) of met 'n middel in die groep van medisyne bekend as angiotensien reseptor- blokkeerders en 'n allergiese reaksie gehad het met swelling van die gesig, lippe, tong, en of keel met probleme om te sluk of asem te haal.
- As jy aan oorerflike, of van onbekende oorsprong, of spontane angio-edeem (swelling van die gesig, lippe, tong, en of keel met probleme om te sluk of asem te haal) ly.
- As jy hipertrofiese obstruktiewe kardiomiopatie het (obstruksie van die uitvloei vanuit die linker ventrikel).
- As jy ernstige niersiekte het.
- As jy vernouing van die bloedvat van die nier aan albei kante het.
- As jy vernouing van die bloedvate in die nier het as jy net een nier het.
- As jy vernouing van die aortiese klep het.
- As jy kaliumsparende diuretika soos spironolaktoon, triamtereen, amiloried neem.
- As jy aliskiren-bevattende produkte neem.
- As jy 'n oorerflike toestand het wat porfirie genoem word.
- As jy litium saam met RAN-PERINDOPRIL 4 neem, aangesien dit tot toksiese bloedvlakke van litium kan lei.
- As jy sakubutriel/valsartan geneem het of tans neem, 'n middel vir hartversaking, aangesien die risiko van angio-edeem (skielike swelling onder die vel in die area soos die keel) vehoog word.
- As jy matige of ernstige niersiekte het, moet jy nie fluorokinolone (antibiotika) saam met RAN-PERINDOPRIL 4 neem nie.

- Swangerskap en borsvoeding (sien **Swangerskap en borsvoeding**).

Indien jy swanger sou raak terwyl jy RAN-PERINDOPRIL 4 neem, moet die behandeling met RAN-PERINDOPRIL 4 onmiddellik gestaak word. Kontak jou dokter om jou behandeling te verander na ‘n ander klas van antihipertensiewe medisyne.

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met RAN-PERINDOPRIL 4:

- As jy enige ander hartprobleme het.
- As jy ‘n lewerprobleem het.
- As jy nierprobleme het of as jy dialise ontvang.
- As jy diabetes het.
- As jy aangesê is om die soutinname in jou dieet te beperk of om ‘n soutvervanging wat kalium bevat, te gebruik.
- As jy narkose moet kry en/of major chirurgie moet ondergaan.
- As jy LDL-aferese moet ondergaan (wat die verwydering van cholesterol vanuit jou bloed is deur ‘n masjien).
- As jy desensitisasie behandeling moet kry om die effek van ‘n allergie teen by- of perdebysteke te verminder.
- As jy onlangs gely het aan diarree of braking of gedehidreer is.
- As jy ‘n bloedprobleem het soos lae of tekort aan witbloedselle (neutropenie/agranulositose), lae bloedplaatjietelling (trombositopenie) of ‘n verlaagde getal van rooiselle (anemie).
- As jy kollageen vaskulêre siekte het (bv. lupus eritematose, rumatoïede artritis of skelroderma), op terapie is wat jou immuunstelsel onderdruk, jy middels soos allopurinol of prokaïenamied neem, of enige kombinasies daarvan.
- As jy fluorokinolone saam met RAN-PERINDOPRIL 4 neem, aangesien dit mag lei tot ernstige nierskade, veral as jy bejaard is of nierprobleme het. Jou dokter moet jou nierfunksie nagaan voordat met behandeling begin word en met gereelde tussenposes tydens behandeling met fluorokinolone en RAN-PERINDOPRIL 4.
- As jy enige van die volgende medisyne neem, word die risiko van angio-edeem verhoog:
    - rasekadotriel (gebruik om diarree te behandel)

- sirolimus, everolimus, temsirolimus en ander medisyne wat behoort aan die klas van sogenaamde mTor-inhibeerders (gebruik om die verwerping van oorgeplante organe te verhoed).
- sakubitriel (beskikbaar as vaste-dosis kombinasie met valsartan), gebruik om langtermyn hartversaking te behandel.

Ander medisyne en RAN-PERINDOPRIL 4

Lig jou gesondheidsorgvoorsiener altyd in as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in).

Voorsorg is nodig as jy die volgende medisyne saam met RAN-PERINDOPRIL 4 neem**:**

- Medisyne vir hoë bloeddruk insluitende diuretika (medisyne wat die hoeveelheid urine verhoog wat deur die niere geproduseer word).
- Aliskiren (gebruik om hoë bloeddruk te behandel).
- Kaliumsparende middels (bv. triamtereen, amiloried), kaliumaanvullings of kaliumbevattende soutvervangers.
- Litium vir manie of depressie.
- Nie-steroïdale anti-inflammatoriese middels (bv. ibuprofeen) vir pynverligting of hoë dosis aspirien.
- Medisyne om diabetes te behandel (soos insulien of metformien).
- Baklofen (gebruik om spierstyfheid te behandel vir siekte soos veelvuldige sklerose).
- Medisyne om geestesversteurings soos depressie, angstigheid, skisofrenie ens. te behandel (bv. trisikliese antidepressante, antipsigotiese middels).
- Immuunonderdrukkers (medisyne wat die verdedigingsmeganisme van die liggaam verminder) gebruik vir die behandeling van outo-immuunversteuring of na oorplantingschirurgie (bv. siklosporien, takrolimus).
- Trimetoprim (vir die behandeling van infeksies).
- Estramustien (gebruik in kankerterapie).
- Allopurinol (vir die behandeling van jig).
- Prokaïenamied (vir die behandeling van onreëlmatige hartklop).
- Vasodilatore insluitende nitrate (produkte wat die bloedvate wyer maak).

- Heparien (medisyne gebruik om bloed te verdun).

- Medsyne wat gebruik word vir die behandeling van lae bloeddruk, skok of asma (bv. efedrien, noradrenalien of adrenalien).
- Goudsoute veral met intraveneuse toediening (gebruik om simptome van rumatoïede artritis te behandel).
- Sakubitriel/valsartan gebruik om langtermyn hartversaking te behandel.
- Fluorokinolone soos moksifloksasien, sparfloksasien (antibiotika) aangesien dit tot ernstige nierskade kan lei.
- Medisyne wat gebruik word om diarree te behandel (rasekadotriel) of om verwerping van oorgeplante organe te verhoed (sirolimus, everolimus, temsirolimus en ander middels wat aan die klas van sogenaamde mTor-inhibeerders behoort.
- Ander medisyne wat gebruik word om hoë bloeddruk te behandel, insluitende angiotensien-II reseptor-blokkeerders.
- Kaliumsparende medisyne wat gebruik word vir die behandeling van hartversaking: eplerenoon en spironolaktoon.

Vra jou dokter as jy onseker is wat hierdie medisyne is.

Lig jou dokter in as jy enige van die medisyne wat hierbo gelys is in die verlede geneem het, maar nou daarmee gestop het.

RAN-PERINDOPRIL 4 saam met voedsel en drinkgoed

Neem RAN-PERINDOPRIL 4 in die oggend voor ‘n maaltyd.

Om alkohol saam met RAN-PERINDOPRIL 4 te neem, kan jou duiselig laat voel. Bevestig met jou dokter of jy alkohol kan gebruik wanneer jy RAN-PERINDOPRIL 4 neem.

Swangerskap en borsvoeding

As jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om ‘n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgvoorsiener raadpleeg vir advies voordat jy hierdie medisyne gebruik.

Swangerskap:

As jy ‘n vrou van kinderbarende ouderdom is, moet jy seker maak dat jy behoorlike voorbehoedmaatreëls tref.

Jy moet jou dokter inlig as jy dink dat jy swanger is (of swanger mag raak). RAN-PERINDOPRIL 4 moet nie tydens swangerskap geneem word nie aangesien dit ernstige skade aan jou baba kan veroorsaak as dit op enige stadium gebruik word.

Borsvoeding:

Lig jou dokter in as jy borsvoed of op die punt is om met borsvoeding te begin. RAN-PERINDOPRIL 4 word nie aanbeveel vir moeders wat borsvoed nie en jou dokter kan ‘n ander behandeling vir jou voorstel as jy verkies om jou baba te borsvoed.

Bestuur en gebruik van masjinerie

Voorsorg is nodig as jy bestuur of take uitvoer wat wakkerheid vereis, aangesien sommige persone duiselig voel wanneer hulle met RAN-PERINDOPRIL 4 behandel word. Moenie bestuur of enige apparaat of masjinerie gebruik totdat jy weet hoe RAN-PERINDOPRIL 4 jou sal affekteer nie omdat jou konsentrasie geaffekteer mag wees.

RAN-PERINDOPRIL 4 bevat laktosemonohidraat

As jy deur jou dokter ingelig is dat jy ‘n onverdraagsaamheid teenoor sekere suikers het, moet jy jou dokter kontak voordat jy hierdie medisyne neem.

3. Hoe om RAN-PERINDOPRIL 4 te neem

Moenie medisyne wat vir jou voorgeskryf is met ander persone deel nie.

Neem RAN-PERINDOPRIL 4 altyd presies soos wat jou dokter of apteker dit voorgeskryf het. Bevestig met jou dokter of apteker as jy onseker is.

Die normale dosis is:

Ligte tot matige hipertensie:

Volwassenes: Die aanvanklike dosis is 4 mg in die oggend voor ontbyt geneem wat tot ‘n enkele dosis van 8 mg verhoog kan word volgens die bloeddruk se respons. Die volle terapeutiese effek kan verskeie weke neem. As die verlangde effek daarom nie binne ‘n maand van behandeling bereik word nie, kan die dosis verhoog word.

Kongestiewe hartversaking

Die behandeling moet onder streng mediese toesig in aanvang neem. Die aanvanklike dosis is 2 mg oraal as ‘n enkeldosis in die oggend wat, in die meeste gevalle, vehoog kan word tot 4 mg (wanneer aanvaarbare bloeddruk aangetoon is).

Jou dokter sal jou inlig oor hoe lank jou behandeling met RAN-PERINDOPRIL 4 sal duur. As jy onder die indruk is dat die effek van RAN-PERINDOPRIL 4 te sterk of te swak is, praat met jou dokter of apteker.

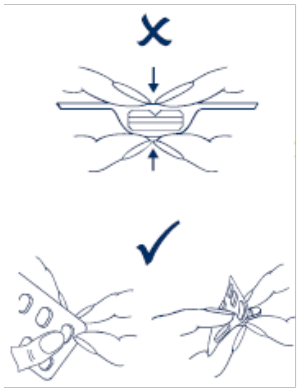
Jou dosis kan aangepas word afhangende van jou nierfunksie in geval jy nierprobleme het. Neem jou tablet(te) met ‘n glas water, verkieslik op dieselfde tyd elke dag, in die oggend, voor ‘n maaltyd.

RAN-PERINDOPRIL 4 word nie vir gebruik by kinders aanbeveel nie.

Om jouself te help herinner om jou medisyne te neem, probeer om in die gewoonte te kom om dit elke dag op dieselfde tyd te neem. Neem jou tablette soos voorgeskryf en vir so lank as wat dit voorgeskryf is; moenie dit stop nie, selfs as jy beter voel, aangesien die simptome kan terugkeer.

Om die tablet intakt uit die stulpverpakking te verwyder, druk die tablet liggies van die boonste na die onderste foelie en trek die aluminiumfoelie af.

Sien onderstaande prentjie vir leiding:



As jy meer RAN-PERINDOPRIL 4 geneem het as wat jy behoort te neem

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem hierdie inligtingstuk of sommige van die tablette saam met jou sodat jou dokter kan weet wat jy geneem het.

As jy vergeet het om RAN-PERINDOPRIL 4 te neem

As jy vergeet het om RAN-PERINDOPRIL 4 op die regte tyd te neem, neem dit so gou as wat jy onthou.

As dit egter amper tyd is vir jou volgende dosis, slaan die dosis oor wat jy vergeet het en gaan terug na jou normale dosisskedule. Moenie ‘n dubbeldosis neem om te vergoed vir die individuele dosisse wat jy vergeet het nie.

As jy ophou om RAN-PERINDOPRIL 4 te neem

Moenie ophou om RAN-PERINDOPRIL 4 te neem nie sonder dat jy met jou dokter gepraat het nie. Medisyne vir hoë bloeddruk of hartversaking moet normaalweg vir die res van jou lewe geneem word. As jy ophou om RAN-PERINDOPRIL 4 te neem, kan jou toestand versleg.

Vra jou dokter of apteker as jy enige verdere vrae het oor die gebruik van RAN-PERINDOPRIL 4.

4. Moontlike newe-effekte

RAN-PERINDOPRIL 4 kan newe-effekte hê.

Nie alle newe-effekte wat vir RAN-PERINDOPRIL 4 aangemeld is, is in hierdie inligtingstuk opgeneem nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl jy RAN-PERINDOPRIL 4 neem, moet jy asseblief jou gesondheidsorgvoorsiener raadpleeg vir advies.

Indien enige van die volgende gebeur, staak die gebruik van RAN-PERINDOPRIL 4 en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, en mond, of keel, wat probleme met sluk of asemhaling kan veroorsaak.
- Uitslag of gejeuk.

Hierdie is almal baie ernstige newe-effekte. As jy hulle het, kon jy ‘n ernstige allergiese reaksie teen RAN-PERINDOPRIL 4 gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Veranderinge in die manier wat jou hart klop, byvoorbeeld as jy opmerk dat dit vinniger of meer onreëlmatig klop.
- Vergeling van die vel en oë, ook geelsug genoem.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- Hoofpyn, duiseligheid, vertigo, naalde-en-spelde gevoel.

- Gesigsversteurings, tinnitus (sensasie van geluide in die ore).
- Lighoofdigheid as gevolg van lae bloeddruk.
- Hoes, kortasemigheid.
- Gastroïntestinale versteuring (naarheid, braking, maagpyn, smaakversteurings, slegte spysvertering of probleme met vertering, diarree, hardlywigheid).
- Allergiese reaksie (soos veluitslae, gejeuk).
- Spierkrampe, moeë gevoel.

Minder dikwelse newe-effekte:

- Gemoedskommelinge, slaapversteurings.
- Brongospasma (borskas voel toe, asemgefluit en kortasemigheid).
- Droë mond.
- Intense gejeuk of ernstige veluitslae, vorming van groepe blasies oor die vel.
- Nierprobleme.
- Impotensie.
- Sweet.
- ‘n Oormaat van eosinofiele (‘n tipe witbloedsel).
- Slaperigheid, vas.
- Palpitasies, tagikardie.
- Vaskulitis (inflammasie van bloedvate).
- Fotosensitiwiteitsreaksie (verhoogde sensitiwiteit van die vel vir die son).
- Artralgie (gewrigspyn), mialgie (spierpyn).
- Malaise, perifere edeem, koors.
- Val.
- Verwarring.
- Kardiovaskulêre versteuring (onreëlmatige hartklop, hartaanval en beroerte).
- Eosinofiliese pneumonie (‘n seldsame tipe van pneumonie).
- Rinitis (geblokte of loopneus).
- Veelvuldige eriteem (ernstige velreaksies).
- Akute nierversaking.
- Verandering in bloedwaarde soos laer aantal wit-en rooibloedselle, laer hemoglobien, laer aantal

bloedplaatjies.

- Inflammasie van die pankreas (wat erge pyn in die maag en rug veroorsaak), hepatitis.
- Verandering in laboratoriumparameters:
- Hoë bloedvlak van kalium, lae vlak van natrium, hipoglukemie (baie lae bloedsuikervlak) in geval van diabetiese pasiënte, verhoogde bloedureum en verhoogde bloedkreatinien.
- Verhoogde vlakke van lewerensieme, hoë vlak van serumbilirubien.

Lig jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk opgeneem is nie.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegster as jy newe-effekte kry. Jy kan ook newe-effekte aanmeld by SAHPRA *via* die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn onder SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van RAN-PERINDOPRIL 4 te verskaf.

5. Hoe om RAN-PERINDOPRIL 4 te bewaar

Bewaar alle medisyne buite die bereik van kinders.

- Bewaar by of onder 25 °C.
- Bewaar in die oorspronklike verpakking.
- Hou die stolpstroke in die buitenste karton.
- Beskerm teen lig/vog.
- Moenie in die badkamer bewaar nie.
- Moenie na die vervaldatum, soos op die etiket aangedui, gebruik nie.
- Bring alle ongebruikte medisyne terug na jou apteker toe.
- Moenie van ongebruikte medisyne in dreinering- of riolerinstelsels bv. toilette ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat RAN-PERINDOPRIL 4 bevat

Die aktiewe bestanddeel is perindopril.

Elke tablet bevat perindopril tert-butielamien 4 mg.

Die ander bestanddele is anhidriese kolloïdale silika, laktosemonohidraat, magnesiumstearaat,

mikrokristallyne sellulose.

Hoe RAN-PERINDOPRIL 4 lyk en inhoud van die verpakking

Wit tot naaswit, kapsulevormige tablette gepers met '**P' & '5**' op enige kant van die keeplyn op een kant en 'n diep breeklyn op die ander kant.

Kartonne bevat 30 tablette verpak in kouevorm stulpstroke van 10 tablette elk. Kouevorm stulpstroke bestaan uit kouevorm stulplaminaat bestaande uit aluminiumfoelie (een kant blink, saggetemper, helder; dowwe kant lakgelamineer aan geörienteerde poliamiedfilm; helder kant lakgelamineer aan PVC-film) PVC en poliamied met 'n rugkant van aluminiumfoelie bedek met hitte seëllak aan die binnekant.

Alternatiewelik word 10 tablette verpak in PVC-stulpstroke in 'n driedubbele gelamineerde aluminiumsakkie bestaande uit helder PVC-film met 'n rugkant van aluminiumfoelie bedek met hitte seëllak aan die binnekant. Drie sulke PVC-stulpstroke word verder in 'n driedubbele gelamineerde aluminiumsakkie met 'n droogmiddel verpak en verseël.

Houer van die Registrasiesertifikaat

RANBAXY PHARMACEUTICALS (PTY) LTD

Lautrestraat 14, Stormill Uitbreiding 1

Roodepoort, 1724

Suid-Afrika

Hierdie inligtingstuk was laas hersien op

25 February 2022

Registrasienommer

42/7.1.3/0107

Botswana: S2 Reg. nr.: BOT0101268

Namibië: NS2 Reg. nr.: 20/7.1.3/0348