1.5.5 Clean Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

SINOPREN 5 TABLETS

SINOPREN 10 TABLETS

SINOPREN 20 TABLETS

Lisinopril

Contains sugar: mannitol.

Each 5 mg tablet contains 25 mg mannitol.

Each 10 mg tablet contains 50 mg mannitol.

Each 20 mg tablet contains 46 mg mannitol.

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

- 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.
- SINOPREN 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 SINOPREN is and what it is used for
2. What you need to know before you take SINOPREN
3. How to take SINOPREN
4. Possible side effects
5. How to store SINOPREN
6. Contents of the pack and other information

1. WHAT SINOPREN IS USED FOR

SINOPREN belongs to a class of medicines called angiotensin-converting enzyme (ACE) inhibitors. It is used to treat high blood pressure (hypertension). It may be used alone or together with other medicines for high blood pressure.

SINOPREN may also be used to treat heart failure or may be used after a heart attack to prevent the development of heart failure.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SINOPREN

Do not take SINOPREN:

- if you are hypersensitive (allergic) to lisinopril, or to any of the other ingredients of SINOPREN.
- if you ever had an allergic reaction to another ACE inhibitor medicine. The allergic reaction may have caused swelling of the hands, feet, ankles, face, lips, tongue or throat. It may also have made it difficult to swallow or breathe (angioedema)
- if a member of your family has had severe allergic reactions (angioedema) to an ACE inhibitor or you have had severe allergic reactions (angioedema) without a known cause
- if you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy)
- if you have severe kidney dysfunction
- if you have a narrowing (stenosis) of the kidney artery
- if you have a narrowing (stenosis) of the aorta (an artery in your heart)
- if you are also taking potassium sparing diuretics such as spironolactone, triamterene, amiloride
- if you have a hereditary condition called porphyria

- if you are also receiving lithium therapy: Administration together with SINOPREN may lead to toxic blood concentrations of lithium
- if you are pregnant or breast-feeding (see **Pregnancy and breastfeeding**)
- if you are taking a blood pressure lowering medicine containing aliskiren.
- If you are taking fluoroquinolones (medicines to treat infections) and you have impaired kidney function.

If you are not sure about any of these please consult your doctor.

Warnings and precautions

Take special care with SINOPREN

Talk to your doctor or pharmacist before taking SINOPREN.

Should a woman become pregnant while receiving SINOPREN, the treatment must be stopped promptly and changed to a different medicine. If a woman is contemplating pregnancy, a different class of medicine should be used.

SINOPREN should be used with caution in the following conditions:

- You are at high risk of low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- You have been very sick (excessive vomiting) or had bad diarrhoea recently.
- You are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents (such as spironolactone, triamterene, amiloride), or potassium-containing salt substitutes.
- You have a condition known as congestive heart failure (your heart fails to pump blood strongly enough to supply all the blood needed throughout the body).
- You have any other a heart problem or heart disease.

- You have a condition involving the blood vessels in the brain or blood vessel disease.
- You have any other kidney problems (including kidney transplantation). These may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of SINOPREN or monitor your blood level of potassium.
- You are having dialysis.
- You have a liver problem.
- You have diabetes. You should monitor your blood for low blood glucose levels, especially during the first month of treatment. The level of potassium in your blood can also be higher.
- You are of black origin as SINOPREN may be less effective. You may also more readily get the side-effect 'angioedema' (a severe allergic reaction).
- You have high levels of cholesterol and you are having a treatment called 'LDL apheresis'.
- The safety and efficacy of SINOPREN in children have not been established.
- You have diabetes.
- If you are taking fluoroquinolones used to treat infections; in particular if you are elderly or have kidney problems; your doctor may check your kidney function at regular intervals. See also information under the heading "Do not take SINOPREN".

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking SINOPREN.

Treatment for allergies such as insect stings: Tell your doctor if 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 SINOPREN while you are having this treatment, it may cause a severe allergic reaction.

Operations: If you are going to have an operation (including dental surgery) tell the doctor or dentist that you are taking SINOPREN. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking SINOPREN.

Other medicines and SINOPREN

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor if you are already taking or planning to take any of the following as they may interact with SINOPREN:

- water tablets (diuretic medicines)
- other medicines to help lower your blood pressure
- nitrate medicines (for heart problems)
- medicines for depression or mental problems containing lithium – see “Do not take SINOPREN”
- potassium tablets or salt substitutes that have potassium in them or other drugs that may increase serum potassium in your body (such as heparin, and co-trimoxazole also known as trimethoprim/sulfamethoxazole).
- non-steroidal anti-inflammatories (NSAIDs) used to treat pain and arthritis.
- aspirin (acetylsalicylic acid), if you are taking more than 3 grams each day.
- medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.
- insulin or medicines that you take by mouth for diabetes.

- fluoroquinolones (class of medicines used to treat infections e.g. ciprofloxacin, levofloxacin, moxifloxacin)
- Immune suppressing drugs (ciclosporin)

The following medicines may increase the risk of angioedema (signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing):

- medicines to break up blood clots (tissue plasminogen activator), usually given in hospital.
- medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors).
- racecadotril used to treat diarrhoea.

Pregnancy, breast-feeding and fertility

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

You must not take SINOPREN if you are pregnant or breastfeeding. 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. SINOPREN is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at this stage.

Driving and using machines

Caution is necessary when driving or performing tasks requiring alertness, as some people may feel dizzy or tired during treatment with SINOPREN. Do not drive or operate

any tools or machines until you know how SINOPREN affects you because your concentration may be affected.

SINOPREN contains mannitol

This may have a mild laxative (bowel loosening) effect.

3. HOW TO TAKE SINOPREN

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

Always take SINOPREN exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.
Your doctor will tell you how long your treatment with SINOPREN will last. Do not stop treatment early without consulting your doctor. If you have the impression that the effect of SINOPREN is too strong or too weak, tell your doctor or pharmacist.

SINOPREN may be taken before, during or after meals. Try to take your tablets at the same time each day. Take special care when you take your first dose of SINOPREN as 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.

Adults:
The dose of SINOPREN depends on your medical condition and whether you are taking any other medicines.
The usual dose varies from 2,5 – 20 mg once a day depending on the condition being treated.
If you are elderly, have kidney problems or are taking diuretic medicines, your doctor may give you a lower dose than the usual dose.

Children:

SINOPREN should not be given to children.

If you take more SINOPREN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center. Take the **SINOPREN** medicine pack with you.

If you forget to take SINOPREN

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking SINOPREN

Do not stop taking SINOPREN, even if you are feeling better, unless your doctor tells you to. If you have any further questions on the use of SINOPREN, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

SINOPREN can have side effects.

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

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

- severe allergic reactions. The signs may include sudden onset of swelling of the face, lips, tongue or throat; difficulty breathing; severe or sudden swelling of your hands, feet and ankles,
- severe skin disorders, like a sudden, unexpected rash or burning, red or peeling skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SINOPREN. 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:

- stroke; heart attack (symptoms may include chest discomfort, pain in one or both arms, shortness of breath, cold sweat, nausea or light-headedness,
- fast heartbeat,
- a very big drop in blood pressure may happen in people with the following conditions: coronary heart disease; narrowing of the aorta (a heart artery), kidney artery or heart valves; an increase in thickness of the heart muscle. If this happens, you may feel dizzy or light-headed, especially if you stand up quickly,
- sudden kidney failure; passing less water (urine) than normal or passing no water,
- liver failure, yellowing of the skin or whites of the eyes (jaundice),
- fainting**.**

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

Tell your doctor if you notice any of the following:

Frequent:

- headache,
- feeling dizzy or light-headed, especially if you stand up quickly,
- diarrhoea,
- a dry cough that does not go away,
- being sick (vomiting),
- kidney problems (shown in a blood test).

Less frequent:

- mood changes,
- change of colour in your fingers or toes; or numbness or tingling in your fingers or toes,
- changes in the way things taste,
- feeling sleepy,
- spinning feeling (vertigo),
- having difficulty sleeping,
- runny nose,
- feeling sick (nausea); stomach pain or indigestion,
- skin rash or itching,
- being unable to get an erection (impotence),
- feeling tired or feeling weak (loss of strength),
- changes in blood tests that show how well your liver and kidneys are working,
- feeling confused,
- a lumpy rash,
- dry mouth,
- hair loss,
- psoriasis (a skin problem),
- changes in the way things smell,

- development of breasts in men,
- changes to some of the cells or other parts of your blood. Your doctor may take blood samples from time to time to check whether SINOPREN have had any effect on your blood,
- sinusitis,
- wheezing,
- low levels of sugar in your blood,
- inflammation of your lungs,
- inflammation of the liver or pancreas,
- severe skin disorders,
- symptoms of depression.

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 or 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 FUROBE 40 mg TABLETS.

5. HOW TO STORE SINOPREN

Store all medicines out of reach of children

Store in a cool place at or below 25 ºC. Protect from light and moisture.

Do not store in bathrooms in order to protect from light.

Do not take the medicine 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 SINOPREN CONTAINS

The active substance is lisinopril dihydrate equivalent to anhydrous Lisinopril.

SINOPREN 5 TABLETS:

Each tablet contains lisinopril dihydrate equivalent to anhydrous lisinopril 5 mg.

SINOPREN 10 TABLETS:

Each tablet contains lisinopril dihydrate equivalent to anhydrous lisinopril 10 mg.

SINOPREN 20 TABLETS:

Each tablet contains lisinopril dihydrate equivalent to anhydrous lisinopril 20 mg.

The other ingredients are:

Anhydrous calcium hydrogen phosphate, ferric oxide, magnesium stearate, maize starch, mannitol and pregelatinised starch maize.

What SINOPREN looks like and the contents of the pack

What SINOPREN looks like**:**

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

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

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

Contents of the pack:

Carton containing three PVdC- coated PVC blister strips of 10 tablets each.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

Stormill, Ext. 1,

Roodepoort,

1724

This leaflet was last revised in

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To be allocated

Registration Number

SINOPREN 5 TABLETS: 35/7.1.3/0209

SINOPREN 10 TABLETS: 35/7.1.3/0210

SINOPREN 20 TABLETS: 35/7.1.3/0211

Namibia only:

SINOPREN 5 TABLETS: NS2 Reg No.:05/7.1.3/0193

SINOPREN 10 TABLETS: NS2 Reg No.:05/7.1.3/0194

SINOPREN 20 TABLETS: NS2 Reg No.:05/7.1.3/0195