

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS** S3

**ALAPREN 5 TABLETS** (Tablets)

**ALAPREN 10 TABLETS** (Tablets)

**ALAPREN 20 TABLETS** (Tablets)

### **Enalapril maleate**

**ALAPREN 5 TABLETS:** Contains sugar: Lactose 40 mg per tablet

**ALAPREN 10 TABLETS:** Contains sugar: Lactose 80 mg per tablet

**ALAPREN 20 TABLETS:** Contains sugar: Lactose 80 mg per tablet

**Read all of this leaflet carefully before you start taking ALAPREN TABLETS**

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

## **1. What ALAPREN TABLETS is and what it is used for**

Enalapril belongs to a class of medicines called ACE inhibitors. ALAPREN TABLETS are used to treat high blood pressure and to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs).

## **2. What you need to know before you take ALAPREN TABLETS**

### **Do not take ALAPREN TABLETS:**

- if you are hypersensitive (allergic) to enalapril, or to any of the other ingredients of ALAPREN TABLETS (listed in section 6).
- If you have previously been treated with a medication in the same group of medicines as ALAPREN TABLETS (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 have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) when the reason why was not known or it was inherited.
- If you have severe kidney dysfunction.
- If you have kidney problems, where the blood supply to your kidney is reduced (renal artery stenosis).
- If you are also taking potassium sparing diuretics such as spironolactone, triamterene, amiloride.
- If you are also receiving lithium therapy: Administration together with ALAPREN TABLETS may lead to toxic blood concentrations of lithium.
- If you have a hereditary condition called porphyria.
- If you are pregnant or breastfeeding (see Pregnancy and Breastfeeding).
- If you are taking aliskiren containing products

- If you are taking antibiotics belonging to fluoroquinolone family (eg. Ciprofloxacin, levofloxacin etc.).

## **Warnings and precautions**

### **Take special care with ALAPREN TABLETS:**

**Should you become pregnant while receiving ALAPREN TABLETS, ALAPREN TABLETS must be stopped immediately. Consult your doctor if you are contemplating pregnancy.**

- If you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
  - aliskiren
- If you are at risk of low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- If you have been very sick (excessive vomiting) or had bad diarrhoea recently.
- If you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents (such as spironolactone, triamtrene, amiloride), or potassium-containing salt substitutes.
- If you have any heart problem or heart disease.
- If 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 enalapril or monitor your blood level of potassium.
- If you are an elderly person (over 65 years of age).
- If you are on dialysis.
- If you have liver problems.

- If 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 ever had an allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing. You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors such as ALAPREN TABLETS. Signs of swelling of the face or arms and legs or difficulty in swallowing or breathing require immediate medical attention because of the risk of angioedema.
- If you have lupus, rheumatoid arthritis, scleroderma, or if you are on therapy that suppresses your immune system.
- If you are taking the medicines allopurinol for gout or any combinations of these.
- If 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.
- The safety and efficacy of ALAPREN TABLETS in children have not been established.

Your doctor will conduct some blood tests before and during the treatment to examine if your kidneys are working properly.

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

**If you are about to have a procedure**

If you are about to have any of the following, tell your doctor that you are taking ALAPREN TABLETS:

- Any surgery or receive anaesthetics (even at the dentist).

- A treatment to remove cholesterol from your blood called “LDL apheresis”.
- A desensitization treatment, to lower the effect of an allergy to bee or wasp stings.

If any of the above applies to you, talk to your doctor or dentist before the procedure.

### **Other medicines and ALAPREN TABLETS**

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 following medicines along with ALAPREN TABLETS:

- Angiotensin II receptor blocker (ARB) (also known as sartans - for example valsartan, telmisartan, irbesartan) or aliskiren
- Medicines containing potassium (including dietary salt supplements).
- Medicines for diabetes (including oral antidiabetic medicines and insulin).
- Lithium (a medicine used to treat a certain kind of depression).
- Medicines for depression called “tricyclic antidepressants”.
- Medicines for mental problems called “antipsychotics”.
- Other medicines to lower blood pressure, such as beta-blockers or water tablets (diuretics), such as furosemide, hydrochlorothiazide, spironolactone, triamterene or amiloride.
- Medicines used for arthritis or gout (allopurinol, cytostatic or immune-suppressive agents, systemic corticosteroids).
- Gold therapy such as sodium aurothiomalate, which can lead to flushing of your face, feeling sick (nausea or vomiting) and low blood pressure-
- Ciclosporin (medicine used for organ transplant, arthritis or psoriasis).
- Non-steroidal anti-inflammatory medicines (NSAIDs), e.g. ibuprofen, including COX-2-inhibitors, e.g. celecoxib (medicines that reduce inflammation, and can be used to help relieve pain).

- Certain cough and cold medicines and cold medicines and weight reducing medicines which contain an ingredient called a “sympathomimetic agent”.
- Alcohol
- Fluoroquinolones eg. Ciprofloxacin, levofloxacin [see also information under the headings “Do not take ALAPREN TABLETS and Take special care with ALAPREN TABLETS”).

### **ALAPREN TABLETS with food and drink**

ALAPREN TABLETS can be taken before, during or after a meal.

### **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 health care provider for advice before taking this medicine.

You must not take ALAPREN TABLETS if you are pregnant or breastfeeding. If you are pregnant or become pregnant while taking ALAPREN TABLETS, stop taking ALAPREN TABLETS and talk to your doctor as soon as possible. If you are a woman of childbearing age, ensure that you take adequate contraceptive measures.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking ALAPREN TABLETS.

### **Driving and using machines**

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

**ALAPREN TABLETS contain lactose**

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

**ALAPREN TABLETS contains sodium**

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take ALAPREN TABLETS**

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

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

\*ALAPREN tablets is not available in a 2,5 mg strength. Please use an alternative enalapril 2,5 mg product available on the market,

Since food does not interfere with the absorption of ALAPREN TABLETS, the dose may be administered before, during or after meals

**Hypertension:** The usual starting dose is 10 to 20 mg once daily. The maintenance dose is usually 20 mg once daily. Your doctor will adjust your dose according to your specific needs.

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

If you are an elderly patient (over 65 years of age) or if you have kidney problems, your doctor will start your treatment with ALAPREN TABLETS on a lower dose of 2,5 mg once daily and adjust your dose according to your response and blood pressure.

**Heart failure:** The usual starting dose of ALAPREN TABLETS is 2,5 mg once daily *under medical supervision*, and your doctor will adjust your dose according to your response. If

you have severe heart failure, your treatment with ALAPREN TABLETS will be started while you are in hospital, where you can be closely monitored by your doctor.

To help yourself remember to take ALAPREN TABLETS, try to take 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 the impression that the effect of ALAPREN TABLETS are too strong or too weak, talk to your doctor or pharmacist.

**If you take more ALAPREN TABLETS 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 this leaflet or some tablets with you so your doctor will know what you have taken.

**If you forget to take ALAPREN TABLETS 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.

**Effects when treatment with ALAPREN TABLETS is stopped:**

Take **ALAPREN TABLETS** for as long as your doctor recommends. Don't stop unless your doctor advises you to.

**4. Possible side effects**

**ALAPREN TABLETS can have side effects.**

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

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

- swelling of the arms, legs, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing,
- rash or itching,

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

**Tell your doctor if you notice any of the following:**

**Frequent side effects:**

- Cough, difficulty in breathing.
- Headache, depression.
- Blurred vision.
- Feeling dizzy, lightheadedness, fainting.
- Chest pain, irregular heartbeat, fast heartbeat.
- Feeling sick (nausea), diarrhoea, stomach pain, disturbances in taste.
- Skin rash.
- Unusual tiredness or weakness.

**Less frequent side effects:**

- Vomiting, indigestion, constipation, loss of appetite, dry mouth, blockage in the bowel (constipation), stomach ulcer, irritated stomach; swollen, red, sore tongue; mouth ulcers and cold sores, dark stools, swelling of your intestine.
- Muscle cramps.
- Asthma, runny nose, sore throat or hoarseness.
- Kidney or urination problems, infection in urinary passage, kidney failure.
- Sudden fall in blood pressure, palpitations.

- Heart attack or stroke (possibly due to very low blood pressure in high-risk patients).
- Changes in blood values such as a lower number of white and red blood cells, lower hemoglobin, lower number of blood platelets.
- 'Raynaud's phenomenon' where your hands and feet may become very cold and white due to low blood flow.
- Hepatitis or jaundice (yellow eyes or skin), liver failure, higher levels of liver enzymes or bilirubin (measured in a blood test).
- Inflammation of the cheeks, gums, tongue, lips, throat.
- Confusion, sleepiness, trouble in sleeping, nervousness, sleep disorders, strange dreams.
- Numbness or weakness of the arms and legs.
- Impotence, enlargement of the mammary glands in males.
- Flushing, generally feeling unwell (malaise), high temperature (fever), ringing in the ears, loss of smell, swollen runny eyes, dry eyes, tearing, flank pain.
- Excessive sweating, itching, hives, hair loss.
- A rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals and other skin related problems.

Low level of blood sugar or sodium, high level of creatinine, potassium, urea in blood (all measured in a blood test).

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 ALAPREN TABLETS.

## **5. How to store ALAPREN TABLETS**

- Store at or below 25 °C, protected from moisture.
- KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.
- 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 ALAPREN TABLETS contains**

The active substance is Enalapril maleate 5 mg, 10 mg or 20 mg per tablet.

The other ingredients:

**ALAPREN 5 TABLETS:** Colloidal anhydrous silica, croscarmellose sodium, lactose, maleic acid, microcrystalline cellulose, zinc stearate

**ALAPREN 10 TABLETS:** Colloidal anhydrous silica, croscarmellose sodium, ferric oxide red (CI No. 77491), lactose, maleic acid, microcrystalline cellulose, zinc stearate

**ALAPREN 20 TABLETS:** Colloidal anhydrous silica, croscarmellose sodium, ferric oxide red (CI No. 77491), ferric oxide yellow (CI No. 77492), lactose, maleic acid, microcrystalline cellulose, zinc stearate

### **What ALAPREN TABLETS looks like and contents of the pack**

#### **ALAPREN 5 TABLETS**

White to off-white round, biconvex uncoated tablets debossed with '5' on one side and plain on other side.

#### **ALAPREN 10 TABLETS**

Pink, round biconvex uncoated tablets debossed with '10' on one side and plain on other side.

**ALAPREN 20 TABLETS**

Peach coloured round, biconvex, uncoated tablets debossed with '20' on one side and plain on other side.

**Contents of the pack:**

**ALAPREN 5 TABLETS:** Carton containing 4 blister strips of 7 tablets in each blister.

**ALAPREN 10 TABLETS:** Carton containing 4 blister strips of 7 tablets in each blister.

**ALAPREN 20 TABLETS:** Carton containing 4 blister strips of 7 tablets in each blister.

**Holder of Certificate of Registration**

Ranbaxy Pharmaceuticals (Pty) Ltd

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**Namibia :** NS2

Reg. No.: ALAPREN 5 TABLETS: 04/7.1.3/1298

ALAPREN 10 TABLETS: 04/7.1.3/1299

ALAPREN 20 TABLETS: 04/7.1.3/1300

**Botswana:** S2

Reg. No.: ALAPREN 5 TABLETS: BOT0801166

ALAPREN 10 TABLETS: BOT0700982

ALAPREN 20 TABLETS: BOT0700983