

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:**

S3

### **Enaside 20/12,5 Tablets**

#### **Enalapril maleate and hydrochlorothiazide**

**Contains sugar (lactose monohydrate) 130,10 mg per tablet.**

**Read all of this leaflet carefully before you start taking Enaside 20/12,5**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Enaside 20/12,5 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 Enaside 20/12,5 is and what it is used for
2. What you need to know before you take Enaside 20/12,5
3. How to take Enaside 20/12,5
4. Possible side effects
5. How to store Enaside 20/12,5
6. Contents of the pack and other information

#### **1. What Enaside 20/12,5 is and what it is used for**

Enaside 20/12,5 contains enalapril maleate and hydrochlorothiazide:

- enalapril belongs to a group of medicines called angiotensin converting enzyme inhibitors (ACE inhibitors), which work by widening your blood vessels

- hydrochlorothiazide belongs to a group of medicines known as water tablets (diuretics), which increase the volume of urine you produce.

The effect of these medicines is to lower your blood pressure. Enaside 20/12,5 is used to treat high blood pressure (hypertension). Taking both medicines that Enaside 20/12,5 contains can increase their effect compared to taking just one.

## **2. What you need to know before you take Enaside 20/12,5**

### **Do not take Enaside 20/12,5**

- if you are hypersensitive (allergic) to enalapril, hydrochlorothiazide or any of the other ingredients of Enaside 20/12,5 (listed in section 6)
- if you have previously been treated with a medication in the same group of medicine as this medicine (ACE inhibitors) and have had allergic reactions with swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing
- if you have severe impaired kidney function
- if you are not passing urine
- if you have a disease characterized by recurrent episodes (also called attacks) of severe swelling of the skin and mucous membranes
- if you have a disease in which the heart muscle becomes abnormally thick (hypertrophied). The thickened heart muscle can make it harder for the heart to pump blood. Symptoms include chest pain, especially during exercise, fainting, sensation of rapid, fluttering or pounding heartbeats (palpitations), shortness of breath
- if you are allergic to any sulfonamide-derived medicines. Ask your doctor if you are not sure what sulfonamide-derived medicines are
- if you are pregnant or breastfeeding
- if you have severe liver impairment
- if you have a condition known as renal artery stenosis (narrowing of the arteries that supply the blood to your

kidneys)

- if you have heart valve (aorta) disease problems
- if you are being treated with spironolactone, triamterene, amiloride
- if you suffer from porphyria
- if you are on lithium therapy or aliskiren-containing medicines
- if you have Addison's disease (a disorder in which the adrenal glands situated on top of your kidney do not produce enough hormones)
- if you have kidney problems and/or are elderly and you are taking medicine used to treat bacterial infections (antibiotics) belonging to the fluoroquinolone group. Contact your doctor to re-evaluate treatment if you are treated with Enaside 20/12,5 together with a fluoroquinolone antibiotic.
- if you are being treated with sacubitril/valsartan, a medicine for heart failure
- if you have previously had or currently have cancer of the skin and/or lip.

### **Warnings and precautions**

Should you become pregnant while receiving Enaside 20/12,5, the treatment must be stopped promptly and switched to a different medicine. Should you contemplate pregnancy, the doctor should institute alternative medication (see Pregnancy section)

Take special care with Enaside 20/12,5:

- if you are on a salt restricted diet, or have suffered from excessive vomiting or diarrhoea recently
- if you have kidney problems, have had a recent kidney transplantation, are a dialysis patient
- if you have any type of liver disease
- if you were taking water tablets (diuretics) prior to starting Enaside 20/12,5. Any other diuretic should be stopped 2-3 days before you start treatment with Enaside 20/12,5
- if you have a heart condition called 'aortic stenosis', 'hypertrophic cardiomyopathy' or 'outflow obstruction'

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- if you have collagen vascular disease, are taking immunosuppressant therapy (used for the treatment of autoimmune disorders such as rheumatoid arthritis or following transplant surgery)
  - if you are taking potassium supplements, potassium containing salt substitutes, or other medicines that may increase potassium in your blood (e.g., heparin [a medicine used to prevent blood clots], trimethoprim-containing products such as cotrimoxazole [medicines used to treat infections])
  - if you have diabetes and are taking antidiabetic medicines, including insulin to control your diabetes (you should monitor your blood for low blood glucose levels, especially during the first month of treatment)
  - if you have a history of ‘angioedema’ while taking other medicines. The signs may have been itching, nettle rash, wheezing or swelling of your hands, throat, mouth or eyelids
  - if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Enaside 20/12,5
  - tell your doctor if you are taking an mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus: medicines used to treat certain types of cancer or to prevent the body’s immune system from rejecting a transplanted organ) or a medicine containing a neprilysin inhibitor such as sacubitril (available as fixed-dose combination with valsartan), used in patients with heart failure, and racecadotril, used in patients with acute diarrhoea. You may be at increased risk for an allergic reaction called angioedema
  - tell your doctor if you are taking either of the following medicines used to treat high blood pressure:
    - an angiotensin II receptor blocker (ARB) (also known as sartans –for example valsartan, telmisartan, irbesartan etc), in particular if you have diabetes-related kidney problems
    - aliskiren
  - tell your doctor if you have previously had a condition called Acute Respiratory Disease Syndrome – a condition in which fluid collects in the air sacs of the lungs, depriving organs of oxygen. Enaside 20/12,5 may cause respiratory problems

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- tell your doctor if you are allergic to sulphonamides or penicillin as this may increase the risk of developing glaucoma.

If you are about to have any of the following procedures, you should tell your doctor who is treating you that you are taking Enaside 20/12,5:

- any surgery or receive anaesthetics (even at the dentist)
- a treatment called LDL apheresis, to remove cholesterol from your blood using a machine

Tell your doctor if you have or will take an anti-doping test since this medication can produce a positive result.

When you first start to take Enaside 20/12,5, your doctor will monitor your blood pressure frequently to ensure you have been given the correct dose. In addition, for some patients the doctor may want to do some tests to measure your potassium, sodium, magnesium, creatinine and liver enzyme levels.

### **Children and adolescents**

Enaside 20/12,5 is not recommended for use in children.

### **Other medicines and Enaside 20/12,5**

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

- an angiotensin II-receptor blocker (ARB) or aliskiren, due to increased risk of serious side effects (see also information under the headings “Do not take Enaside 20/12,5” and “Warnings and precautions”)
- potassium sparing water tablets (diuretics) such as spironolactone, eplerenone, triamterene or amiloride, potassium supplements, potassium-containing salt substitutes or other drugs that may increase potassium in your blood (e.g., heparin [a medicine used to prevent blood clots], trimethoprim-containing products such as cotrimoxazole [medicines used to treat infections])

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- water tablets (diuretics) such as thiazides, furosemide, bumetanide, as they may increase the blood pressure lowering effect.
  - Other medicines that lower blood pressure, such as nitroglycerin, nitrates, and vasodilators
  - lithium, used for the treatment of some psychiatric illnesses (see “Do not take Enaside 20/12,5”, Enaside 20/12,5 may increase the levels of lithium in the blood
  - medicines used for, stiffness and inflammation associated with painful conditions, particularly those affecting your muscles, bones and joints:
    - including gold therapy which can lead to flushing of your face, feeling sick (nausea), vomiting and low blood pressure, when taken with Enaside 20/12,5,
    - and non-steroidal anti-inflammatory drugs (NSAIDs), for example diflunisal or diclofenac. They may prevent your blood pressure from being well controlled and may increase the level of potassium in your blood.
  - tricyclic antidepressants such as amitriptyline, used for depression, antipsychotics such as phenothiazines, used for severe anxiety - these medicines also cause a reduction in blood pressure
  - barbiturates (sedatives used for sleeplessness or epilepsy), pain killers such as morphine or anaesthetics, because your blood pressure may become too low
  - cholestyramine or colestipol (used to help control cholesterol levels), they may reduce the effect of Enaside 20/12,5
  - ACTH (to test whether your adrenal glands are working properly), corticosteroids (used to treat certain conditions such as rheumatism, arthritis, allergic conditions, asthma or certain blood disorders), they may cause dehydration and increased potassium levels
  - allopurinol (used to treat gout), as it may cause a reduction in white blood cells
  - medicines for the treatment of cancer (cyclophosphamide, methotrexate), as their side effects may be increased
  - procainamide, amiodarone or sotalol (used to treat abnormal heart rhythms)

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- digitalis (used to treat heart rhythm problems)
  - carbenoxalone (used to treat stomach ulcers)
  - excessive use of laxatives
  - antidiabetic medicines such as insulin or oral medicines such as metformin, as there may be an increased blood glucose lowering effect and adjustment of the antidiabetic medicine dose might be required
  - an mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus; medicines used to treat certain types of cancer or to prevent the body's immune system from rejecting a transplanted organ). See also information under the heading "Warnings and precautions". These medicines increase the risk of angioedema (painful swelling under the skin)
  - A medicine containing a neprilysin inhibitor such as sacubitril (available as fixed-dose combination with valsartan) and racecadotril. The risk of angioedema (swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) may be increased. See also information under the headings "Do not take Enaside 20/12,5" and "Warnings and precautions".
  - Fluoroquinolones (antibiotics used to treat bacterial infections), as they may damage your kidneys when taken together with Enaside 20/12,5
  - Calcium supplements and/or vitamin D supplements
  - When beta-blockers or diazoxide are taken together with thiazides as in Enaside 20/12,5, the increase in blood sugar levels may be even greater
  - Anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia) such as atropine and biperiden
  - Amantadine (medicine used to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses)
  - Other medicines used to treat high blood pressure, such as methyl dopa

- A medicine called ciclosporin (used in patients after organ transplant surgery or to treat autoimmune disorders such as psoriasis, rheumatoid arthritis, and lupus)

### **Enaside 20/12,5 with food and alcohol**

Enaside 20/12,5 can be taken with or without food. However, if you drink alcohol while taking Enaside 20/12,5, it may cause your blood pressure to drop too much and you may experience dizziness, light-headedness or faintness. You should keep your alcohol intake to a minimum.

### **Pregnancy and breastfeeding**

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.

Patients planning pregnancy should be changed to alternative antihypertensive treatments.

When pregnancy is diagnosed, treatment with Enaside 20/12,5 should be stopped immediately, and, if appropriate, alternative therapy should be started.

Enaside 20/12,5 is contraindicated during pregnancy and breastfeeding.

### **Driving and using machines**

It is not always possible to predict to what extent Enaside 20/12,5 may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which Enaside 20/12,5 affects you. Enaside 20/12,5 can cause dizziness or weariness.

### **Enaside 20/12,5 contains lactose**

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 Enaside 20/12,5**

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

Always take Enaside 20/12,5 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dosage is 1 tablet, administered once daily. If necessary, the dosage may be increased to a maximum of 2 tablets, administered once daily.

Your doctor will tell you how long your treatment with Enaside 20/12,5 will last. If you have the impression that the effect of Enaside 20/12,5 is too strong or too weak, tell your doctor or pharmacist

#### **If you take more Enaside 20/12,5 than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

#### **If you forget to take Enaside 20/12,5**

Skip the missed dose and take the next dose as usual. Do not take a double dose to make up for forgotten individual doses.

#### **If you stop taking Enaside 20/12,5**

Do not stop taking your medicine, unless your doctor tells you to. If you do your blood pressure may increase. If your blood pressure becomes too high, it may affect your heart and kidneys.

### **4. Possible side effects**

Enaside 20/12,5 can have side effects.

Not all side effects reported for Enaside 20/12,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Enaside 20/12,5, please consult your health care provider for advice.

If any of the following happens, stop taking / using Enaside 20/12,5 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
- fainting
- severe skin conditions with reddening, scaling and blistering of the skin (Stevens Johnson syndrome and toxic epidermal necrolysis).

These are all very serious side effects. If you have them, you may have had a serious reaction to Enaside 20/12,5. You may need urgent medical attention or hospitalisation.

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

- liver failure or hepatitis. This may cause yellowing of your skin (jaundice).
- severe dizziness, light-headedness, especially at the start of treatment or when your dose is increased or when you stand up
- extreme thirst, weakness, fatigue, muscle pain and cramps, as you may be dehydrated
- chest pain, changes in heart rhythm (feeling like your heart is racing)

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:*

- depression
- dizziness, headache, syncope, taste alterations
- blurred vision
- chest pain, rhythm disturbances, heart pain, tachycardia, fast heart rate
- cough, difficulty breathing
- nausea, diarrhoea, abdominal pain, vomiting
- weakness, fatigue
- increase in blood sugar levels
- sleep disturbances
- abnormal sensation, typically tingling or pricking ('pins and needles')
- muscle cramps
- impotence, decreased libido

*Less frequent side effects*

- decreased number of red blood cells and low haemoglobin (anaemia) - Symptoms may include fatigue, skin pallor, shortness of breath, light-headedness, dizziness or a fast heartbeat
- signs of infection like fever, fatigue, sore throat may indicate lower white blood cell count
- a sense of heightened awareness or a shaky feeling (caused by low blood sugar)
- confusion, feeling sleepy, difficulty sleeping, feeling nervous, feeling like you are spinning (vertigo), ringing in your ears
- flushing
- runny nose, sore throat and hoarseness, difficulty breathing or asthma
- being sick, indigestion, constipation, not feeling like eating properly (anorexia), stomach irritation, dry mouth, flatulence, gout

- burning, aching pain with an empty feeling and hunger, particularly when the stomach is empty (caused by a peptic ulcer)
- increased sweating, itching, hives (urticaria), hair loss
- protein in your urine (usually detected by a test)
- impotence
- ringing in your ears, feeling lethargic, high temperature
- kidney problems – you may notice a change in urine output, pain, fever

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. 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 Enaside 20/12,5.

### **5. How to store Enaside 20/12,5**

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original container until required for use.

### **6. Contents of the pack and other information**

#### **What Enaside 20/12,5 contains**

- The active substances are enalapril maleate and hydrochlorothiazide. Each tablet contains 20 mg enalapril maleate and 12,5 mg hydrochlorothiazide as active ingredients.

- The other ingredients are lactose monohydrate, pregelatinised starch, maleic acid, iron oxide yellow, dried maize starch and sodium stearyl fumarate.

### **What Enaside 20/12,5 looks like and contents of the pack**

Enaside 20/12,5 are packed into either

- Aluminium / Aluminium Blisters of 10 tablets; the blisters are then packed in an outer carton containing 30 tablets.
- HDPE container as 100 tablets.

### **Holder of Certificate of Registration**

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