PATIENT INFORMATION LEAFLET

Scheduling status

S3

NATRAPRESS 5 mg Tablets

NATRAPRESS 10 mg Tablets

NATRAPRESS 20 mg Tablets

Enalapril maleate

Contains sugar:

NATRAPRESS 5 mg tablets – 128,808 mg lactose monohydrate per tablet

NATRAPRESS 10 mg tablets – 126,07 mg lactose monohydrate per tablet

NATRAPRESS 20 mg tablets – 121,81 mg lactose monohydrate per tablet

Read all of this leaflet carefully before you start taking NATRAPRESS

- 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.
- NATRAPRESS 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 NATRAPRESS is and what it is used for

NATRAPRESS contains enalapril maleate which belongs to the group of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors). This medicine works by widening your blood vessels. This lowers your blood pressure.

NATRAPRESS tablets are used:

- to treat high blood pressure
- to treat heart failure (weakening of heart function)
- to prevent the signs of heart failure (the signs include shortness of breath and swelling of the ankles and feet).

2. What you need to know before you take NATRAPRESS

Do not take NATRAPRESS

- if you are allergic to the active ingredient enalapril maleate or similar medicines (i.e. ACE inhibitors), or to any of the other ingredients in the tablet.
- if you have a history of angioedema (symptoms such as itching, nettle-rash, wheezing or swelling of the hands, throat, mouth or eyelids) related to previous ACE inhibitor therapy.
- if you have suffered from hereditary or angioedema of unknown cause.
- if you have a condition called aortic stenosis (the narrowing of the exit of the left ventricle of the heart).
- if you suffer from hypertrophic cardiomyopathy (a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart) or outflow obstruction.
- if you have severe kidney disease.
- if you have renal artery stenosis (narrowing of the blood vessels) in one or both kidneys.
- if you are taking diuretics (water tablets).
- if you have porphyria.

- if you are on lithium therapy (a medicine used to treat a certain kind of depression).
- if you are pregnant or breastfeeding.
- if you take aliskiren containing medicine (medicine used for high blood pressure).

If any of the above applies to you then you should speak to your doctor.

Warnings and precautions

Take special care with NATRAPRESS

- if you have a heart problem.
- if you have a condition involving the blood vessels in the brain.
- if you have low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- if you have kidney problems, are a dialysis patient, are taking diuretics (water tablets).
- 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, including NATRAPRESS.
- 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). You may be at increased risk for an allergic reaction called angioedema.
- if you are on a salt restriction diet, or have suffered from excessive vomiting or diarrhoea.
- if you have a liver problem.
- 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 blood cells (anaemia).
- 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.

- if you are taking any 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 undergo desensitisation treatment, that is treatment to reduce the effect of an allergy to bee or wasp stings.
- if you are to undergo any surgery or receive anaesthetics (even at the dentist).
- if you are about to have treatment to remove cholesterol from your blood called 'LDL apheresis'.

Routine tests

- When you first start to take NATRAPRESS, 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 and creatinine (a waste product found in urine) or liver enzyme levels.

Other medicines and NATRAPRESS

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

NATRAPRESS may affect or be affected by other medicines, such as:

- an angiotensin II receptor blocker (ARB) or aliskiren, medicines used for high blood pressure.
- other blood pressure lowering medicines, such as beta-blockers as they may additionally reduce your blood pressure.

- diuretics (water tablets) such as thiazides, loop diuretics such as furosemide, bumetanide.
- other antihypertensive medicines, nitroglycerine and other nitrates or other vasodilators; concomitant use with NATRAPRESS may cause hypotension (low blood pressure).
- potassium sparing diuretics (water tablets) such as spironolactone, triamterene or amiloride, potassium supplements, or potassium-containing salt substitutes.
- lithium, a medicine used to treat a certain kind of depression. NATRAPRESS should not be taken with lithium.
- non-steroidal anti-inflammatory medicines (NSAIDs), used to relieve pain, stiffness and inflammation associated with painful conditions, particularly those affecting the muscles, bones and joints. These medicines, taken with NATRAPRESS may prevent your blood pressure from being well controlled and may increase the level of potassium in your blood.
- tricyclic antidepressants, medicines used for depression.
- antipsychotics, medicines used for mental problems.
- certain pain or arthritis medicines including gold therapy.
- an mTOR inhibitor (e.g. temsirolimus, sirolimus, everolimus), a medicine used to treat certain types of cancer or to prevent the body's immune system from rejecting a transplanted organ.
- certain cough and cold medicines and weight reducing medicines which contain something called a 'sympathomimetic agent'.
- oral antidiabetic medicines and insulin to treat diabetes.
- alcohol.

NATRAPRESS with food, drink and alcohol

NATRAPRESS can be taken with or without food.

However, if you drink alcohol while taking NATRAPRESS, it may cause your blood pressure to drop and you may experience dizziness, light-headedness or faintness. You should also keep your alcohol intake to a minimum.

Pregnancy and breastfeeding

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

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will advise you to stop taking NATRAPRESS before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of NATRAPRESS. NATRAPRESS must not be taken during pregnancy.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. Breastfeeding new-born babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking NATRAPRESS.

You must not take NATRAPRESS if you are breastfeeding your infant.

Driving and using machines

Certain side effects that have been reported with NATRAPRESS may affect patients' ability to drive or operate machinery. Dizziness or weariness may occur (see POSSIBLE SIDE EFFECTS).

NATRAPRESS contains lactose.

If you have the rare hereditary conditions of lactose/fructose or galactose intolerance you should not take NATRAPRESS.

3. How to take NATRAPRESS

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

Always take NATRAPRESS exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

The dose is decided by your doctor, depending on your condition and whether you are taking other medicines. It is important to continue taking NATRAPRESS for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

You can take your tablets with or without food. Take NATRAPRESS with a glass of water.

Dosage for high blood pressure

The initial dose is 10 mg per day up to 20 mg per day depending on your blood pressure.

The dosage is adjusted according to the needs of the patient.

Dosage for heart disorders

In patients with heart problems, the initial dose is 2,5 mg and it should be gradually increased, to the usual maintenance dose of 20 mg given in a single dose or two divided doses, over a 2 to 4 week period.

Reduced renal function

In patients with kidney problems, your dose of NATRAPRESS will need to be adjusted depending on how well your kidneys are functioning.

Your doctor will let you know what your dose should be.

If you take more NATRAPRESS than you should

The most common signs and symptoms of overdose are fall in blood pressure and stupor (a state of almost complete lack of consciousness). Other symptoms may include dizziness or light-headedness due to a fall in blood pressure, forceful and rapid heartbeat, rapid pulse, anxiety, cough, kidney failure, and rapid breathing.

In the event of over-dosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take NATRAPRESS

If you have forgotten to take a tablet, you should take the next tablet at the usual time.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking NATRAPRESS

If you stop taking your medicine, your blood pressure may increase. If your blood pressure becomes too high it may affect the function of your heart and kidneys. Do not stop taking your medicine, unless your doctor has advised you to do so.

4. Possible side effects

NATRAPRESS can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

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

- severe dizziness, light-headedness, especially at the start of treatment or when the dose is increased or when you stand up.

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:

- light-headedness due to low blood pressure
- headache, mood alterations, depression
- blurred vision
- heart attack or stroke, rapid forceful heartbeat, chest pain, angina
- dizziness, fainting
- cough, difficult breathing
- nausea, diarrhoea, abdominal pain, changes in taste
- rash, swelling of the face, lips, tongue or throat
- weakness, tiredness
- generally feeling unwell (malaise), high temperature (fever)
- high levels of potassium in the blood, increased levels of creatinine in your blood (both are usually detected by a test)

Less frequent side effects:

- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets
- bone marrow suppression
- anaemia
- swollen glands in neck, armpit or groin
- autoimmune diseases

- low level of blood sugar and sodium
- vertigo (spinning sensation)
- confusion, sleeplessness or sleepiness, nervousness, strange dreams or sleep problems
- ringing in the ears (tinnitus)
- fast or uneven heart beats (palpitations)
- flushing
- 'Raynaud's phenomenon' where your hands and feet may become very cold and white due to low blood flow
- runny, sore nose or stuffiness, sinusitis, sore throat, hoarseness
- asthma-associated tightness in chest
- accumulation of fluid or other substances in the lungs (as seen on X-rays)
- inflammation of your nose
- inflammation of the lungs causing difficulty breathing (pneumonia)
- slow movement of food through your intestine (ileus), inflammation of your pancreas
- being sick (vomiting), indigestion, constipation, anorexia
- irritated stomach (gastric irritations), dry mouth, ulcer
- inflammation of the cheeks, gums, tongue, lips, throat
- liver failure, inflammation of the liver, jaundice (yellowing of the skin and eyes) elevated liver enzymes, and raised levels of bilirubin (measured in a blood test)
- increased sweating, hair loss, itching, nettle-rash or hives, itchy scaly red patches (psoriasis)
- rash that looks like targets (erythema multiforme)
- 'Stevens-Johnson syndrome' and 'toxic epidermal necrolysis' (serious skin conditions where you have reddening and scaling of your skin, blistering or raw sores), exfoliative dermatitis/erythroderma (severe skin rash with flaking or peeling of the skin), pemphigus (small fluid-filled bumps on the skin)
- muscle cramps

- reduced kidney function or kidney failure (symptoms may be lower back pain and reduction in the volume of urine passed), high levels of protein in the urine and high level of blood urea (measured in a blood test), reduced amount of urine
- impotence, enlargement of breasts in males (gynaecomastia).

A complex side effect has also been reported which may include some or all of the following: fever, inflammation of the blood vessels, pain and inflammation of muscles and joints, blood disorders affecting the components of the blood and usually detected by a blood test, rash, hypersensitivity to sunlight and other effects on the skin.

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: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of NATRAPRESS**.**

5. How to store NATRAPRESS

Store all medicines out of reach of children.

Store at or below 25°C, in the original package. Keep blisters in the carton until required for use.

Do not use NATRAPRESS after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 NATRAPRESS contains

The active substance is enalapril maleate.

The other ingredients are corn starch, lactose monohydrate, maleic acid, hydroxypropyl methyl cellulose and zinc stearate.

NATRAPRESS 10 mg contains the colourant ferric oxide red and NATRAPRESS 20 mg contains ferric oxide red and ferric oxide yellow.

What NATRAPRESS looks like and contents of the pack

NATRAPRESS 5 mg: White coloured barrel shaped uncoated tablet debossed with “5” on one side and plain on the other side.

NATRAPRESS 10 mg: Pink coloured barrel shaped uncoated tablet debossed with “10” on one side and plain on the other side.

NATRAPRESS 20 mg: Peach coloured barrel shaped uncoated tablet debossed with “20” on one side and plain on the other side.

The film-coated tablets are packed in Aluminium/Aluminium foil blister strips. The blister strips are packed in cartons containing 28 or 30 tablets.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein, Cape Town

7570

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