PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ACTI-PREX PLUS

4 mg/1,25 mg Perindopril tert-butylamine/Indapamide tablets

Contains sugar (58,47 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking ACTI-PREX PLUS.

- 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.
- ACTI-PREX PLUS 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

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1. What ACTI-PREX PLUS is and what it is used for

ACTI-PREX PLUS is a combination of Perindopril and Indapamide. They are anti-hypertensive medicines, which are used in the treatment of high blood pressure.

Perindopril belongs to a group of medicines called angiotensin-converting enzyme inhibitors (sometimes called ACE inhibitors). ACE inhibitors work by relaxing the blood vessels which makes it easier for the heart to pump blood around the body.

Indapamide belongs to a group of medicines called diuretics. These work by allowing your kidneys to produce more urine than normal.

Each of the individual medicines work together to lower your blood pressure and control it.

2. What you need to know before you take ACTI-PREX PLUS

Do not take ACTI-PREX PLUS:

- if you are hypersensitive (allergic) to perindopril, other ACE inhibitors or to indapamide or any other sulphonomide or any of the other ingredients of ACTI-PREX PLUS listed in section 6.
- if you have kidney problems.
- if you are receiving dialysis or any other type of blood filtration. Depending on the machine being used, ACTI-PREX PLUS might not be suitable for you.
- if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing).
- if you have experienced symptoms such as wheezing, swelling of the face or tongue, intense itching or severe skin rashes with previous ACE-inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema).
- if you have a condition in which your heart muscles are abnormally thick (hypertrophic obstructive cardiomyopathy).
- if you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or renal artery stenosis (narrowing of the artery supplying the kidney with blood).
- if you are taking any of the following medicines:
    - potassium sparing diuretics such as spironolactone, triamterene and amiloride.
    - lithium.

- if you have porphyria. if you have diabetes or impaired kidney function and you are being treated with a blood pressure lowering medicine containing aliskiren.
- if you are being treated with sacubitril/valsartan, a medicine for heart failure (see "Warnings and Precautions" and "Other medicines and ACTI-PLEX PLUS").
- if you take fluoroquinolones (antibiotics).
- if you are pregnant or breastfeeding.
- if you have severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain).
- if you have low blood potassium.

Warnings and precautions

Take special care with ACTI-PREX PLUS:

- if you have any heart or liver or kidney problems.
- if you are taking an angiotensin II receptor blocker (ARBs or also known as sartans) to treat high blood pressure, in particularly if you have diabetic-related kidney problems.
- if you have been taking diuretics (water tablets) for a long time or you have been on a low salt diet.
- if you suffer from a condition known as collagen vascular disease (this is sometimes called connective tissue disease, for example lupus or scleroderma).
- if you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood).
- if you have a history of angioedema (wheezing, swelling of the face or tongue, intense itching or severe skin rashes) with previous ACE-inhibitor treatment.
- if you are on kidney dialysis (some kinds of dialysis membrane may not be suitable).
- if you have abnormal increased levels of a hormone called aldosterone in your blood (primary aldosteronism).

- if you develop a cough. Your doctor may choose another medicine for you.
- if you are elderly.
- if you have atherosclerosis (hardening of the arteries).
- if you suffer from diabetes mellitus.
- if you are of black origin since you may have a higher risk of angioedema and ACTI-PREX PLUS may be less effective in lowering your blood pressure than in non-black patients.
- if you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease).
- if you have had photosensitivity reactions.
- if you suffer from hyperparathyroidism (overactive parathyroid gland).
- if you are an athlete you should be aware that ACTI-PREX PLUS contains an active ingredient called indapamide which may give a positive reaction in drug tests.
- If you have gout.

You should also inform your doctor if you:

- are pregnant or think you might be pregnant and if you are breastfeeding. ACTI-PREX PLUS is contraindicated in pregnancy and should be stopped immediately and if appropriate, alternative therapy should be started.
- have suffered from recent diarrhoea or vomiting or are dehydrated. Your potassium levels should be monitored regularly. You may experience a sudden drop in blood pressure.
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.
- are to undergo LDL apheresis (removal of cholesterol from your blood).
- are to undergo anaesthesia and/or surgery.
- have changes in your vision or pain in one or both or your eyes while taking ACTI-PREX PLUS. This could be a sign that you are developing glaucoma, increased pressure in your eye(s). You should discontinue ACTI-PREX PLUS and seek medical attention.

Children and adolescents

ACTI-PREX PLUS should not be given to children and adolescents.

Other medicines and ACTI-PLEX PLUS:

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

Other medicines can affect the efficacy and safety of ACTI-PREX PLUS. On the other hand, ACTI-PREX PLUS can affect the efficacy and safety of other medicine. Remember to tell your doctor about ACTI-PREX PLUS if you receive another medicine during your treatment or shortly after your treatment with ACTI-PREX PLUS. It is especially important to inform your doctor if you use:

- lithium to treat depression as its use with ACTI-PREX PLUS should be avoided.
- baclofen (to treat your muscle stiffness occurring in diseases such as multiple sclerosis).
- anti-inflammatory pain killers (NSAIDs – e.g. ibuprofen, diclofenac, indomethacin) or high dose salicylates (e.g. aspirin).
- medicines to treat mental illnesses such as depression, anxiety, schizophrenia or other psychoses (e.g. tricyclic antidepressants, neuroleptics).
- any other medicines for treating high blood pressure or heart problems, including angiotensin II receptor blockers (ARB) or aliskiren or diuretics (medicines which increase the amount of urine produces by the kidneys.
- sacubitril/valsartan (used to treat long-term heart failure). See section "Do not take ACTI-PREX PLUS" and "Warnings and Precautions".
- fluoroquinolones (antibiotics).
- estramustine (used in cancer therapy).

- potassium sparing diuretics (spironolactone, triamterene, amiloride), potassium salts, other medicines which can increase potassium in your body (such as heparin and co-trimoxazole, also known as trimethropirm/sulfamethoxazole).
- insulin or any medicine taken by mouth for diabetes, including metformin or gliptins.
- medicines which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTor inhibitors).
- allopurinol (for gout) or procainamide (for irregular heartbeat).
- immunosuppressants (for disorders such as rheumatoid arthritis, or following transplant surgery e.g. ciclosporin), steroid medicine or anticancer medicine.
- corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis.
- injectable gold (used to treat rheumatoid polyarthritis).
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol).
- amphotericin B by injection (to treat severe fungal disease).
- stimulant laxatives (e.g. senna).
- are to undergo a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like kidney or stomach visible on an X-ray).
- other medicines that might cause low potassium levels, e.g., cisapride, diphemanil (used to treat gastric and digestive problems); antibiotics, such as erythromycin, moxifloxacin, sparfloxacin, pentamidine (used to treat pneumonia).

If you need to have an operation, it is important that you tell the surgeon or dentist that you are taking ACTI-PREX PLUS. It may affect the anaesthetic or other treatment used.

Inform you doctor if you are taking any of the above medicine. It may be necessary to adjust the dose.

Pregnancy, breastfeeding 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 professional for advice before taking ACTI-PREX PLUS.

Do not use ACTI-PREX PLUS if you are pregnant or breastfeeding as it is contraindicated.
If you become pregnant while taking ACTI-PREX PLUS, speak to your doctor before taking any more tablets.

Driving and using machines

ACTI-PREX PLUS usually does not affect alertness but different reactions such as dizziness or weakness in relation to the decrease in blood pressure may occur in certain patients. If affected your ability to drive or operate machinery may be impaired.

ACTI-PREX PLUS 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 ACTI-PREX PLUS

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

Always take ACTI-PREX PLUS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

ACTI-PREX PLUS should preferably be taken in the morning before a meal.

The usual dose is one (1) ACTI-PREX PLUS tablet per day as a single dose.

Your doctor will tell you how long your treatment with ACTI-PREX PLUS will last. Do not stop treatment early. If you have the impression that the effect of ACTI-PREX PLUS is too strong or too weak, tell your doctor or pharmacist.

If you take more ACTI-PREX PLUS 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 an overdose has been taken you may experience symptoms such as severely reduced blood pressure associated with nausea, vomiting, cramps, dizziness, sleepiness, mental confusion and a disturbances in the salt balance.

If you forget to take a dose of ACTI-PREX PLUS:

Try to take your medicine at the same time every day. If you have missed a dose of ACTI-PREX PLUS, take it as soon as you remember unless it is nearly time to take your next one. Do not take a double dose to make up for a forgotten individual dose.

If you stop taking ACTI-PREX PLUS:

It is important that you keep taking ACTI-PREX PLUS tablets until your doctor tells you to stop. Do not stop just because you feel better. If you stop taking your ACTI-PREX PLUS, your condition may get worse.

4. Possible side effects

ACTI-PREX PLUS can have side effects.

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

If any of the following happens, stop taking ACTI-PREX PLUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ACTI-PREX PLUS. 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 skin reactions including rash, blistering or detachment of skin (Stevens-Johnson syndrome) or toxic epidermal necrolysis.
- heart problems such as heart attack (symptoms may include chest pain, tightness of the chest, shortness of breath or trouble breathing), chest pain (angina), abnormal heart rhythm, irregular or faster heart rate.
- weakness, loss of coordination or consciousness.
- severe stomach pain which may reach through to your back. This could be a sign of pancreatitis (inflammation of the skin).

- fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of the skin and eyes, also called jaundice. This may be due to inflammation of the liver or changes in the way your liver is working.

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

Tell your doctor if you notice any of the following other frequent side effects associated with the use of ACTI-PREX PLUS:

- dizziness, headache, pins and needles, altered or impaired sense of taste
- vision disturbance
- spinning sensation (vertigo), ringing in the ears (tinnitus)
- low blood pressure
- cough, shortness of breath
- stomach pain, constipation, diarrhoea, indigestion, nausea, vomiting
- itching, rash
- muscle cramps
- weakness

Tell your doctor if you notice any of the following less frequent side effects associated with the use of ACTI-PREX PLUS:

- runny or stuffy nose
- mood and sleep disturbances
- confusion
- excessive sleepiness, loss of consciousness
- palpitations
- dry mouth
- hives
- rash or purple spots under the skin

- excessive sweating
- sensitivity to light
- formation of blisters
- joint pain, muscle pain
- erectile dysfunction
- general discomfort
- swelling of the lower legs and hands
- fever
- fatigue

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. This includes any possible side effects not listed in this leaflet. 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 ACTI-PREX PLUS.

5. How to store ACTI-PREX PLUS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C, protected against moisture.
- Do not remove blisters from the outer carton until required for use.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ACTI-PREX PLUS contains

The active substances are perindopril tert-butylamine and indapamide.

Each ACTI-PREX PLUS tablet contains 4 mg perindopril tert-butylamine and 1,25 mg indapamide.

ACTI-PREX PLUS contains sugar (58,47 mg lactose monohydrate per tablet).

The other ingredients are hydrophobic colloidal silica, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

What ACTI-PREX PLUS looks like and contents of the pack

ACTI-PREX PLUS are white, rod shaped tablets having ‘P I’ debossed on one side and plain on the other.

ACTI-PREX PLUS are packed in a clear PVC film coated with PVDC/Aluminium blister pouch with desiccant.

Blister strips are packed in an outer cardboard box with a leaflet in pack sizes

30’s, 90’s or 100’s.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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