Patient Information Leaflet

Scheduling Status

S3

Proprietary Name, Strength and Pharmaceutical Form

ACTI-PREX™, 4 mg, TABLETS

Perindopril Tert-butylamine

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ACTI-PREX™** 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.

1. WHAT ACTI-PREX™ CONTAINS

The active substance is Perindopril tert-butylamine 4 mg.

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

2. WHAT ACTI-PREX™ ARE USED FOR

Perindopril belongs to a class of medicines known as angiotensin converting enzyme (ACE) inhibitors. This medicine works by causing blood vessels to relax, reducing your blood pressure and making it easier for your heart to pump blood around your body.

Perindopril Tablets are used for the treatment of hypertension (high blood pressure) or symptomatic heart failure (where your heart does not work as it should). It is also used for reducing the risk of further problems in patients who have heart or circulation problems, such as recent heart attack.

3. BEFORE YOU TAKE ACTI-PREX™

Do not take ACTI-PREX™

- If you are allergic (hypersensitive) to perindopril or any of the other ingredients.

- If you have suffered angioedema (swelling of the feet, ankles, hands, face, lips, tongue or throat, difficulty in swallowing or breathing) from taking ACE inhibitors before.
- If you or your family has a history of angioedema (as above).
- Kidney problems.
- If you show hypersensitivity to other sulphonamide-derived medicines.
- Porphyria.
- If you are on lithium therapy.
- If you are pregnant or breastfeeding.

Take special care with ACTI-PREX™ if you:

- have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood).
- have any other heart or liver or kidney problems, or if you are receiving dialysis.
- have a collagen disease such as systemic lupus erythematosus or scleroderma.
- are on a salt restricted diet or use salt substitutes which contain potassium.
- suffer from diabetes which is not well controlled.

You should also inform your doctor if you:

- are pregnant or think you might be pregnant and if you are breastfeeding
- have or have had kidney stones or kidney disease
- are to undergo anaesthesia and/or surgery
- have suffered from recent diarrhoea or vomiting
- 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).

Taking ACTI-PREX™ with food and drink:

ACTI-PREX™ should be taken before food; the tablets should be taken with water. Alcohol with **ACTI-PREX™** should be avoided as it may make you feel dizzy.

Pregnancy and Breastfeeding:

ACTI-PREX™ should not be taken during pregnancy and breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ACTI-PREX™**.

Driving and using machinery:

Your tablets are unlikely to affect your ability to drive a car or to operate machinery. However, you should not drive or operate machinery if you experience any dizziness.

Important information about some of the ingredients of ACTI-PREX™:

This medicine 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.

Taking other medicines with ACTI-PREX™:

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

In particular:

- Diuretics (water tablets), potassium supplements or potassium-containing salt substitutes
- Lithium (for depression)
- Certain painkillers called NSAIDS, including aspirin
- Any other medicines for blood pressure or heart problems
- Insulin or any medicines taken by mouth for diabetes
- Certain medicines for mental illnesses such as depression, anxiety, schizophrenia or other psychoses
- Vasodilators (products to widen blood vessels) including nitrates
- Certain medicines called sympathomimetics that are found in some decongestants, cough/cold remedies and asthma medication
- Immunosuppressants for disorders such as rheumatoid arthritis, or following transplant surgery
- Allopurinol (for gout), procainamide (for irregular heartbeat) heparin (to thin blood)

HOW TO TAKE ACTI-PREX™

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

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

The dose will be different for different medical conditions and patients, and whether you are taking any other medicines. The recommended starting dose is 2 mg or 4 mg given once

daily in the morning. This dose may be increased to 8 mg depending upon your condition and how you respond to treatment.

If you are taking diuretics (water tablets), your doctor may reduce or even discontinue these at the beginning of your treatment with **ACTI-PREX™**.

Your doctor will tell you how long your treatment with **ACTI-PREX™** will last. Do not stop treatment early.

If you have the impression that the effect of **ACTI-PREX™** is too strong or too weak, tell your doctor or pharmacist.

ACTI-PREX™ may be used alone or with other medicines which also lower blood pressure.

ACTI-PREX™ is not recommended for use in children.

If you take more ACTI-PREX™ than you should:
If an overdose has been taken, there may be signs of a drop in blood pressure such as faintness or dizziness. You may also experience long-term effects such as drowsiness, nausea, vomiting or breathlessness. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take with you any remaining tablets and the pack so that the medicine can be identified.

If you forget to take ACTI-PREX™:
Try to take your medicine at the same time every day. If you miss a dose, take it as soon as possible unless it is nearly time to take your next one. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with ACTI-PREX™ is stopped:
Do not stop taking this medicine without first consulting your doctor.

5. POSSIBLE SIDE EFFECTS
ACTI-PREX™ can have side effects:

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

The most frequently reported side effects in adults are

- Cough, shortness of breath
- Light-headedness due to low blood pressure (particularly after the first few doses, if the dose is increased or when water tablets are also taken)
- Headache, dizziness, vertigo, tiredness, pins and needles, muscle cramps, blurred vision, eye pain, tinnitus (noises in the ears)
- Nausea, vomiting, abdominal pain, changes in taste, indigestion, diarrhoea, constipation
- Skin rashes, itching

The less frequently reported side effects are:

- Changes in mood or sleep
- Bronchospasm (tightening of the chest, wheezing and shortness of breath)
- Dry mouth
- Kidney problems
- Impotence
- Sweating
- Angioedema (swelling of the feet, ankles, hands, face, lips, tongue or throat, difficulty in swallowing or breathing). This is a serious reaction which can occur with all ACE inhibitors. It must be treated immediately, usually in hospital
- Confusion
- Irregular heartbeat, angina, heart attack and stroke
- Eosinophilic pneumonia (a type of pneumonia) rhinitis (blocked up or runny nose)
- Pancreatitis (inflammation of the pancreas)
- Hepatitis (inflammation of the liver)
- Erythema multiforme (skin reaction like an allergy)
- Changes in the blood: your doctor may decide to carry out blood tests at intervals to monitor for this

If any of the following happens, stop taking **ACTI-PREX™** 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,

- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ACTI-PREX™**. 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;

- Angina
- Changes in the way your heart beats
- Difficulty breathing

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

Tell your doctor if you notice any of the following:

- Cough
- Headache
- Dizziness
- Tiredness
- Muscle cramps
- Dry mouth
- Impotence

6. STORING AND DISPOSING OF ACTI-PREX™

Store all medicines out of reach of children.
Store at or below 25 °C. Protect against light and moisture.
Keep blister in carton until required for use.
Do not use after the expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. PRESENTATION OF ACTI-PREX™

ACTI-PREX™ tablets are packed in containers with 28, 30 and 500 tablets.
Aluminium/Aluminium blisters containing 30 tablets in a carton.

8. IDENTIFICATION OF ACTI-PREX™

White, oblong tablets scored on both the edges have ‘PP’ debossed on one side and ‘4’ on the other

9. REGISTRATION NUMBER

41/7.1.3/0175

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Activo Health (Pty) Ltd
147 Garsfontein Road
Alphen Park
Pretoria
0081

11. DATE OF PUBLICATION

To be allocated

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