Approved Patient Information Leaflet for Medicines for Human Use:

TENOPRESS 25 mg, 50 mg, 100 mg

SCHEDULING STATUS

S3

TENOPRESS 25 mg film-coated tablets

TENOPRESS 50 mg film-coated tablets

TENOPRESS 100 mg film-coated tablets

Atenolol

Sugar free

TENOPRESS 25 mg:

Each film-coated tablet contains atenolol 25 mg.

TENOPRESS 50 mg:

Each film-coated tablet contains atenolol 50 mg.

TENOPRESS 100 mg:

Each film-coated tablet contains atenolol 100 mg.

Read all of this leaflet carefully before you start taking this medicine

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

2. What you need to know before you take TENOPRESS

3. How to take TENOPRESS

4. Possible side effects

5. How to store TENOPRESS

6. Contents of the pack and other information

1. What TENOPRESS is and what it is used for

TENOPRESS contains a medicine called atenolol. Atenolol belongs to a group of medicines called beta-blockers.

TENOPRESS is used in the management of angina pectoris and hypertension.

2. What you need to know before you take TENOPRESS

Do not take TENOPRESS

- If you are hypersensitive (allergic) to atenolol or any of the other ingredients of TENOPRESS (listed in section 6).
- If you have a condition called cardiogenic shock (a condition where the heart is unable to supply enough blood to the organs of the body).
- If you have ever had any of the following heart problems:
- heart failure which is not under control (this usually makes you breathless and causes your ankles to swell)
- second- or third-degree heart block (a condition which may be treated by a pacemaker)
- very slow or very uneven heart beats, very low blood pressure or very poor circulation.
- If you have a condition called sick sinus syndrome (a group of heart rhythm disorders).
- If you have a tumour called phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure.

- If you have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).
- If you suffer from bronchospasm or asthma or a history of obstructive airways disease.
- If you suffer from heart failure or severe peripheral arterial disease.

Warnings and precautions

Take special care with TENOPRESS:

- You have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.
- You have first-degree heart block.
- You have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster.
- If you are being treated for phaeochromocytoma, your doctor will give you another medicine, called an alphablocker, to take as well as TENOPRESS.
- You have asthma, wheezing or any other similar breathing problems, or you get allergic reactions, for example to insect stings. If you have ever had asthma or wheezing, do not take this medicine without first checking with your doctor.
- You have a type of chest pain (angina) called Prinzmetal's angina.
- You have poor blood circulation or controlled heart failure.
- Severe peripheral vascular disease (circulation disorder) and a condition called peripheral gangrene may be worsened.
- If you are due to have an operation, you should inform your doctor or anaesthetist that you are taking TENOPRESS.
- You have problems with your kidneys. You may need to have some check-ups during your treatment.
- If you use medicines for diabetes, phenothiazines (medicine used to treat mental disorders) and antidysrhythmic agents (medicines used to treat abnormal heart rate), you must tell your doctor.

- If you are using a medicine called clonidine and are being transferred to TENOPRESS. When stopping clonidine, you may experience extreme high blood pressure. Your doctor will monitor this transfer (see “Taking other medicines with TENOPRESS”).
- TENOPRESS will reduce your heart rate, if your pulse drops to less than 50 – 55 beats per minute, your dosage should be reduced.
- If you have a history of severe allergic reactions to any allergens (example insect stings), as TENOPRESS may cause a more severe reaction and you may be unresponsive to usual doses of medicine (adrenaline) used to treat your allergic reaction.
- If you have psoriasis, as TENOPRESS may aggravate your psoriasis (make it worse).
- If you are elderly, as your dosage of TENOPRESS should be reduced. If you are elderly, your doctor will start your treatment with a lesser dose.

Children

TENOPRESS should not be given to children as safety and efficacy has not been established.

Other medicines and TENOPRESS

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

- Anaesthetic medicines (medicines to sedate you during an operation) such as quinidine, procainamide, lignocaine) should be avoided with TENOPRESS (see “Take Special Care with TENOPRESS”).
- Hypoglycaemic agents (oral blood sugar lowering medication or insulin), phenothiazines and Class I antiarrhythmic agents such as disopyramide (used to treat an irregular heartbeat or rapid heartbeat). N.B such medicines can have life threatening consequences (see “Take Special Care with TENOPRESS”).
- Verapamil, diltiazem and nifedipine (for high blood pressure and chest pain).
- Digoxin (heart medication). May cause a decrease in your heartbeat, which can be dangerous. Your doctor should monitor your pulse rate and response regularly.

- Clonidine (for high blood pressure or migraine). If you are taking clonidine and TENOPRESS together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will give you careful instructions about how to do it.
- Medicines called calcium blockers may cause heart failure.
- Medicines called verapamil may cause heart failure.
- Sympathomimetic agents e.g adrenaline or epinephrine may interfere with TENOPRESS.
- Ibuprofen and Indomethacin (medicines used for pain) may interfere with TENOPRESS.
- Oral blood sugar lowering medication or insulin (see “Take Special Care with TENOPRESS”).

Pregnancy and breastfeeding

TENOPRESS should not be taken by pregnant women and women who are breastfeeding.

TENOPRESS is excreted into breastmilk.

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 TENOPRESS.

Driving and using machines

It is unlikely for TENOPRESS to affect your ability to drive and use machinery, however, please make sure how TENOPRESS affects you before driving or using machinery. You must take into account that occasional dizziness or fatigue may occur.

3. How to take TENOPRESS

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

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

Adults:

In the management of hypertension

The usual dose of TENOPRESS tablets is 50 – 100 mg daily, as a single daily dose. Additional doses are unlikely to be of any benefit. TENOPRESS may be combined with diuretics or other antihypertensive agents to achieve a further reduction in blood pressure.

For angina pectoris

The usual dose is 50 – 100 mg daily, given as single or in divided doses.

Elderly:

May have increased or decreased sensitivity to the effects of the usual adult dose and a dose reduction may be necessary.

The usual dose for both indications is 50 mg once daily.

Duration of administration

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

If you take more TENOPRESS than you should

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

If you forget to take TENOPRESS

If you forget to take a dose of the TENPRESS, take it as soon as you remember, unless it is time for your next dose.

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

4. Possible side effects

TENOPRESS can have side effects.

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

If any of the following happens, stop taking TENOPRESS 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.
- Yellowing of the skin and eyes, also called jaundice.

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

- Chest pain
- Angina
- Changes in the way your heart beats, for example, if you notice it beating faster
- Difficulty breathing

Tell your doctor if you notice any of the following:

Frequent side effects:

- Unusual tiredness or weakness.
- Nausea or vomiting.
- An upset stomach or stomach pain.
- Cold hands and feet.
- Low blood pressure (dizziness, tiredness).

- Slow heartbeat.

Less frequent side effects:

- Depressive mood, confusion, psychoses and hallucinations, mood changes, nightmares and sleep disturbances.
- Dizziness, headache and tingling of your hands.
- Hearing loss.
- Skin rash.
- Low blood sugar levels.
- Fluid retention and mass gain.
- Hair loss.
- Dry eyes and vision disturbances.
- Being unable to get an erection (impotence).
- Muscle weakness.
- Difficulty breathing if you are suffering from asthma or a lung disease.
- Reduced number of platelets in your blood (this may make you bruise more easily).
- Purplish marks on your skin.
- Heart failure deterioration, worsening of heart block.
- Raynaud's phenomenon (temporary discoloration of the skin and numbness of the fingers or toes).
- Low blood pressure (dizziness, tiredness).
- Dry mouth, constipation.
- Changes to some of the cells or other parts of your blood. Your doctor may do blood tests to check if TENOPRESS has had any effect on your blood.

Side effects with frequency unknown:

- Constipation

- Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints).

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 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 TENOPRESS**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store TENOPRESS

Store all medicines out of reach of children

Keep this medicine in a dry place at or below 25 °C.

Protect from light.

Keep blister packs in carton until required for use.

Keep the container tightly closed.

DO NOT USE AFTER THE DATE, WHICH IS STAMPED ON THE PACK.

6. Contents of the pack and other information

What TENOPRESS contains

- The active substance is atenolol.
- The other ingredients are magnesium carbonate, sodium starch glycollate, sodium lauryl sulphate, colloidal silicon dioxide, maize starch, magnesium stearate, hypromellose, titanium dioxide, purified talc, polyethylene glycol 6000 and colour sunset yellow (E11).

TENOPRESS 25 mg:

Orange, circular, biconvex film-coated tablet with T-25 embossing on one side.

TENOPRESS 50 mg:

Orange, circular, biconvex film-coated tablets with T-50 embossing on one side and a non-functional break line on the other side.

TENOPRESS 100 mg:

Orange, circular, biconvex film-coated tablets with T-100 embossing on one side.

What TENOPRESS looks like and contents of the pack

TENOPRESS is available in Blister packs of Clear PVDC coated PVC film and Aluminium foil, in pack sizes of 3 x 10's or 2 x 14's.

TENOPRESS is also available in Bulk packs of HDPE containers in pack sizes of 250 tablets (25 mg and 50 mg strengths) and 100 and 500 tablets (100 mg strength).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

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