

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

TENORETIC® (100 mg Tablet)

TENORET® 50 (50 mg Tablet)

The active substances are atenolol and chlorthalidone

Read all of this leaflet carefully before you start taking TENORETIC/TENORET 50

- 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.
- TENORETIC/TENORET 50 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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2. What you need to know before you take TENORETIC/TENORET 50
3. How to take TENORETIC/TENORET 50
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1. What TENORETIC/TENORET 50 is and what it is used for

TENORETIC/TENORET 50 tablets are used to treat high blood pressure.

TENORETIC/TENORET 50 tablets contain 2 active ingredients. Atenolol is a beta-blocker which has effects on your heart and circulation. Chlorthalidone is a diuretic which has blood pressure lowering activities.

2. What you need to know before you take TENORETIC/TENORET 50

Do not take TENORETIC/TENORET 50:

- if you are allergic to atenolol or chlorthalidone or any of the other ingredients of TENORETIC/TENORET 50 tablets.
- if you have or have suffered from any heart conditions including heart failure or heart block.
- if you have or have suffered from a very slow heart rate or very irregular heartbeat, very low blood pressure or very poor circulation.
- if you have ever been told that you have phaeochromocytoma.
- if you have not been eating for a long time.

TENORETIC/TENORET 50 tablets must not be given to children.

The tablets are only for you and must never be given to anyone else.

If you are not sure whether you should start taking TENORETIC/TENORET 50 tablets, contact your doctor.

Warnings and precautions

Take special care with TENORETIC/TENORET 50 tablets:

- if you have any health problems, such as asthma or breathlessness, diabetes, circulation disorders, gout, heart problems, or problems with your kidneys or thyroid.
- if you have ever been told that you suffer from a particular type of chest pain (angina), called Prinzmetal's angina.
- if you have ever had an allergic reaction to anything such as an insect bite/sting.

You may notice that your pulse rate becomes slower while taking the tablets. This is to be expected, but if you are concerned, please tell your doctor about it.

If you have diabetes, TENORETIC/TENORET 50 tablets may alter your response to insulin or other anti-diabetic treatments. It may also modify your normal response to low blood sugar, which usually involves an increase in heart rate and the production of sugar in your body.

If you go into hospital, let the medical staff know, and in particular let the anaesthetist know (if you are having an operation) that you are taking TENORETIC/TENORET 50 tablets.

If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking TENORETIC/TENORET 50. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this.

Only stop taking your tablets if your doctor tells you and then only do so gradually.

Other medicines and TENORETIC/TENORET 50

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of TENORETIC/TENORET 50 tablets with these medicines may cause undesirable interactions. This also applies to medicines used some time ago. Please consult your doctor, pharmacist or other health care professional, for advice.

In particular, tell you doctor if you are taking:

- Disopyramide or amiodarone (for irregular heart beat).
- Other treatments for hypertension or angina (in particular verapamil, diltiazem, nifedipine, clonidine). If you are taking clonidine for hypertension or to prevent migraine, do not stop taking either your clonidine or TENORETIC/TENORET 50 tablets without consulting your doctor.
- Treatment for heart failure (digoxin).
- Lithium (for certain psychiatric disturbances).
- Non-steroidal anti-inflammatory medicines (NSAIDs) for pain relief (such as indomethacin or ibuprofen).
- Any nasal decongestant or other cold remedies, which you may well have bought from a pharmacy.

Pregnancy and breastfeeding

Before taking TENORETIC/TENORET 50 tablets, tell your doctor if you are pregnant or trying to become pregnant.

Before taking TENORETIC/TENORET 50 tablets, tell your doctor if you are breast-feeding.

If you are pregnant or breast-feeding your baby while taking TENORETIC/TENORET 50, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machines

TENORETIC/TENORET 50 is unlikely to adversely affect your ability to drive a car or to operate machinery. However, some patients may occasionally experience dizziness and fatigue when taking TENORETIC/TENORET 50 tablets and should not drive a car or operate machinery if experiencing these effects.

3. How to take TENORETIC/TENORET 50

Do not share medicines prescribed for you with others.

- Follow your doctor's instructions about when and how to take your tablets. Please READ THE LABEL on the container. Ask your doctor or pharmacist if you are not sure.
- The usual dose is 1 tablet daily.
- Swallow the tablet whole with a drink of water.
- Try to take your tablet at the same time each day.
- Do not stop taking your tablets even if you are feeling well, unless your doctor tells you. Then only do so gradually.

If you have the impression that the effect of TENORETIC/TENORET 50 tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more TENORETIC/TENORET 50 than you should

If you have taken more TENORETIC/TENORET 50 tablets than you should, talk to your doctor or pharmacist immediately.

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

If you forget to take TENORETIC/TENORET 50

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

4. Possible side effects

TENORETIC/TENORET 50 tablets can have side effects.

Not all side effects reported for TENORETIC/TENORET 50 are included in this leaflet. Should your general health worsen while taking TENORETIC/TENORET 50, please consult your doctor, pharmacist or other health care professional for advice.

Frequent side effects that may occur:

- Cold fingers and toes
- The heart beating more slowly
- Diarrhoea
- Nausea
- Tiredness
- Low levels of sodium in the blood, which may cause weakness, vomiting and cramps

Less frequent side effects that may occur:

- Disturbed sleep
- Heart block (which may cause an abnormal heart beat, dizziness, tiredness or fainting)
- Worsening of your blood circulation if you already suffer from poor circulation
- Numbness and spasm in the fingers which is followed by warmth and pain (Raynaud's phenomenon)
- Breathlessness and/or swollen ankles, if you also have heart failure
- Dizziness, particularly when standing up
- Headache
- Confusion
- Mental changes or disturbances of the mind
- Mood changes

- Dry mouth
- Hair loss
- Dry eyes
- Skin rash, including worsening of psoriasis
- Tingling of the hands
- Worsening of breathing difficulties, if you have or have had asthma or chronic bronchitis
- Disturbance of vision
- Thrombocytopenia (bruising more easily)
- Purpura (purple spots on the skin)
- Impotence
- Jaundice (which you may notice as yellow colouring of your skin and eyes)
- Pancreatitis (inflammation)

Not known (frequency cannot be estimated from the available data):

Decrease in vision or pain in your eyes due to high pressure [possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma]

Tell your doctor or pharmacist if you think you have any of these or any other problems with your tablets.

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: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TENORETIC/TENORET 50.

5. How to store TENORETIC/TENORET 50

Store all medicines out of reach of children.

Store at or below 25 °C

Store your tablets protected from light and moisture.

Keep your tablets in the container they came in.

Do not take your tablets after the expiry date on the container. Dispose of them in an appropriate way.

6. Contents of the pack and other information

What TENORETIC/TENORET 50 contains

TENORETIC:

Each tablet contains 100 mg atenolol and 25 mg chlorthalidone.

TENORET 50:

Each tablet contains 50 mg atenolol and 12,5 mg chlorthalidone.

The other ingredients are gelatin, glycerol, magnesium carbonate heavy, magnesium stearate, maize starch, hypromellose, sodium lauryl sulphate, titanium dioxide.

What TENORETIC/TENORET 50 looks like and contents of the pack

TENORETIC:

White, round, biconvex, film-coated tablets which are intagliated with 100 25 on one face and bisected on the reverse face.

TENORET 50:

White, round, biconvex, film-coated tablets which are intagliated with 50 12.5 on one face and bisected on the reverse face.

TENORETIC/TENORET 50:

Blister packs of 30 tablets.

Holder of Certificate of Registration

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