

Package Leaflet: Information for the User
Tenoretic® 100 mg/25 mg film-coated tablets
(atenolol/chlortalidone)

Your medicine is known by the above name, but will be referred to as Tenoretic® throughout this leaflet

This medicine is also available in another strength.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tenoretic® is and what it is used for
2. What you need to know before you take Tenoretic®
3. How to take Tenoretic®
4. Possible side effects
5. How to store Tenoretic®
6. Contents of pack and other information

1. WHAT TENORETIC® IS AND WHAT IT IS USED FOR

Tenoretic® is used to treat high blood pressure (hypertension). It contains two different medicines: atenolol and chlortalidone. These medicines work together to lower your blood pressure.

- Atenolol belongs to a group of medicines called beta-blockers. It works by making your heart beat more slowly and with less force.
- Chlortalidone belongs to a group of medicines called diuretics. It works by increasing the amount of urine produced by your kidneys.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TENORETIC®

Do not take Tenoretic®:

- If you are allergic to Tenoretic®, Tenoret, Tenormin, atenolol, chlortalidone or any of the other ingredients of this medicine (listed in section 6).
- 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 problems with your kidneys.
- 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 are pregnant, are trying to become pregnant or are breast-feeding.

Do not take Tenoretic® if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tenoretic®.

Warning and precautions

Talk to your doctor or pharmacist before taking Tenoretic®:

- **If 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.**
- If you have a type of chest pain (angina) called Prinzmetal's angina.
- If you have poor blood circulation or controlled heart failure.
- If you have first-degree heart block.
- If you have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster.
- If you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.
- If you have problems with your adrenal glands.
- If you have liver problems.

- 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 a week of taking Tenoretic®. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Tenoretic®.

Children

This medicine is not for use in children.

Other medicines and Tenoretic®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Tenoretic® can affect the way some other medicines work and some medicines can have an effect on Tenoretic®.

In particular, tell your doctor if you are taking any of the following medicines:

- Clonidine (for high blood pressure or migraine). If you are taking clonidine and Tenoretic® 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.
- Verapamil, diltiazem and nifedipine (for high blood pressure or chest pain).
- Disopyramide or amiodarone (for an uneven heart beat).
- Digoxin (for heart problems).
- Adrenaline, also known as epinephrine (a medicine that stimulates the heart).
- Baclofen (a medicine used for muscle relaxation).
- Ibuprofen or indometacin (for pain and inflammation).
- Insulin or medicines that you take by mouth for diabetes.
- Lithium (for certain mental illnesses).
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Betaxolol, carteolol, levobunolol and timolol (eye drops for glaucoma).

Operations

If you go into hospital to have an operation, tell the anaesthetist or medical staff that you are taking Tenoretic®. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Tenoretic®.

Pregnancy and breast-feeding

- Do not take Tenoretic® if you are pregnant or trying to get pregnant, ask your doctor for advice before using this medicine.
- Do not take Tenoretic® if you are breast-feeding, ask your doctor for advice before using this medicine.

Driving and using machines

- Your medicine is not likely to affect you being able to drive or use any tools or machines. However, it is best to wait to see how your medicine affects you before trying these activities.
- If you feel dizzy or tired when taking this medicine, ask your doctor for advice.

Tenoretic® contains sodium laurilsulfate

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that it is to say essentially 'sodium-free'.

3. HOW TO TAKE TENORETIC®

The score line is not intended for breaking the tablet.

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

- Your doctor will tell you how many tablets to take each day and when to take them. Read the label on the carton to remind you what the doctor said.
- Swallow your Tenoretic® tablet with a drink of water.

Adults

The recommended dose for an adult is one tablet each day.

Children

Your medicine must not be given to children.

If you take more Tenoretic® than you should

If you take more Tenoretic® than prescribed by your doctor, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so that the tablets can be identified.

If you forget to take Tenoretic®

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tenoretic®

Do not stop taking Tenoretic® without talking to your doctor. In some cases, you may need to stop taking it gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tenoretic® can cause side effects, although not everybody gets them.

Allergic reactions:

If you have an allergic reaction, see a doctor straight away. The signs may include raised lumps on your skin (weals) or swelling of your face, lips, mouth, tongue or throat.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Cold hands and feet.
- You may notice that your pulse rate becomes slower while you are taking the tablets. This is normal, but if you are concerned please tell your doctor about it.
- Diarrhoea.
- Feeling sick (nausea).
- Feeling tired.
- Changes in the amount of certain substances in your blood.

It can cause:

- higher levels of sugar (glucose) than normal,
- low levels of sodium, which may cause weakness, being sick (vomiting) and cramps,
- low levels of potassium,
- an increase in the amount of uric acid.

Your doctor may take blood samples every so often to check on these levels.

Uncommon (may affect up to 1 in 100 people)

- Disturbed sleep.

Rare (may affect up to 1 in 1,000 people)

- Heart block (which can cause an abnormal heart beat, dizziness, tiredness or fainting).
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease).
- Dizziness (particularly when standing up).
- Headache.
- Feeling confused.
- Changes in personality (psychoses) or hallucinations.
- Mood changes.
- Nightmares.
- Dry mouth.
- Thinning of your hair.
- Dry eyes.
- Skin rash.
- Tingling of your hands.
- Disturbances of vision.
- Bruising more easily or purplish marks on your skin.
- Being unable to get an erection (impotence).
- Jaundice (causing yellowing of your skin or the whites of your eyes).
- Pancreatitis (inflammation of a large gland behind the stomach).
- A reduced number of white blood cells.

Very rare (may affect up to 1 in 10,000 people)

- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether Tenoretic® has had any effect on your blood.

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

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

- 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).
- Depression.

Conditions that may get worse

If you have any of the following conditions, they may get worse when you start to take your medicine.

This happens rarely affecting less than 1 in 1,000 people:

- Psoriasis (a skin condition).
- Being short of breath or having swollen ankles (if you have heart failure).
- Asthma or breathing problems.
- Poor circulation.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TENORETIC®

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Keep the blister in the outer carton in order to protect from light and moisture.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tenoretic® contains

The active substances are atenolol and chlortalidone. Each tablet contains 100 mg of atenolol and 25 mg of chlortalidone.

The other ingredients are: heavy magnesium carbonate, maize starch, sodium lauryl sulphate, gelatin, magnesium stearate, hypromellose, glycerol 85%, titanium dioxide.

What Tenoretic® looks like and contents of the pack

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

Tenoretic® are packaged in aluminium/plastic calendar blister packs of 28 tablets.

Manufactured by AstraZeneca UK Ltd., Macclesfield, Cheshire, UK.

or

AstraZeneca AB, PET Packaging, Gartnavagen, Sodertalje, 151 85, Sweden.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

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Tel: 020 8896 9054 for help.
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