

PACKAGE LEAFLET: INFORMATION FOR THE USER
Tenoretic 100mg/25mg Film-coated Tablets
(atenolol 100mg, chlortalidone 25mg)

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Tenoretic 100mg/25mg film-coated tablets, but it will be referred to as Tenoretic throughout the remainder of this leaflet.

In this leaflet:

1. What Tenoretic is and what it is used for
2. Before you take Tenoretic
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4. Possible side effects
5. How to store Tenoretic
6. Further 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. Before you take Tenoretic

Do not take Tenoretic if:

- You are allergic (hypersensitive) to Tenoretic, Tenoret, Tenormin, atenolol, or chlortalidone.
- You are allergic to any of the other ingredients in your medicine (see Section 6: 'Further information').
- 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.
- You have a tumour called phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure.
- You have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).
- You have problems with your kidneys.
- You have not been eating much recently.
- 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.

Take special care with Tenoretic

Check with 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.**
- You have low levels of potassium in your blood (hypokalaemia), which may cause muscle weakness, thirst or 'pins and needles'.
- You have low levels of sodium in your blood (hyponatraemia), which may cause weakness, being sick (vomiting) and cramps.
- You have gout.
- You have a type of chest pain (angina) called Prinzmetal's angina.
- You have poor blood circulation or controlled heart failure.
- You have first-degree heart block.
- You have diabetes. Your medicine may change how you respond to having low blood sugar. This medicine may prevent or diminish the increase in heart rate that may alert you of a hypoglycaemic attack (low blood sugar).
- You have thyroid problems.

- You have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.
- You have problems with your adrenal glands.
- You have liver problems.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, 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, noradrenaline also known as norepinephrine and isoprenaline (medicines that stimulate the heart).
- Baclofen (a medicine used for muscle relaxation).
- Ibuprofen or indometacin (for pain and inflammation).
- Insulin or other medicines for diabetes.
- Lithium (for certain mental illnesses).
- Resperine (for high blood pressure).
- Guanethidine (for high blood pressure).
- Cimetidine (for stomach problems).
- 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.
- Do not take Tenoretic if you are breast-feeding.

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, do not drive or use any tools or machines.

Important information about some of the ingredients of Tenoretic

Tenoretic contains glycerol which may cause headache, stomach upset or diarrhoea.

3. How to take Tenoretic

Always take Tenoretic exactly as your doctor has told you. You should 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 whole with a drink of water.
- Try to take your tablets at the same time each day.

Adults

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

People with kidney problems

If you have severe problems with your kidneys, you should not take this medicine, if you are unsure discuss with your doctor.

Children and adolescents

Your medicine must not be given to children and adolescents up to 18 years.

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.

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.

The following side effects may happen with this medicine:

Common (affects less than 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.
- May affect the amount of certain substances in your blood. It can cause the following:
 - reduced numbers of white blood cells,
 - 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 (affects less than 1 in 100 people)

- Disturbed sleep.
- Blood tests showing higher levels of liver enzymes.

Rare (affects less than 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).

Very rare (affects less than 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.
- Blood tests may show increased levels of antibodies.

Not known (cannot be estimated from available data)

- Constipation.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: medsafety@hpra.ie

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 reach and sight of children.
- Do not store above 25°C. Store your tablets in the original package. Keep the blister strip in the carton. This will protect your medicine from light and moisture.
- Do not use after the expiry (Exp) date shown on the carton and blister. The date refers to the last day of that month

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. Further information

What Tenoretic 100 mg/25 mg Film-coated Tablets contain

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

The other ingredients are gelatin, iron oxide, macrogol, magnesium carbonate, magnesium stearate, maize starch, methylhydroxypropylcellulose and sodium laurilsulfate.

What Tenoretic 100 mg/25 mg Film-coated Tablets look like and contents of the pack

Tenoretic 100 mg/25 mg Film-coated Tablets are round, brown, film-coated tablets, imprinted TENORETIC on one side and AstraZeneca logo on the reverse side.

They come in a calendar blister strips (box of 28 tablets) in an over-labelled outer carton.

The tablets are marketed in the UK under the name 'Tenoretic Film-coated tablets'. The Tenoretic tablets that are already available in the Irish market are white in colour.

Manufactured by: AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

Procured from within the EU and repackaged by PPA Holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

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Tenoretic is a trade mark of the AstraZeneca group of companies.

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