

PACKAGE LEAFLET: INFORMATION FOR THE USER
Tenoret 50mg/12.5mg Film-coated Tablets
(atenolol 50mg, chlortalidone 12.5mg)

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 Tenoret 50mg/12.5mg film-coated tablets, but it will be referred to as Tenoret throughout the remainder of this leaflet.

In this leaflet:

1. What Tenoret is and what it is used for
2. Before you take Tenoret
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4. Possible side effects
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1. What Tenoret is and what it is used for

Tenoret 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.

Tenoret is half the strength of another medicine called Tenoretic. Tenoret may also be called 'Half Strength Tenoretic'.

2. Before you take Tenoret

Do not take Tenoret if:

- You are allergic (hypersensitive) to Tenoret, Tenoretic, 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 Tenoret if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tenoret.

Take special care with Tenoret

- Check with your doctor or pharmacist before taking Tenoret 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 Tenoret.

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 Tenoret can affect the way some other medicines work and some medicines can have an effect on Tenoret.

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 Tenoret 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).
- Reserpine (for high blood pressure).
- Guanethidine (for high blood pressure).
- 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 Tenoret. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Tenoret.

Pregnancy and breast-feeding

- Do not take Tenoret if you are pregnant or trying to get pregnant.
- Do not take Tenoret 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 Tenoret

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

3. How to take Tenoret

- Always take Tenoret 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 cartons to remind you what the doctor said.
 - Swallow your Tenoret 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 Tenoret than you should

If you take more Tenoret 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 Tenoret

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 Tenoret

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

4. Possible side effects

Like all medicines, Tenoret 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 Tenoret 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 HPRA 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 Tenoret

- 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 Tenoret 50 Film-coated Tablets contain

The active substances are atenolol and chlortalidone. Each tablet contains 50mg (milligrams) of atenolol and 12.5mg of chlortalidone. The other ingredients are gelatin, iron oxide, magnesium carbonate, magnesium stearate, methylhydroxypropylcellulose, sodium laurilsulfate and maize starch.

What Tenoret 50 Film-coated Tablets look like and contents of the pack

Tenoret 50 tablets are brown. They have the name Tenoret 50 on one face and AstraZeneca logo on the other. They come in a pack (blister strip) containing 28 tablets in an over-labelled outer carton.

The tablets are marketed in the UK under the name ‘Tenoret 50 Film-coated tablets’. The Tenoret 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.

**TENORET FILM-COATED TABLETS
PPA: 1328/108/1**

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

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