

Package leaflet: Information for the patient
Tenoret 50 mg/12.5 mg Film-coated Tablets
atenolol 50 mg, chlortalidone 12.5 mg

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

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2. What you need to know before you take Tenoret
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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. What you need to know before you take Tenoret

Do not take Tenoret if:

- if you are allergic to atenolol or 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 a tumour called pheochromocytoma 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 have problems with your kidneys.
- if you have not been eating much recently.
- if 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.

Warnings and precautions

Talk to 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.**
- if you have low levels of potassium in your blood (hypokalaemia), which may cause muscle weakness, thirst or 'pins and needles'.
- if you have low levels of sodium in your blood (hyponatraemia), which may cause weakness, being sick (vomiting) and cramps.
- if you have gout.
- 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. This medicine may prevent or diminish the increase in heart rate that may alert you to a hypoglycaemic attack (low blood sugar).
- if you have thyroid problems.
- 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 are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Tenoret.

Children and adolescents

This medicine is not for use in children and adolescents up to 18 years.

Other medicines and Tenoret

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 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 and fertility

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking 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, do not drive or use any tools or machines.

Tenoret contains glycerol

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

3. How to take Tenoret

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 Tenoret tablet whole with a drink of water.

Try to take your tablet at the same time each day.

Adults

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

Renal impairment

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

Use in 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.

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

4. Possible side effects

Like all medicines, this medicine 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 (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.
- 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 (may affect up to 1 in 100 people)

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

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).

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 Tenoret has had any effect on your blood.
- Blood tests may show increased levels of antibodies.

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).

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:

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 this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package. Keep the blister strip in the outer carton in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the blister strip and carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information**What Tenoret contains**

- the active substances are atenolol and chlortalidone. Each tablet contains 50 mg (milligrams) of atenolol and 12.5 mg of chlortalidone.
- the other ingredients are gelatin, glycerol, heavy magnesium carbonate, magnesium stearate, maize starch, hypromellose, sodium laurilsulfate and titanium dioxide.

What Tenoret look like and contents of the pack

Tenoret 50 mg/12.5 mg Film-coated Tablets are white. They have the name Tenoret 50 on one side. They come in a pack (blister strip) containing 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

AstraZeneca AB

SE-151 85

Södertälje

Sweden

Manufacturer

AstraZeneca AB

Gärtunavägen

SE-151 85 Södertälje

Sweden

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