

Package leaflet: Information for the patient

Atenetic 50mg/12.5mg & 100mg/25mg Film-coated Tablets atenolol & chlortalidone

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 Atenetic is and what it is used for
2. What you need to know before you take Atenetic
3. How to take Atenetic
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6. Contents of the pack and other information.

1. What Atenetic is and what it is used for

Atenetic is used to treat high blood pressure. Atenetic tablets contain a combination of two active medicines, atenolol and chlortalidone. These medicines work together to lower your blood pressure. You have been prescribed this medicine because your blood pressure was not being adequately controlled using atenolol or chlortalidone alone.

Atenolol belongs to a class of medicines called selective beta-blockers. It works by making your heart beats more slowly and with less force. Chlortalidone belongs to the class of drugs called diuretics. It works by increasing the amount of urine produced by your kidney.

2. What you need to know before you take Atenetic

Do not take Atenetic if:

- you are allergic to atenolol or chlortalidone or any of the other ingredients of this medicine (listed in section 6).
- you suffer or have ever had any of the following heart problems:
 - an abnormally slow or uneven heart beat (Bradycardia)
 - you have a condition known as heart block (2nd or 3rd degree heart block). A condition which may be treated by a pacemaker.
 - heart failure which is not under control
 - very low blood pressure or very poor circulation
- you have a higher than normal level of acid in your blood (Metabolic acidosis)
- you suffer from severe kidney failure
- you are pregnant, are trying to become pregnant or are breast-feeding
- you have an untreated tumour of the adrenal glands called pheochromocytoma, causing high blood pressure

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Atenetic if:

- **you suffer from lung diseases and 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 suffer from diabetes or low blood sugar. 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 controlled heart failure or problems with blood circulation
- you have first-degree heart block
- you have a type of chest pain called Prinzmetal's angina
- you suffer from liver or kidney disease
- you suffer from gout.
- 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 any thyroid problems, including thyrotoxicosis (overactive thyroid gland). This medicine may hide the symptoms of thyrotoxicosis
- you have problems with your adrenal glands
- 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 Atenetic. 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 applies to you, talk to your doctor or pharmacist before taking Atenetic.

Other medicines and Atenetic

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

You must tell your doctor or pharmacist if you are taking any of the following:

- Disopyramide or amiodarone (used to treat uneven heart rhythm)
- Verapamil, diltiazem and nifedipine (to treat high blood pressure, angina or irregular heart rhythm)
- Clonidine (to treat high blood pressure or prevent migraine). If you are taking clonidine and Atenetic 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
- Noradrenaline or adrenaline, also known as epinephrine, norepinephrine and isoprenaline (a medicine that stimulates the heart)
- Digoxin (for heart failure or abnormal rhythm)
- Lithium (for psychiatric disorders)
- Baclofen (used for muscle relaxation)
- Medicines used to treat pain and inflammation e.g. ibuprofen or indometacin

- Guanethidine or reserpine (for high blood pressure)
- Reserpine (for high blood pressure)
- Betaxolol, carteolol, levobunolol and timolol (eye drops for glaucoma)
- Insulin or other medicine for diabetes

Operations

If you are going to have an operation and getting a general anaesthetic, inform your doctor or anaesthetist that you are taking Atenetic. You can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Atenetic.

Children and adolescents

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

Pregnancy and breast-feeding:

Do not take Atenetic if you are pregnant or breastfeeding.

If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

Driving and using machines:

Atenetic is not likely to affect your ability 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 while taking this medicine, do not drive or use machines.

Atenetic contains sodium

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

3. How to take Atenetic Film-coated tablets

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. Swallow your tablet whole with a drink of water. Try to take your tablet at the same time each day.

Adults: The recommended dose is one 50mg/12.5mg tablet daily. Your doctor may prescribe a higher strength of Atenetic 100mg/25mg if your blood pressure is not adequately controlled.

Use in children and adolescents: Atenetic is not recommended for children and adolescents under 18 years old.

Patients with kidney problems: Your doctor may prescribe you with a lower dose. Atenetic is not recommended for patients with severe kidney problems.

If you take more Atenetic than you should

If you take more Atenetic 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 Atenetic

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

If you stop taking Atenetic

Do not stop taking Atenetic 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.

Stop treatment and contact a doctor immediately if you experience any of the following side effects:

- **Allergic reaction** e.g. itchy skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

The following rare side effects (may affect up to 1 in 1,000 people):

- Heart block (which can cause an abnormal heart beat, dizziness, tiredness or fainting)
- Worsening of heart failure (being short of breath or having swollen ankles)
- Pancreatitis (inflammation of a large gland behind the stomach)
- Liver toxicity (Jaundice) including abnormal collection of bile within the liver, causing yellowing of your skin and the whites of your eyes

The following conditions may get worse (may affect less than 1 in 1,000 people):

- Psoriasis (a skin condition)
- Asthma or breathing problems
- Poor circulation

Other side effects are:

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 this medicine. 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:
 - 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)

- Tingling or “pins and needles” in your hands or limbs
- Numbness and spasm in your fingers which follow by warmth and pain (Raynaud’s disease)
- Dizziness, particularly when standing up
- Headache
- Feeling confused
- Changes in personality (psychoses)
- Hallucinations (seeing or hearing things that are not there)
- Mood changes
- Nightmares
- Dry mouth
- Thinning or loss of hair
- Dry eyes
- Skin rash
- Disturbances of vision
- Bruising or bleeding more easily or purplish marks on your skin
- Being unable to get an erection (impotence)

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

- Blood test may show increased levels of antibodies
- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether Atenetic 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)

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, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atenetic

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

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

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

6. Contents of the pack and other information

What Atenetic Film-coated tablets contain:

There are two strengths of Atenetic Film-coated tablets available, 50 mg/12.5 mg and 100 mg/25 mg.

One tablet of Atenetic 50 mg/12.5 mg Film-coated tablets contains the active substances 50 mg of atenolol and 12.5 mg of chlortalidone, whilst one tablet of Atenetic contains the active substances 100 mg/25 mg Film-coated tablets contains 100 mg of atenolol and 25 mg of chlortalidone.

The other ingredients are: magnesium carbonate, sodium laurilsulfate, povidone, pregelatinised maize starch, maize starch, stearic acid, magnesium stearate, sodium starch glycolate, The tablet coating contains: hypromellose, macrogol 400, titanium dioxide (E171) and talc.

What Atenetic Film-coated tablets look like and contents of the pack:

Atenetic Film-coated tablets 50 mg/12.5 mg are white, film-coated, tablets with two sides that curve out, embossed with "AC 62" on one side and "G" on the reverse.

Atenetic Film-coated tablets 100 mg/25 mg are white, film-coated, tablets with two sides that curve out, embossed with "AC 125" on one side and "G" on the reverse.

Atenetic Film-coated tablets 50 mg/12.5 mg and 100 mg/25 mg are available in blister packs of 28 or 98 tablets. Your pharmacist will dispense the number of tablets prescribed by your doctor.

Marketing Authorisation Holder

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Manufacturer:

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