

Atecor-CT 50 mg/12.5 mg & 100 mg/25 mg 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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1 What Atecor-CT is and what it is used for

Atecor-CT is used to treat high blood pressure (hypertension). It contains two different medicines called atenolol and chlortalidone.

- Atenolol belongs to a group of medicines called 'beta-blockers'. It works by slowing down your heartbeat and making it beat with less force.
- Chlortalidone belongs to a group of medicines called water tablets (diuretics). It works by increasing the amount of urine made by your kidneys.

These medicines work together to lower your blood pressure.

2 What you need to know before you take Atecor-CT

Do not take Atecor-CT if:

- you are allergic to atenolol, chlortalidone or any of the other ingredients of this medicine (listed in section 6)
- you are allergic to sulphonamide derived medicines e.g. some antibiotics
- you have heart failure that has not been treated or is not under control. Signs may include shortness of breath and swelling of your ankles.
- you have a second or third degree heart block (you may have a pacemaker)
- you have sick sinus syndrome or a very slow or a very uneven heartbeat
- you have very low blood pressure or very poor circulation
- you have cardiogenic shock. This is when your heart does not pump your blood around your body well enough. Signs may include confusion, sweating, a fast heartbeat and pale skin.
- you have a tumour called pheochromocytoma 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 are pregnant, are trying to become pregnant or are breastfeeding
- you have kidney problems
- you have been told by your doctor that you have a low level of potassium in your blood (hypokalaemia)
- you are in a pre-coma state because of liver or kidney problems or 'Addison's disease'
- you have had verapamil or diltiazem as an injection into your veins in the last 48 hours.

Do not take Atecor-CT and tell your doctor or pharmacist if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk with your doctor or pharmacist before taking Atecor-CT if:

- you have breathing problems such as asthma, wheezing
- you get allergic reactions, such as to insect stings
- you have gout
- you have a type of chest pain (angina) called Prinzmetal's angina
- you have poor blood circulation
- you have heart failure that is under control
- you have first degree heart block
- you have diabetes. Your medicine may change how you feel when you have low blood sugar. You may feel your heart beating faster.
- you have a thyroid problem such as 'thyrotoxicosis'. Atecor-CT may hide the symptoms of 'thyrotoxicosis', a condition caused by an overactive thyroid gland.
- you have liver problems
- 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 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 Atecor-CT. This can lead to permanent vision loss, if not treated. If you already have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this.

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

Your doctor will monitor your sodium and potassium levels, especially older people being treated for heart failure, patients on a low potassium diet or those with stomach problems.

Other medicines and Atecor-CT:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not take Atecor-CT and tell your doctor or pharmacist if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Clonidine (for high blood pressure or migraine). Do not stop taking clonidine unless your doctor tells you to. If you have to stop taking clonidine, your doctor will give you careful instructions on how to do so.
- Verapamil or diltiazem for high blood pressure or chest pain, orally, or as an injection into your vein in the past 48 hours
- Nifedipine for high blood pressure or chest pain
- Disopyramide or amiodarone – for an uneven heartbeat
- Digoxin – for heart problems
- Adrenaline, also known as epinephrine, noradrenalin, also known as norepinephrine – medicines that stimulate the heart
- Ibuprofen or indometacin – for pain and swelling
- Baclofen (a medicine used for muscle relaxation)
- Lithium – for mental health problems
- Insulin or other medicines for diabetes
- Medicines to treat colds or blocked sinuses. This includes medicines you can buy without a prescription.
- Reserpine, Guanethidine (for high blood pressure).

Operations:

Tell your doctor or medical staff that you are taking Atecor-CT if you are going to have an operation. This is because you may get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking this medicine.

Pregnancy, breastfeeding and fertility:

- Do not take Atecor-CT if you are pregnant or trying to get pregnant
- Do not take Atecor-CT if you are breastfeeding.

If you are pregnant or breastfeeding, 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:

Atecor-CT is not likely to affect you being able to drive or to 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.

Atecor-CT contains lactose and sodium.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3 How to take Atecor-CT

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.
- The tablet can be divided into equal doses.
- Read the label on the carton to remind you what the doctor said.
- Try to take your tablet at the same time each day.

- Swallow the tablet dose whole with a drink of water.

The recommended dose is:

Adults:

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

Children and adolescents:

Atecor-CT must not be given to children and adolescents.

People with kidney problems:

If you have a severe problem with your kidneys, you should not take this medicine. If you are unsure discuss it with your doctor.

If you take more Atecor-CT than you should:

- If you take more Atecor-CT than you should, talk to your doctor or go to a hospital straight away.
- Take the medicine pack with you so that the doctor knows what you have taken.

If you forget to take Atecor-CT:

- Take your tablets as soon as you remember, then go on as before.
- However, if it is almost time for the next dose, skip the missed dose.
- Do not take a double dose to make up for the forgotten individual dose.

If you stop taking Atecor-CT:

Do not stop taking Atecor-CT without talking to your doctor. The doctor may need to slowly lower the dose.

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Atecor-CT and see a doctor or go to hospital straight away if you notice any of the following serious side effects:

- swelling of your face or throat, difficulty in breathing or feeling dizzy. These may be signs of an allergic reaction.
- an abnormal heartbeat, feeling dizzy, tired or fainting. These could be signs of a heart block.
- shortness of breath or having swollen ankles. These could be signs of heart failure or your heart failure getting worse.
- breathing problems such as wheezing. These could be signs of your asthma getting worse.
- increased thirst, weakness and headaches. These could be signs of high blood sugar which could lead to unconsciousness (non ketotic hyperosmolar coma).
- reddening, pain or tenderness of your skin. These could be signs of 'necrotic vasculitis'. This is when your blood vessels swell and may stop the blood flow to your skin. This can cause your skin to die.
- burn like marks on your skin. These could be signs of 'epidermal necrosis' or 'lyell syndrome'. This can cause your skin to die and can affect all of your body. This can be life-threatening.
- bleeding or bruising due to a reduction in blood platelets (thrombocytopenia)
- severe pain in the abdomen and back (pancreatitis).

These side effects are either rare (may affect less than 1 in 1000 people) or the frequency is unknown.

Other side effects include:

- **Common: may affect up to 1 in 10 people**
 - cold or poor blood circulation in your hands and feet
 - your pulse rate may become slower. This is normal, but if you are worried tell your doctor about it.
 - diarrhoea
 - feeling sick or being sick
 - feeling tired
 - low levels of sodium in your blood which may cause weakness, being sick and cramps
 - low levels of potassium
 - an increase in amount of uric acid
 - higher levels of sugar (glucose) than normal
 - reduced number of white blood cells.
- **Uncommon: may affect up to 1 in 100 people**
 - problems sleeping
 - high levels of a liver enzyme called transaminase (shown by blood tests).
- **Rare: may affect up to 1 in 1,000 people**
 - heart block (which can cause an abnormal heart beat, dizziness, tiredness or fainting)
 - feeling numb and spasm in your fingers which is followed by warmth and pain (Raynaud's Disease)
 - tingling or pins and needles of your hands and feet
 - feeling dizzy (particular when standing up)
 - headache
 - feeling confused, anxious or scared
 - nightmares
 - changes in personality (psychoses), seeing or hearing things that are not there (hallucinations)
 - mood changes
 - dry mouth
 - dry eyes
 - thinning of your hair
 - skin rash

- dry scaly skin (psoriasis) that may get worse when you start to take your medicine
- problems with eyesight
- bruising more easily or purple marks on your skin
- being unable to get an erection (impotence)
- jaundice (yellowing of your skin or the whites of your eyes)
- swelling of a large gland behind the stomach (pancreatitis).

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 Atecor-CT 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)
- low levels of magnesium or chlorine in your blood
- a high level of calcium in your blood
- 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 HPRC 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 Atecor

Do not store above 25°C.
Store in the original package.

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

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 any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Atecor-CT contains

The active substances are atenolol and chlortalidone.

Atecor-CT 50 mg/12.5 mg:

Each film-coated tablet contains 50 mg atenolol and 12.5 mg chlortalidone.

– The other ingredients are:

Maize starch, sodium starch glycollate (type A), sodium laurilsulfate, magnesium stearate, magnesium carbonate heavy, hypolose. The coating of the tablets contains hypromellose, lactose monohydrate, titanium dioxide (E171) and macrogol 4000.

Atecor-CT 100 mg/25 mg:

Each film-coated tablet contains 100 mg atenolol and 25 mg chlortalidone.

– The other ingredients are:

Maize starch, sodium starch glycollate (type A), sodium laurilsulfate, magnesium stearate, magnesium carbonate heavy, hypolose. The coating of the tablets contains hypromellose, lactose monohydrate, titanium dioxide (E171) and macrogol 4000.

What Atecor-CT looks like and contents of the pack

Atecor-CT 50 mg/12.5 mg Film-coated tablets are white, round, biconvex, film-coated tablets with a score notch on one side. The tablets can be divided into equal doses.

Atecor-CT 100 mg/25 mg Film-coated tablets are white, round, biconvex, film-coated tablets with a score notch on one side. The tablets can be divided into equal doses.

Aluminium/PP blister: 10 and 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Bantry, Co Cork, Ireland.

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