

PACKAGE LEAFLET: INFORMATION FOR THE USER

Atecor 25mg, 50mg & 100mg Tablets

Atenolol

ROWEX®

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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet, See section 4.

What is in this leaflet:

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

1 What Atecor is and what it is used for

Atecor contains a substance called atenolol. Atenolol belongs to a group of medicines called beta-blockers and is used for the treatment of:

- high blood pressure (essential hypertension)
- preventing chest pain (angina)
- irregular or uneven heartbeats (cardiac arrhythmias)
- protect the heart in early treatment after a heart attack (myocardial infarction)
- long-term prophylaxis after recovery from a heart attack (to prevent another attack).

This medicine works by making your heart beat more slowly and with less force.

2 What you need to know before you take Atecor

Do not take Atecor if:

- you are allergic to atenolol or any of the other ingredients of this medicine listed in section 6
- you have heart failure which is not under control (this usually makes you breathless and causes your ankles to swell)
- you suffer from other heart conditions:
 - second or third degree heart block (a condition which may be treated by a pacemaker)
 - bradycardia (very slow or uneven heartbeat)
 - low blood pressure (hypotension)
 - poor circulation (peripheral arterial disease)
- you have a tumour called phaeochromocytoma that is not 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 should first consult your doctor about these conditions.

Warnings and precautions:

The initial treatment of severe high blood pressure should be very gradual so as to avoid a sudden drop of blood pressure.

Talk to your doctor or pharmacist or nurse before taking Atecor if:

- you have asthma, wheezing or any other similar breathing problems
- you get allergic reactions, for example to insect stings
- you have a type of chest pain (angina) called Prinzmetal's angina
- you are already being treated for a heart condition, or have heart failure that is under control
- you have poor blood circulation
- you have first degree heart block
- you have diabetes (your medicine may change how you respond to having low blood sugar)
- you have thyrotoxicosis (a condition caused by an overactive thyroid gland)
- you have liver or kidney problems, it is very important to tell your doctor so that your other medications may be adjusted if necessary
- you have a skin rash or skin condition called psoriasis and/or dry eyes.

Children and adolescents:

Do not give this medicine to children and adolescents.

Other medicines and Atecor:

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicine.

This is because Atecor can affect the way some other medicines work and some medicines can have an effect on Atecor.

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

- Water tablets (diuretics), guanethidine, reserpine or other medicines for high blood pressure
- Clonidine (for high blood pressure or migraine). If you are taking clonidine and Atecor 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 careful instructions about how to do it
- Calcium channel blockers e.g. verapamil, nifedipine or diltiazem, (for high blood pressure or chest pain)
- Disopyramide, quinidine or amiodarone (for an uneven heartbeat)
- Digoxin (for heart problems)
- Adrenaline, also known as epinephrine (a medicine that stimulates the heart)
- Lidocaine, procainamide and noradrenaline, (also known as norepinephrine) (for heart problems)
- Ibuprofen or indometacin (for pain and inflammation).
- Insulin or medicines that you take by mouth for diabetes.
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Tricyclic antidepressants e.g. amitriptylene
- Barbiturates e.g. phenobarbital
- Phenothiazines e.g. chlorpromazine
- Ampicillin an antibiotic that may reduce the atenolol serum levels
- Baclofen to relax muscles

Operations:

If you go to hospital to have an operation, tell the anaesthetist or medical staff that you are taking Atecor, because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Atecor.

Pregnancy and 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.

If you are pregnant or breast-feeding you should not take Atecor, unless it is considered essential by your doctor.

Driving and using machines:

As with all beta-blockers Atecor is not likely to affect your ability to drive or to use machines. However, it is best to wait and 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 contains:

Atecor contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Atecor

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

The recommended dose is:

Adults:

Your doctor will decide how much Atecor you should take each day, depending on your condition. The dose is normally taken once a day.

- **High blood pressure** (hypertension): 50 mg to 100 mg daily.
- **Chest pain** (angina): 50 mg to 100 mg daily or 50 mg twice daily.
- **Uneven heartbeats** (arrhythmias): maintenance dose of 50 mg to 100 mg daily.
- **The early treatment of a heart attack** (myocardial infarction): 50 mg twice daily. Your doctor may change this to 100 mg once daily.
- **To help prevent another heart attack:** 100 mg daily.

Elderly people:

If you are an elderly person, your doctor may decide to give you a lower dose, particularly if you have problems with your kidneys.

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People with severe kidney problems

If you have severe problems with your kidneys, your doctor may ask you to take Atecor less often.

Children and adolescents:

Atecor must not be given to children

If you take more Atecor than you should:

- If you take more than the prescribed dose, or in the event of an overdose, talk to your doctor or go to a hospital straight away.
- If possible take the medicine pack with you so that the doctor knows what you have taken.

If you forget to take Atecor:

- Take your tablets as soon as you remember, then go on as before. Do not take more than the total daily dose in 24 hours.
- 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 doses.

If you stop taking Atecor:

Do not stop taking Atecor even if you are feeling well, without talking to your doctor. Then only do so gradually. Your doctor will tell you how to do this.

If you have any further questions on the use of this medicine, 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. The following side effects may happen with this medicine:

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

- Allergic reaction: The signs may include raised lumps on your skin (wheals) or swelling of your face, lips, mouth, tongue or throat or feeling dizzy.
- An abnormal heartbeat feeling dizzy, tired or fainting. These could be signs of 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 wheezes. These could be signs of your asthma getting worse.
- Increased thirst, weakness and headache. These could be signs of high blood sugar which could lead to unconsciousness.

Other side effects include:

Common (may affect 1 to 10 users in 100)

- Your pulse rate may become slower. This is normal but if you are worried tell your doctor about it.
- Cold or poor blood circulation in your hands and feet
- Diarrhoea
- Constipation
- Feeling sick (nausea, vomiting)
- Feeling tired

Uncommon (may affect 1 to 10 users in 1,000):

- Disturbed sleep
- High serum enzyme values (transaminase).

Rare (may affect 1 to 10 users in 10,000):

- Heart block (which can cause an abnormal heartbeat, dizziness, tiredness or fainting)
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's Disease)
- Tingling of your hands
- Poor circulation that may get worse when you first start taking this medicine
- Dizziness (particularly when standing up)
- Headaches
- Feeling confused
- Nightmares
- Changes in personality (psychoses) or hallucinations
- Mood changes
- Dry mouth
- Unable to get an erection (impotence)
- Thinning of your hair
- Dry eyes
- Skin rash
- Psoriasis (dry scaly skin condition) that may get worse when you start to take your medicine
- Problems with your eyesight (disturbances of vision)
- Bruising more easily (due to a reduced number of platelets in your blood)
- Purple marks on your skin
- Jaundice (causing yellowing of your skin or the whites of your eyes).

Very rare (may affect 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 Atecor has had any effect on your blood.

Not known (frequency cannot be estimated from available data):

Lupus-like syndrome (a disease where the immune system produces antibodies that attack 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 10,000 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; email: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Atecor

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

Store in the original package.

Do not store above 25°C.

Do not use these tablets after the expiry date which is marked on both the outer carton and on each blister strip of tablets. 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

The active substance is atenolol.

Atecor 25 mg:

Each tablet contains 25 mg atenolol

- The other ingredients are:

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

Atecor 50 mg:

Each tablet contains 50 mg atenolol.

- The other ingredients are:

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

Atecor 100 mg:

Each tablet contains 100 mg atenolol.

- The other ingredients are:

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

What Atecor looks like and contents of the pack

Atecor 25 mg Tablets are white, round, biconvex, film-coated tablets with a score notch on one side and '25' embossed on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal parts.

Atecor 50 mg Tablets are white, round, biconvex, film-coated tablets with a score notch on one side and '50' embossed on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal parts.

Atecor 100 mg Tablets are white, round, biconvex, film-coated tablets with a score notch on one side and '100' embossed on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal parts.

Atecor 50 mg and 100 mg Tablets are blister packed in strips of 10 tablets each and are available in sales packs of 30 and 100 tablets. Atecor 25 mg Tablets are blister packed in strips of 10 tablets and are available in a pack size of 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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