

Atenolol Tablets USP 25mg/50mg/100mg

(Atenolol)

Package leaflet: Information for the patient

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

1. What Atenolol is and what it used for

Atenolol contains a medicine called atenolol. This belongs to a group of medicines called beta-blockers. Atenolol is used to:

- Treat high blood pressure (hypertension).
- Treat uneven heart beats (arrhythmias).
- Help prevent chest pain (angina).
- Protect the heart in the early treatment after a heart attack (myocardial infarction).

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

2. What you need to know before take Atenolol

Do not take Atenolol:

- If you are allergic to atenolol 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 phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure. If you are being treated for phaeochromocytoma, your doctor will give you another medicine, called an alpha-blocker, to take as well as Atenolol.
- If you have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Atenolol 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 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. You may feel your heart beating faster.
- You have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.
- You have problems with your kidneys. You may need to have some check-ups during your treatment.

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

Other medicines and Atenolol

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

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 Atenolol 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, quinidine or amiodarone (for an uneven heart beat).
- Digoxin (for heart problems).
- Adrenaline, also known as epinephrine (a medicine that stimulates the heart).
- 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).

Operations

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

Pregnancy, breast-feeding and fertility

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.

3. How to take Atenolol

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

Adults

- **High blood pressure (hypertension):** the recommended dose is 50 mg to 100 mg a day.
- **Chest pain (angina):** the recommended dose is 100 mg a day or 50 mg twice a day.
- **Uneven heart beats (arrhythmias):** the recommended dose is 50 mg to 100 mg a day.
- **The early treatment of a heart attack (myocardial infarction):** the recommended dose is 50 mg to 100 mg a day.

Elderly

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

People with severe kidney problems

If you have severe kidney problems your doctor may decide to give you a lower dose.

Use in Children

This medicine must not be given to children.

If you take more Atenolol than you should

If you take more Atenolol 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 Atenolol

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 Atenolol

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

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.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- 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.
- Cold hands and feet.
- Diarrhoea.
- Feeling sick (nausea).
- Feeling tired.

Uncommon (may affect up to 1 in 100 people)

- Disturbed sleep.

Rare (may affect up to 1 in 1,000 people)

- Heart block (which can cause dizziness, abnormal heart beat, tiredness or fainting).
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease).
- Mood changes.
- Nightmares.
- Feeling confused.
- Changes in personality (psychoses) or hallucinations.
- Headache.
- Dizziness (particularly when standing up).
- Tingling of your hands.
- Being unable to get an erection (impotence).
- Dry mouth.
- Dry eyes.
- Disturbances of vision.
- Thinning of your hair.
- Skin rash.
- Reduced numbers of platelets in your blood (this may make you bruise more easily).
- Purplish marks on your skin.
- Jaundice (causing yellowing of your skin or the whites of your eyes).

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 Atenolol has had any effect on your blood.

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

- 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.

5. How to store Atenolol

- 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 blister strip. The expiry date refers to the last day of that month.
- 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 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 Atenolol contains

a) Each film-coated tablet contains:
Atenolol USP 25mg
Excipients q.s.

b) Each film-coated tablet contains:
Atenolol USP 50mg
Excipients q.s.

c) Each film-coated tablet contains:
Atenolol USP 100mg
Excipients q.s.

The other ingredients are gelatin, heavy magnesium carbonate, magnesium stearate, hypromellose, sodium laurilsulfate, maize starch, titanium dioxide, glycerol.

What Atenolol look like and contents of the pack

White, round, biconvex, film-coated tablets.
Pack Size: 7, 14, 24, 30, 50, 90, 100 and 500 tablets.

**7. MANUFACTURED IN INDIA BY:
TAJ PHARMACEUTICALS LTD.**

Mumbai, India

Unit No. 214.Old Bake House,

Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001

at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m.
EST

E-mail: tajgroup@tajpharma.com