PACKAGE LEAFLET:
INFORMATION FOR THE PATIENT

Atenolol 25 mg, 50 mg and 100 mg Tablets

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 is used for

Atenolol belongs to a group of medicines called beta-blockers, which help your heart to beat more slowly and with less force, reducing blood pressure. Beta blockers also help blood vessels to open to improve blood flow.

Atenolol is used to treat:
- High blood pressure (hypertension)
- Chest pain (angina pectoris)
- Irregular heartbeat (cardiac arrhythmias)
- Protect the heart in the early treatment after a heart attack

2. What you need to know before you take Atenolol

Do not take Atenolol if:
- **You have a history of wheezing or asthma. Consult your doctor or pharmacist first**
- You are allergic to Atenolol or any of the ingredients of this medicine (listed in section 6)
- You suffer from heart problems such as:
  - o Uncontrolled heart failure
  - o 2nd or 3rd degree heart block
  - o Weakened heart unable to pump blood around the body (cardiogenic shock)
  - o A very slow heart rate (less than 45 beats per minute) [bradycardia]
  - o Irregular heartbeat (sick sinus syndrome)
- You have low blood pressure (hypotension)
- You have very poor circulation
- You have **untreated** phaeochromocytoma (tumour of the adrenal gland)
- You suffer from an increased level of acid in the blood (metabolic acidosis)

Warnings and precautions
Talk to your doctor before taking Atenolol:
- If you suffer from heart conditions such as:
  - o Heart failure (controlled)
  - o 1st degree heart block
  - o If you have a type of chest pain called Prinzmetal's angina
- If you have diabetes. Your medicine may change how you respond to having low blood sugar levels. You may feel your heart beating faster. Atenolol could also increase the risk of severe hypoglycaemia when used with certain type of antidiabetic drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- If you have thyroid problems (thyrotoxicosis) as Atenolol may hide the symptoms
- If you have kidney problems as you may require a lower dose
- If you have poor circulation (Raynaud's disease, intermittent claudication) as Atenolol may make these conditions worse
- If you have a history of breathing problems such as asthma, difficulty breathing or wheezing or reversible obstructive airways disease
- If you have a history of serious allergic reaction (anaphylaxis) as your usual dose of adrenaline (epinephrine) used to treat allergic reactions may not work. Atenolol may cause allergic reactions such as swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema) and skin rashes with the formation of wheals (urticaria) [see "Side effects" section]
- If you are due to have surgery (see "Other medicines and Atenolol" section and section 3 "If you stop taking Atenolol")
- If you are elderly as you may require a lower dose
- If you have **treated** phaeochromocytoma (tumour of the adrenal gland)

Other medicines and Atenolol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those obtained without a prescription. This includes herbal medicines.

Medicines which may interact with or be affected by Atenolol:
- If you are due to have an anaesthetic you must tell the medical staff that you are taking Atenolol
- Medicines for regulating the heartbeat such as disopyramide or amiodarone (antiarrhythmics)
- Insulin or oral medicines used to treat diabetes such as drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- Calcium channel blockers, such as verapamil, diltiazem and nifedipine (used to treat high blood pressure and chest pain)
- Medicines for heart conditions, such as digoxin (cardiac glycosides)
- Medicines used to treat severe allergic reactions, such as adrenaline (epinephrine) (sympathomimetics)
- Medicines used to relieve pain and inflammation, such as ibuprofen and indometacin (Non-Steroidal Anti-Inflammatory Drugs - NSAIDs)
- Clonidine used for high blood pressure or migraine. If clonidine and Atenolol are used together your doctor will advise you to stop taking Atenolol several days before stopping clonidine. If Atenolol is going to be used instead of clonidine, your doctor will probably advise you to begin taking Atenolol several days after clonidine has been stopped

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 for advice before taking this medicine.

Pregnancy
Adverse effects such as low blood sugar (hypoglycaemia) and slower heart rate (bradycardia) may occur in the foetus and newborn infant, if used in the second trimester (middle months 3-6) and third trimester (last 3 months). Therefore, use of Atenolol during pregnancy is **not** recommended. The potential benefit must be weighed against the possible risks.

Breast-feeding
As this medicine passes into breast milk, breast-feeding is **not** recommended.

Driving and using machines
Atenolol is unlikely to affect your ability to drive or use machinery, however, you may feel dizzy or tired (fatigue). If affected, do not drive or operate machinery.

Atenolol contains lactose
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Atenolol contains sodium
The 25 mg and 50 mg medicines contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
The 100 mg medicine contains 25 mg sodium (main component of cooking/table salt) in each tablet.
This is equivalent to 1.25 % of the recommended maximum daily dietary intake of sodium for an adult.

Atenolol 100 mg Tablets contains Sunset Yellow FCF (E110)
May cause allergic reactions.

3. How to take Atenolol

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Atenolol tablets are for oral use and should be swallowed whole.

Adults and children over 12 years of age
High blood pressure (hypertension):
- The recommended starting dose is 25 mg.
- The usual maintenance dose is one 50-100 mg tablet daily.
- After 1 or 2 weeks of treatment, your high blood pressure should return to normal.
- If necessary, your doctor may also prescribe you other antihypertensive medicines to reduce your blood pressure further.

Chest pain (angina pectoris):
- The usual dose is 50-100 mg daily.
- If required, 100 mg can be divided and given in two doses.

Abnormal heart rhythm (cardiac dysrhythmias):
- Initial treatments may be given as injections.
- The usual maintenance dose is 50-100 mg daily, given as a single dose.

After a heart attack (myocardial infarction):
- 10 minutes after receiving an injection of Atenolol, if there are no side effects, you may be given one 50 mg Atenolol tablet orally, followed by another 50 mg tablet 12 hours later.

- The usual maintenance dose is 100 mg daily in one or two doses for 6 days.

Elderly:
Your dose may need to be reduced, particularly if you suffer from kidney problems.

Patients with kidney problems:
- If you suffer from kidney problems, your dose will be adjusted (reduced):
  - o Mild to moderate kidney failure - 50 mg daily or 100 mg once every 2 days
  - o Moderate to severe kidney failure - 50 mg once every 2 days or 100 mg once every 4 days
- If you are on haemodialysis, you should be given 50 mg after each dialysis. You should be carefully monitored for a fall in blood pressure.

Use in children under 12 years of age
Atenolol is **not** recommended for use in children under 12 years of age.

If you take more Atenolol than you should
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.
Symptoms of an overdose include: a slow heartbeat (bradycardia), low blood pressure (hypotension), difficulty breathing or wheezing (bronchospasm) and heart problems.

If you forget to take Atenolol
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do **not** take a double dose to make up for a forgotten dose.

If you stop taking Atenolol
- It is important that you keep taking Atenolol for as long as your doctor has told you to.
- Stopping treatment with Atenolol should be done gradually and over a period of 1-2 weeks.
- You should be monitored by your doctor whilst stopping, especially if you suffer from heart problems or have been taking Atenolol for a long time.
- If you are due to have surgery and your doctor decides to stop your treatment with Atenolol, this should be done gradually and completed at least 24 hours before the operation.

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.

Seek medical advice immediately if you develop the following:
- Allergic reaction: swelling of the face, throat or tongue, difficulty breathing or dizziness (anaphylaxis)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Condition which causes joint pain, skin rashes and fever (Lupus-like syndrome)

Common side effects (may affect up to 1 in 10 people):
- Slower heartbeat (bradycardia)
- Cold hands and feet
- Feeling tired (fatigue)
- Gastrointestinal disturbances such as stomach pains, heartburn, constipation or indigestion

Uncommon side effects (may affect up to 1 in 100 people):
- Disturbed sleep
- Increase in liver enzyme levels (detected through blood tests)

Rare side effects (may affect up to 1 in 1,000 people):
- Heart failure, heart block
- Mood changes
- Nightmares
- Feeling confused
- Changes in personality (psychoses)
- Seeing or hearing things that are not real (hallucinations)
- Headache
- Dizziness
- Tingling or numbness in the hands or feet (paraesthesia)
- Low blood pressure which may include fainting (syncope) or dizziness when changing position (postural hypotension)
- Worsening of pain and/or cramping in the lower leg (intermittent claudication)
- Poor blood circulation which makes the toes and fingers numb and pale (Raynaud's disease)
- Being unable to get an erection (impotence)
- Dry mouth
- Liver problems including a pregnancy-related liver disorder causing build-up of bile acids in the bloodstream causing persistent itch (intrahepatic cholestasis)
- Disturbances of vision including dry eyes
- Hair loss (alopecia)
- Skin rash or worsening of psoriasis (skin disease causing scaly pink patches)
- Reduced numbers of platelets in your blood, which may increase the risk of bleeding or bruising (thrombocytopenia)
- Skin rash caused by small blood vessels bleeding into the skin (purpura)
- Worsening of asthma or breathing problems (bronchospasm)

Very rare side effects (may affect up to 1 in 10,000 people):
- An increase in ANA (Antinuclear Antibodies)

Not known (frequency cannot be estimated from the available data):
- Skin rashes with the formation of wheals (urticaria)

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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 carton/blister after "EXP". The expiry date refers to the last day of that month.
- Store in the original package in order to protect 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 to protect the environment.

6. Contents of the pack and other information

What Atenolol contains:
- Each 25 mg film-coated tablet contains 25 mg of Atenolol
- Each 50 mg film-coated tablet contains 50 mg of Atenolol
- Each 100 mg film-coated tablet contains 100 mg of Atenolol

The other ingredients are: lactose, microcrystalline cellulose, talc, maize starch, povidone, lactose (tablettose), sodium starch glycollate, sodium lauryl sulfate, colloidal silicon dioxide, stearic acid, magnesium stearate, titanium dioxide (E171), PEG 6000 and methylcellulose.
Atenolol 100 mg also contains the colouring agent Sunset Yellow FCF (E110).

What Atenolol looks like and the contents of the pack:
- Atenolol 25 mg are white, round, bi-convex, film-coated, unscored tablets marked "A25" of approximate size 6.4 mm x 3.2 mm
- Atenolol 50 mg are white/off-white, round, bi-convex, film-coated, unscored tablets marked "A50" of approximate size 8.8 mm x 3.6 mm
- Atenolol 100 mg are orange, bi-convex, film-coated, unscored tablets marked "A100" of approximate size 10.4 mm x 4.9 mm

Atenolol is available in:
Atenolol is available in a blister pack of 28 tablets or a plastic container containing 100 tablets.

Not all pack sizes or pack types may be marketed.

Product Licence Numbers:
- Atenolol 25 mg Tablets: PL 11311/0019
- Atenolol 50 mg Tablets: PL 11311/0014
- Atenolol 100 mg Tablets: PL 11311/0015

Marketing Authorisation Holder & Manufacturer:
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