

PACKAGE LEAFLET: INFORMATION FOR THE USER
ATENOLOL 25 mg, 50 mg & 100 mg TABLETS
 [Atenolol]

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

1. WHAT ATENOLOL TABLETS ARE AND WHAT THEY USED FOR
 Atenolol is one of a group of medicines called beta-blockers. These medicines work by blocking the beta-adrenoreceptors mainly in the heart.

Atenolol Tablets may be used for:

- High blood pressure
- Relief of chest pain (angina)
- Controlling heart beats which are irregular or too fast
- Protecting the heart after a heart attack.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ATENOLOL TABLETS

Do not take Atenolol Tablets if you:

- Are allergic to atenolol or any of the other ingredients of this medicine (listed in section 6)
- Have heart or blood vessel disease including untreated heart failure (due to recent heart attack), slow heart beat or low blood pressure
- Have disturbances in heart rhythm including sick sinus syndrome or heart block
- Have high blood pressure due to a tumour near the kidney (phaeochromocytoma)
- Have 'metabolic acidosis', abnormal chemical levels in the blood such as potassium, sodium, calcium and urea
- Have very poor circulation.

Warnings and precautions

Talk to your doctor or pharmacist before taking Atenolol Tablets if you:

- Have heart failure or disease that is being controlled
- Have chest pain (Prinzmetal's angina)
- Have ever had asthma or wheezing, you should not take this medicine unless you have discussed these symptoms with the prescribing doctor
- Have Raynaud's disease (poor circulation causing cold hands)
- Have liver or kidney problems
- Have thyrotoxicosis (a condition caused by an overactive thyroid gland). Atenolol may hide the symptoms of thyrotoxicosis
- Have diabetes
- Suffer from allergies
- Have psoriasis (a common skin condition which has thickening patches of red inflamed skin, often covered by silvery scales).
- Attend hospital or the dentist for surgery involving anaesthetic. Atenolol may need to be stopped before you have a general anaesthetic.

Children

Do not give this medicine to children because it is unlikely to be safe.

Other medicines and Atenolol Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular any of the following:

- Medicines used to treat high blood pressure including clonidine, alfuzosin, nifedipine, verapamil, diltiazem
- General anaesthetics used in operations, inform your doctor or anaesthetist
- Medicines to treat an irregular heart-beat (Anti-arrhythmics), such as disopyramide, quinidine, amiodarone, lidocaine, procainamide, flecainide
- Medicines used to treat diabetes such as insulin and metformin
- Medicines used to treat heart conditions such as digoxin
- Non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and inflammation such as ibuprofen and indometacin
- Pseudoephedrine which is used to treat colds and comes in many cold preparations
- Adrenaline (epinephrine) and isoprenaline which are heart stimulants
- Noradrenaline (norepinephrine) and dobutamine which are used to treat heart attacks
- Medicines to treat depression such as amitriptyline and imipramine
- Medicines called Monoamine Oxidase Inhibitors (MAOIs) which are used to treat depression (e.g. phenelzine)
- Barbiturates such as phenobarbital which is used to treat epilepsy
- Medicines to treat mental illness such as chlorpromazine
- Mefloquine which is used to prevent malaria
- Medicines used to treat headache and migraine (e.g. ergotamine and methysergide)
- Aldesleukin which is used to treat kidney cancer
- Alprostadil used to treat erection problems

- Baclofen and tizanidine which is used to relax muscles
- Levodopa used to treat Parkinson's Disease
- Phenothiazines used in psychiatric disorders, such as schizophrenia
- Moxisylyte used to treat Raynaud's syndrome (a circulatory problem).

Atenolol Tablets with alcohol

Alcohol may cause your blood pressure to drop too low. You should avoid or limit how much alcohol you drink whilst taking this medicine. Discuss this with your doctor if you have any concerns.

Pregnancy and breast-feeding

Your doctor will only prescribe Atenolol Tablets if the benefits to you outweigh the risks of the unborn child. Breast-feeding is not recommended whilst taking Atenolol Tablets. Check with your doctor if you are unsure.

Driving and using machines

Atenolol Tablets may make you feel tired or dizzy. Make sure you are not affected before you drive or operate machinery.

Other precautions you should take:

If you see another doctor, attend hospital or the dentist for surgery involving an anaesthetic, let them know what medicines you are taking. Atenolol may need to be stopped before you have a general anaesthetic.

3. HOW TO TAKE ATENOLOL TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Follow your doctor's instructions. Check the pharmacy label to see how many tablets to take and how often to take them. If you are still unsure ask your doctor or pharmacist.

Your doctor will start you on a low dose and increase it as required. You must not stop taking Atenolol abruptly; your doctor will reduce your dosage gradually.

The tablets should be swallowed whole with water.

The usual adult dose is:

- **High blood pressure:** 50mg - 100mg daily
- **Angina:** 100mg once daily or 50mg twice daily
- **Irregular heartbeats:** 50-100mg daily, given as a single dose
- **After a heart attack:** Initial treatment will usually be by injection, followed by 50mg by mouth 15 minutes after the injection, a further 50mg 12 hours later and then 100mg 12 hours later to be given once daily.
- **Elderly:** The above dosages may sometimes be reduced especially if you have damaged kidneys.
- **Patients with kidney disease:** You will usually be given a lower dose depending on how severe your kidney damage is. Patients on haemodialysis should be given 50mg by mouth after each dialysis.

Dimension: 240 x 200 mm

Front Side

ARTWORK DETAIL LABEL

Product	ATENOLOL TABLETS 25 mg, 50 mg & 100 mg			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	240 x 200 mm Same Size		Pack	----
New Item Code	1036478	Old Item Code	1035423	
Colour Shades	■ BLACK		No. of Colours	1
Change Control No.	PC-ODF/2018/601 Record Number: 174267		Artwork Version	5.0
Design/Style	Front & Back Printing. To be supplied unfold.			
Substrate	60 GSM Paper.			
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.				

- Swallow these tablets with a glass of water at the same time(s) each day.
- Take this medicine for as long as your doctor tells you to, it may be dangerous to stop without their advice. Beta-blockers should not be stopped suddenly.

Use in children

This medicine must not be given to children.

If you take more Atenolol Tablets than you should

If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. If an overdose has been taken there may be signs such as slow or irregular heartbeat, low blood pressure, difficulty breathing and fainting.

If you forget to take Atenolol Tablets

If you forget to take a tablet take one as soon as you remember, unless it is nearly time to take the next one.

Do not take a double dose to make up for a forgotten dose.

Take the remaining doses at the correct time.

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

4. POSSIBLE SIDE EFFECTS

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

If you experience any of the following side effects **contact your doctor** immediately:-

- All medicines can cause allergic reactions, although serious allergic reactions are very rare. STOP TAKING YOUR TABLETS and tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash, reddening of the skin or itching (especially affecting your whole body)
- Liver problems such as liver disease (yellowing of the skin or whites of the eyes)
- Increased bruising or bleeding from the nose or gums
- Worsening of heart failure or heart attack (symptoms of heart pain worsening generally on an already diagnosed condition).

Common side effects (may affect up to 1 in 10 people):

- Feeling sick or being sick
- Diarrhoea
- Stomach cramps
- Constipation
- Coldness and blueness of the fingers
- Slow heart rate
- Fatigue (tiredness).

Uncommon side effects (may affect up to 1 in 100 people):

- Sleep disturbances such as insomnia and nightmares
- Visual disturbances such as impaired vision

- Sore eyes
- Increases in a liver enzyme called transaminase in the blood, measured by a blood test.

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

- Dizziness
- Headaches
- Dry eyes
- Conjunctivitis (eye infection)
- Rash which can be itchy, blood spots, bruising and discolouring to the skin (purpura)
- Worsening of psoriasis (skin condition)
- Hair loss (alopecia)
- Pins and needles
- Hallucinations (seeing or hearing things that are not real)
- Confusion
- Depression (feeling low)
- Impotence
- Dry mouth
- Mood changes
- Breathing difficulty
- Mental disorders such as schizophrenia
- Heart block a common disorder of the heartbeat
- Low blood pressure and feeling faint on standing
- Leg cramps, pain and numbness made worse
- Raynaud's phenomenon-poor circulation causing cold hands
- Temporary tightening of the chest that may occur in patients with asthma or a history of asthma
- Problems with the bile and liver leading to jaundice (yellowing of skin and whites of eyes).

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

- An increase in some white blood cells that would be measured by a blood test.

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)
- Changes in heart rhythm
- Low blood pressure (fainting on standing)
- Worsening of heart failure (where the heart cannot pump blood around the body properly) or heart attack
- Muscle tiredness
- Low blood sugar (hypoglycaemia)
- High blood sugar (hyperglycaemia)
- Overactive thyroid, your doctor may identify this in a blood test
- There may be changes in the proteins in your blood; your doctor may identify this from a blood test
- Dyspnoea (shortness of breath)
- Malaise (general feeling of being unwell)
- Hypoglycaemia (low blood sugar) with symptoms of sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat.

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 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 TABLETS

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

Do not store above 25° C.

Store in the original package.

Keep the container or bottle tightly closed.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration.

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 Tablets contain

The active substance is atenolol.

Each tablet contains either 25 mg, 50 mg or 100 mg of the active substance.

The other ingredients are: Gelatin, heavy magnesium carbonate, magnesium stearate, microcrystalline cellulose, maize starch, sodium lauryl sulphate, talc.

What Atenolol Tablets look like and contents of the pack

Description:

Atenolol Tablets 25 mg, 50 mg & 100 mg: Circular, white, flat tablet scored on one side.

Contents of pack:

Atenolol Tablets 25 mg, 50 mg & 100 mg: 14 tablets in a blister and 2 such blisters in a carton

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.

Unit 4, Metro Centre,
Tolpits Lane, Watford, Herts.

UK, WD18 9SS

Tel: 01923 255580

Fax: 01923 255581

This leaflet was last revised in 04/2018.



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Back Side

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