

PACKAGE LEAFLET: INFORMATION FOR THE USER

Atenomel 25mg Tablets **Atenomel 50mg Tablets** **Atenomel 100mg 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 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 Atenomel Tablets are and what they are used for
2. What you need to know before you take Atenomel Tablets
3. How to take Atenomel Tablets
4. Possible side effects
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1. What Atenomel Tablets are and what they are used for

Atenomel Tablets contain the active substance atenolol. Atenolol belongs to a group of medicines called beta-blockers. These medicines control the heart rate and blood pressure by making your heart beat more slowly and with less force. Atenomel is used to:

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

2. What you need to know before you take Atenomel Tablets

Do not take Atenomel Tablets

- 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 disorders:
 - 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 with a pacemaker)
 - very slow or irregular heart-beat, very low blood pressure or very poor circulation.
- if you have phaeochromocytoma (high blood pressure caused by a tumour, usually near the kidney) which is not treated
- if you have been told that you have metabolic acidosis (abnormal levels of acid in your blood)

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

Warnings and Precautions

Talk to your doctor or pharmacist before taking Atenomel

- **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.**
- If you suffer from a type of chest pain (angina) called Prinzmetal's angina
- If you have poor circulation or controlled heart failure
- If you have first-degree heart block
- If you have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster
- If you have thyrotoxicosis (caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis
- If you have a kidney disorder. You may need to have regular check-ups during your treatment.
- If you have psoriasis (a skin condition)
- If you have phaeochromocytoma, an alpha-beta blocker should be given concomitantly

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

Treatment should not be withdrawn abruptly. See Section 3 "How to take Atenomel Tablets"

Other medicines and Atenomel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- medicines used to lower blood pressure such as guanethidine, reserpine, diuretics (drugs used to increase the flow of urine), vasodilators (drugs which widen the blood vessels)
- Disopyramide and amiodarone (medicines for regulating the heartbeat)
- Verapamil, diltiazem and nifedipine (which are used to treat high blood pressure or angina)
- Clonidine (for high blood pressure or migraine). If you are taking clonidine in combination with atenolol, you must not stop taking clonidine unless told to do so by your doctor. If you have to stop taking clonidine you should follow your doctor's instructions carefully on how to do it
- Digoxin (a medicine for heart failure)
- Insulin and oral anti-diabetic drugs used to treat diabetes. With atenolol there is a greater risk of hypoglycaemia (low sugar levels) and you may not get the usual warning signs of low sugar
- Lidocaine, procainamide and beta-adrenoceptor stimulants such as noradrenaline (also known as norepinephrine) used for heart problems
- Ibuprofen or indometacin (drugs used to relieve pain and reduce inflammation)
- Adrenaline (epinephrine) used as a heart stimulant
- Nasal decongestants or other cold remedies (including the ones you can buy in the pharmacy)

Operations and Anaesthetics:

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

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

Driving and using machinery:

This medicine is unlikely to affect your ability to drive or operate machinery, but it may cause dizziness or fatigue. However, it is best to wait to see how your medicine affects you before trying these activities.

Atenolol tablets contain lactose

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 Atenolol Tablets

Always take Atenolol Tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should swallow your tablets whole with water.

Adults:

The recommended dose for adults is:

Hypertension (high blood pressure): The recommended dose is 50 mg once daily. If required your doctor may increase the dose to 100 mg once daily.

Angina (chest pain): The recommended dose is 100 mg once daily or 50 mg twice daily.

Irregular heartbeats: The recommended dose is 50 mg to 100 mg once daily.

The early treatment of a heart attack (myocardial infarction): The recommended dose is 50 mg twice a day. Your doctor may then change this to 100 mg once a day.

To help prevent another heart attack: The recommended dose is 100 mg a day.

You should try to take your tablets at the same time every day.

Use in children:

Atenolol is not recommended for use in children due to lack of data on safety and efficacy.

Older people:

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

People with kidney problems:

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

If you take more Atenolol Tablets than you should:

If you have taken too many tablets you should contact your nearest hospital casualty department or your doctor immediately.

If you forget to take Atenolol Tablets:

If you forget to take a dose, do so as soon as you remember and then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Atenolol Tablets:

Do not stop taking Atenolol Tablets even if you are feeling well, unless your doctor tells you to do so. Treatment should not be withdrawn abruptly. The dosage should be withdrawn gradually over a period of 7 – 14 days, to facilitate a reduction in beta-blocker dosage. Patients should be followed during withdrawal especially those with ischaemic heart disease.

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. The following side effects may occur with this medicine:

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.

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
- Problems with your heart or worsening problems with your heart
- Fatigue
- Sweating
- Feeling drowsy
- Increased dream activity
- Depression
- A sudden, unexpected rash or burning, red or peeling skin
- Conjunctivitis.

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

- Disturbed sleep
- Muscle weakness or muscle cramps
- Diabetes or worsening diabetes

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

- Heart block (which can cause an abnormal heart beat, dizziness, 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):

- Worsening angina attacks if you have experienced chest pains (angina pectoris)
- Reduced libido, impotence
- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether Atenomel 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.

You may experience symptoms of an over active thyroid such as increased heart rate and tremor, may be hidden during treatment with Atenomel.

You may experience symptoms of low blood sugar (hypoglycaemia), such as increased heart rate or tremor, may be hidden by Atenomel, particularly if you are dieting for prolonged periods or subject to great physical exertion.

Problems with your cholesterol levels may occur during treatment with Atenomel.

Your doctor may monitor you for signs of bruising or bleeding under the skin while you are taking Atenomel.

Your doctor may monitor your liver function while you are taking Atenomel.

Your doctor may monitor your kidney function if you have severe kidney disease.

Do not be concerned by this list of side effects. You may not get any of them.

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; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atenomel Tablets

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 store above 25°C.

Store in the original package.

Keep blister in the outer carton.

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 Atenomel Tablets contain:

- The active substance is atenolol 25 mg, 50 mg or 100 mg.
- The other ingredients are maize starch, pregelatinised maize starch, lactose monohydrate, povidone, sodium laurilsulfate, silica colloidal anhydrous and magnesium stearate.

What Atenomel Tablets look like and contents of pack:

Atenomel 25 mg Tablets: White, round, biplanar tablet marked 'C23'.

Atenomel 50 mg Tablets: White, round, biconvex tablet with a breakline and marked 'C24'.

Atenomel 100 mg Tablets: White, round, biconvex tablet with a breakline marked 'C25'.

Atenomel 25 mg, 50 mg and 100 mg tablets are available in packs containing 14, 15, 28, 30, 56, 60 and 100 tablets

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary

Manufacturer:

STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany

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