ATEHEXAL TABLET®

Atenolol (25mg, 50mg, 100mg)

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What Atehexal is used for

Atehexal contains the active ingredient atenolol.

Atehexal is used to:
• Treat high blood pressure (hypertension)
• Treat uneven heart beats (arrhythmias)
• Help relieve chest pain (angina)
• Protect the heart in the early treatment after a heart attack (myocardial infarction)

How Atehexal works

Atehexal belongs to a group of medicines known as beta-blockers.

It works by decreasing the heart rate and force of contraction of the heart which resulting in decreased blood pressure.

Before you use Atehexal

- *When you must not use it*

• Have ever had a reaction or been told that you are allergic to atenolol or to any of the excipients
• Have ever had swelling of the face, lips tongue, throat, hands or feet
• Have a slow heart beat or serious problems with the heart rhythm (second or third degree heart block)
• Your heart is not pumping efficiently despite medication (uncontrolled heart failure)
• Have been told that you have acidosis (excess acid in the blood)
• Have been told that you have tumor in adrenal gland (phaeochromocytoma) and are not being treated
• Very slow or very uneven heart beats, very low blood pressure or very poor circulation

- *Before you start to use it*

Tell your doctor if you:
• Suffer from any heart disease
• Have chest pain (angina pectoris) eg. Prinzmetal's angina
• Have poor blood circulation or controlled heart failure
• Have first-degree heart block
• Have coronary artery disease (narrowing of blood vessels to the heart)
• Have diabetes
• Suffer from hyperthyroidism (over production of thyroid hormone)
• Suffer from any type of breathing problems such as asthma
• Suffer from kidney problems
• About to undergo surgery involving use of anaesthesia
• Have a family history of swelling of the face, lips, tongue, throat, hands or feet
• Are pregnant, planned to become pregnant or are breast feeding.

If you are not sure whether you should start taking this medicine, consult your doctor.

- *Taking other medicines*

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:
• Verapamil, diltiazem and nifedipine (for high blood pressure or chest pain)
• Medicines for irregular heartbeat (eg. disopyramide, amiodarone)
• Medicines to treat diabetes, including insulin. Taking together with Atehexal may increase the risk of low blood sugar
• Epinephrine, used in treating severe allergic reactions and to stimulate the heart
• Certain medicines for muscles problems (eg. baclofen)
• Anesthetics
• Non-steroidal anti-inflammatory drugs (NSAIDS) for pain relief (eg. indomethacin and ibuprofen)
• Digoxin (for heart problems)
• Clonidine, for lowering blood pressure and to treat migraine.

This may not be a complete list of all interactions that may occur. Ask your doctor or pharmacist if atenolol may interact with other medicines that you take.

- *Pregnancy and lactation*

Avoid these tablets if you are pregnant. Ask your doctor or pharmacist for advice before taking any medicine.

If you are breast feeding, you should not take Atehexal as it will be excreted in the breast milk.

How to use Atehexal

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Swallow the Atehexal tablet whole with a drink of water and about the same time each day.

- *How much to use*

Your doctor will decide your dose as it depends on your conditions.

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

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

Patient with liver problems
Dosage adjustment is not required.

Children
Your medicine must not be given to children.

- *When to use it*
Take your medicine as directed and the duration of treatment is to be determined by your doctor or pharmacist.

- *How long to use it*
Continue to take your medicine as long as your doctor tells you. This medicine helps to control your condition but does not cure it. It is important to keep taking this medicine even if you feel well.

- *If you forget to use it*
Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*
Contact your doctor immediately or go to the nearest Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The following symptoms may be observed in overdose:
• Excessive fall of blood pressure
• Slow pulse and heart blocks of various degree (including cardiac arrest)
• Heart failure and shock because of cardiac arrest
• Dizziness
• Breathing difficulties (wheezing, etc)
• Vomiting
• Loss of consciousness

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

While you are using it
- *Things you must do*
• Always take Atehexal exactly according to the instructions given to you by your doctor or pharmacist. If you are unsure, check with your doctor or pharmacist.
• Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
• Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
• If you become pregnant, or plan on becoming pregnant while taking Atehexal, tells your doctor immediately.
• If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Atehexal.

- *Things you must not do*
• Do not stop taking your medicines without consulting your doctor. It is important to keep taking your medicine even if you feel well.
• Do not use Atehexal after the expiry date which is stated on the carton and blister.
• Do not give this medication to anyone else, even if they have the same condition as you.

- *Things to be careful of*
Taking Atehexal may cause dizziness or light-headedness, particularly at the first dose or after dose is increased. Drinking alcohol may worsen the symptoms. If you have any of these symptoms, do not drive or operate any machinery.

Side effects
Like many medicines, Atehexal may cause side effects in some patients, particularly when you first taking them but not everyone will get it.

Tell your doctor or pharmacist if you notice the following common side effects and it worries you:
• Cold extremities (feeling cold at hands and feet)
• Fatigue
• Diarrhoea
• Slow heart beat
• Gastrointestinal disturbance eg. nausea and stomachache

Uncommon:
• Sleep disturbances
• Liver problem (eg. increased liver enzymes)

Rare:
• Heart block (which can cause dizziness, abnormal heart beat, tiredness or fainting)
• Numbness and spasm in your finger 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)
• Abnormal sensation of skin eg. tingling of hands
• Being unable to get an erection (impotence)
• Dry mouth
• Dry eyes
• Disturbances of vision
• Hair loss
• 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:
• Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether Atehexal has had any effect on your blood.

Conditions that may get worsen:
If you have any of the following conditions, they may get worse when you start to take your medicines. 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
Please consult doctor immediately as you may need medical attention.

Allergic reactions:
If you have an allergic reaction, see a doctor straight away. The signs may include swelling of your face, lips, mouth, tongue or throat.

Tell your doctor or pharmacist if you notice anything else that makes you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (*Public –> Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety*)

Storage and Disposal of Atehexal

Storage

Store in a cool, dry place below 30°C. Protect from heat, light and moisture.

Keep out of the reach and sight of children.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Atehexal tablet comes in white, round and biconvex film-coated tablets with one sided score notch.

- *Ingredients*

- Active ingredient

Atehexal® 25: It contains 25mg of Atenolol.
Atehexal® 50: It contains 50mg of Atenolol.
Atehexal® 100: It contains 100mg of Atenolol.

- Inactive ingredients

Maize starch, sodium starch glycollate, sodium dodecyl sulphate,heavy magnesium carbonate, magnesium stearate, hydroxypropylcellulose, opadry white (coating agent).

- *Packing*

Atehexal tablet comes in original packages of box with 30, 50 and 100 film coated tablets.

- *MAL Number*

Atehexal® 25: MAL20021163AZ
Atehexal® 50: MAL20021164AZ
Atehexal® 100: MAL20021165AZ

Manufacturer

Salutas Pharma GmbH
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For:

HEXAL AG
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Product Registration Holder

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Date of revision

03/04/2017