

AZEMTI

Diltiazem Hydrochloride 30mg Tablet

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1. What AZEMTI is used for

AZEMTI is used to treat (long- term) and prevent chest pain and mild to moderate high blood pressure.

2. How AZEMTI works

AZEMTI contains the active substance diltiazem hydrochloride, which belongs to a group of medicines called 'calcium channel blockers'.

It works by making your blood vessels wider, which makes it easier for your heart to pump blood around the body. This helps to prevent the chest pain.

3. Before you take AZEMTI

- When you must not use it

Do not take AZEMTI if you are allergic to diltiazem hydrochloride or any of the ingredients listed at the end of this leaflet.

Do not take AZEMTI with dantrolene infusion (a muscle relaxant) because it may cause a serious heart failure.

Do not take AZEMTI if you have galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, as the medicine contains lactose monohydrate.

Do not take AZEMTI if you have severe blood pressure, have a heart condition such as; a severe slow heartbeat (bradycardia), disturbance in heart rhythm (sick sinus syndrome), heart failure with reduced blood flow to your lungs, congestive heart failure, heart block,

narrowing of the opening of the aortic valve in the heart (aortic stenosis), shock caused by heart problems (cardiogenic shock).

Do not take AZEMTI if you have an inherited disorder of the red blood pigment haemoglobin (porphyria).

Do not take AZEMTI if you are pregnant, might become pregnant or breast feeding.

AZEMTI is not recommended in children and adolescents younger than 18 years. The safety and effectiveness of AZEMTI has not been established in this age group.

Do not take AZEMTI if the expiry date (EXP) printed on the pack has passed. The expiry date refers to the last date of the month.

Do not take AZEMTI if the packaging shows signs of tempering or the tablets do not look quite right.

- Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Liver or kidney problems.
- Heart problems.
- Diabetes. The treatment for your diabetes may need to be adjusted.
- Mood changes, including depressions.
- Gut problems.
- Over 65 years old.

Tell your doctor if you plan to have surgery which requires a general anaesthetic.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently.

taken any other medicines, including medicines obtained without a prescription, herbal medicines, or natural products. Especially:

- Dantrolene infusion (a muscle relaxant).
- Antiarrhythmic drugs such as quinidine, amiodarone and digoxin (used to treat an irregular heartbeat).
- ACE inhibitor e.g. Lisinopril.
- Aldesleukin (used in some cancers).
- Antihypertensive such as clonidine.
- Antipsychotics.
- Lithium (used for mental health problems).
- Benzodiazepines e.g. midazolam or triazolam (used for sedation and anaesthesia).
- Rifampicin (used to treat tuberculosis).
- Imipramine and other tricyclic antidepressants (used for depression)
- Phenobarbital, phenytoin or carbamazepine (to treat epilepsy).
- Ciclosporin (used to suppress immune system e.g. after organ transplantation).
- Theophylline (used in breathing problems such as asthma).
- Digitalis glycosides e.g. digoxin (used for some heart conditions).
- Beta blockers such as propranolol (used for some heart problems).
- H2 antagonist e.g. cimetidine and ranitidine (used to treat conditions

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caused by excess acid such as stomach ulcers).

- Diuretics (water tablets).
- Alpha blockers such as prazosin
- Anaesthetics.
- Statins e.g. lovastatin, simvastatin, fluvastatin and atorvastatin (used to treat high cholesterol).
- Corticosteroids (used to treat inflammations and allergic reactions).
- Medicines used for angina (chest pain) such as glyceryl trinitrate or isosorbide dinitrate.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacists.

4. How to take AZEMTI

Swallow the AZEMTI tablets whole on an empty stomach. Do not crush, chew or break.

Follow all directions given to you by your doctor and pharmacists carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the pack, ask your doctor or pharmacist.

- How much to take it

Your doctor will decide on the best dose for you.

For anti-chest pain therapy, AZEMTI tablet is taken on an empty stomach every eight hours. Usually the initial dose for adults is one tablet (30mg) 3 times a day. Dosage should be increased gradually until optimum response is achieved. Dosage can be increased up to 360 mg/day diltiazem.

In hypertensive (anti high blood pressure) treatment, the recommended daily dosage of diltiazem tablets varies between 120 mg and 240 mg according to the severity of the condition treated and patient's response.

- When to use it

AZEMTI should be taken before meals.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect and it will also help you remember when to take it.

- How long to take it

Keep taking AZEMTI for as long as your doctor tells you to. Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. If you want to stop taking your tablets, discuss this with your doctor first.

Tell your doctor if you feel the medicines are not helping your condition.

- If you forget to take it

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

- If you are taking too much (overdose)

If you take too many go to the nearest hospital casualty department or tell your doctor at once. Take the container or any of the remaining tablets with you. Do this even if there are no signs of discomfort or poisoning.

The signs of overdose might include: dizzy or weak, blurred vision, chest pain, shortness of breath, fainting, slurred speech and confusion may happen.

5. While you are taking AZEMTI

- Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking

AZEMTI.

Tell any other doctors, dentist and pharmacist who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are diabetic, tell your doctor if you noticed a change in your glucose test results.

- Things you must not do

Do not stop taking AZEMTI or change the dosage if you feel better without checking with your doctor.

Do not take AZEMTI to treat any other complaints unless your doctor tells you to.

Do not give AZEMTI to anyone else, even if they have the same condition as you.

- Things to be careful of

AZEMTI may cause dizziness or tiredness. If you feel any of these, avoid driving or operating machinery.

6. Side effects

Tell your doctor or pharmacist as soon as possible if you do not well while you are taking AZEMTI.

Like all other medicine, AZEMTI may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatments if you get some of the side effects. Ask your doctor or pharmacist to answer any question you may have.

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Do not be alarmed by this list of possible side effects. You may not experience any of them.

If any of the following happened, stop taking AZEMTI and tell your doctor immediately, or go to Accident and Emergency Department at the nearest hospital:

- If you get blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be an illness called 'Stevens-Johnson syndrome'.
- If you get a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may feel generally unwell and have a fever, chills and aching muscle. This could be an illness called "Toxic Epidermal Necrolysis".
- If you have a skin rash or skin lesions with a pink/red ring and a pale center which maybe itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'

This above list includes very serious side effects. You may need urgent medical attention or hospitalization.

Tell your doctor immediately if you notice any of the following:

- Slow or uneven heartbeat
- Very fast, uneven or forceful heartbeat (palpitations)
- Skin rash
- Shortness of breath, feeling tired along with swollen ankles and legs. This could be signs of heart failure.
- Unusual movements of the tongue, muscle spasms in your face, rolling eyes and trembling
- High temperature, feeling tired, loss of appetite, stomach pain, feeling sick. This can be signs of inflammation of the liver.
- Get sunburn easier, and which

maybe more severe than in someone not taking AZEMTI. You should use sun protection whilst taking this medicine.

- Breast enlargement in men.

The above list includes serious side effects which may require medical attention.

Tell your doctor if you notice any of the following side effects and they worry you:

- Water retention causing swelling of the lower legs
- Indigestion, stomach pain, constipation, and diarrhea.
- Headache
- Flushing (feeling of warmth)
- Feeling sick (nausea) or being sick (vomiting)
- General feeling of being unwell
- Weakness or tiredness
- Feeling dizzy
- Skin redness
- Heart block, palpitation
- Feeling dizzy, faint when you stand or sit up quickly.
- Nervousness
- Difficulty sleeping
- Dry mouth
- Bleeding or bruising under the skin
- Mood changes, including depression.
- Enlargement of gums, sensitivity to light, sweating
- Enlargement breasts in men, tremor, slurred speech, restlessness.
- Muscle spasm, anxiety.

Above list includes the common and milder side effects of your medicine.

Tell your doctor if you notice anything that is making 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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and disposal of AZEMTI

- Storage

Store below 25°C in the outer carton in order to be protected from light.

Keep out of reach and sight of children.

Heat and dampness can destroy some medicines.

Available in pack of 32's (2x 16's), 48's (3 x 16's), 100's (10 x 10's) and 112's (7 x 16's).

- Disposal

If your doctor tells you to stop taking AZEMTI, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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.

8. Product Description

- What it looks like

AZEMTI is in the form of white, smooth, cylindrical tablets.

- Ingredients

Active ingredient: diltiazem hydrochloride. Each tablet contains 30mg of diltiazem hydrochloride

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Inactive ingredients:

Lactose monohydrate, Hypromellose and
magnesium stearate

- MAL number:

MAL09062133AZ

Manufacturer

Gensentillaç Sanayi ve Ticaret A.Ş.

Sanayi Caddesi, No: 13

Yenibosna, Bahçelievler,

İstanbul/TURKEY

Product Registration Holder

MEDIDATA SDN BHD (33924-T)

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Petaling Jaya, Selangor D.E. Malaysia.

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