

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALDIZEM 60MG

Prolonged-Release Tablets

DILTIAZEM HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Aldizem is and what it is used for
2. Before you take Aldizem
3. How to take Aldizem
4. Possible side effects
5. How to store Aldizem

1. WHAT ALDIZEM IS AND WHAT IT IS USED FOR

Aldizem contains a medicine called diltiazem hydrochloride. This 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 caused by angina.

Aldizem is used for:

- Angina (chest pain)
- Stopping you getting angina in the future

2. BEFORE YOU TAKE ALDIZEM

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to diltiazem hydrochloride or any of the other ingredients of Aldizem
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You are breast-feeding or planning to breast-feed (see Section below: 'Pregnancy and breast-feeding')
- You are having a medicine called dantrolene used for severe muscle spasms or severe fever (see Section below: 'Taking other medicines')
- You have a very slow heartbeat - less than 50 beats per minute

- You have heart failure and problems with blood flow to your lungs. With these illnesses, you may feel out of breath and have swollen ankles
- You are already taking a medicine containing ivabradine for the treatment of certain heart diseases
- You have any other serious problems with your heart. This includes having an uneven heartbeat (unless you have a pacemaker)

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

Take special care with Aldizem

Check with your doctor or pharmacist before taking your medicine if:

- You have any other problem with your heart, apart from angina or those described in the previous section
- You are going to have an operation
- You are at risk of mood changes, including depression
- You are at risk of gut problems

Your doctor will check you more closely particularly when you first start taking the tablets if:

- You are over 65 years old
- You have liver or kidney problems
- You have diabetes

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because Aldizem can affect the way some other medicines work. Also some medicines can affect the way Aldizem works.

In particular, do not take this medicine and tell your doctor if you are taking:

- Dantrolene (an infusion) used for severe muscle spasms or severe fever (called 'malignant hyperthermia')
- Medicines containing ivabradine used for the treatment of certain heart diseases

Aldizem may increase the effect of the following medicines:

- Medicines for high blood pressure such as doxazosin, tamsulosin, atenolol, propranolol or acebutolol
- Medicines used for an uneven heartbeat such as amiodarone and digoxin
- Medicines used for angina such as glyceryl trinitrate or isosorbide trinitrate
- Medicines used for high levels of cholesterol such as simvastatin, fluvastatin and atorvastatin
- Ciclosporin used to stop the rejection of organs after a transplant
- Phenytoin used for epilepsy
- Aspirin used for relieving pain and reducing fever
- Iodinated contrast media (used for tests involving X-rays)
- Carbamazepine used for epilepsy
- Theophylline used for breathing problems
- Lithium used for some types of mental illness
- Medicines used for sleeplessness or anxiety, such as triazolam or midazolam
- Methylprednisolone used for inflammation and allergic reactions

Aldizem may make the following medicine work less well:

- Rifampicin used for tuberculosis

The following medicines can increase the effect of Aldizem:

- Medicines for stomach ulcers such as cimetidine and ranitidine.

Aldizem with food and drink

It is advisable to limit the amount of grapefruit juice you drink while taking Aldizem as it can increase the blood levels of the active ingredient diltiazem and may increase your chance of getting side effects. If you are concerned you should stop drinking grapefruit juice and consult your doctor.

Pregnancy and breast-feeding

- You should not take Aldizem if you are pregnant, might become pregnant or think you may be pregnant. This is because Aldizem can cause problems for your baby.

Talk to your doctor if you might be pregnant.

- Do not breast-feed if you are taking Aldizem. This is because small amounts may pass into mother's milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Driving and using machines

You may feel dizzy while taking this medicine.

If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Aldizem

Aldizem contains:

- Lactose. If you have been told by your doctor that you can not tolerate some sugars, talk to your doctor before taking this medicine.
- Hydrogenated castor oil. May cause stomach upset and diarrhoea.

3. HOW TO TAKE ALDIZEM

Always take Aldizem exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

Adults:

- The usual dose is one tablet three times a day.

If necessary, your doctor may increase this to:

- Two tablets three times a day or
- Two tablets four times a day

Over 65 years or adults with liver or kidney problems:

- The usual dose is one tablet twice a day.

Children:

Aldizem should not be given to children.

If you take more Aldizem than you should

If you take more tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling dizzy or weak, blurred vision, chest pain, shortness of breath, fainting, an unusually fast or slow heartbeat, coma, slurred speech, and confusion.

If you forget to take Aldizem

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 stop taking Aldizem

Keep taking Aldizem until your doctor tells you to stop. Do not stop taking them just because you feel better. If you stop, your illness may get worse.

Tests

Your doctor may do regular tests while you are taking this medicine. These might include a check on your heart and blood tests to check on your liver and kidneys.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aldizem can cause side effects, although not everyone gets them.

Stop taking and see a doctor or go to a hospital straight away if:

Frequency unknown

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face throat or tongue
- You have a red or lumpy skin rash, swollen eyelids, face, lips, throat, or tongue, difficulty in breathing or swallowing
- 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'
- 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 muscles. This could be an illness called Toxic 'Epidermal Necrolysis'
- You have a skin rash or skin lesions with a pink/red ring and a pale centre which may be 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'

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Common (affects less than 1 in 10 people)

- Slow or uneven heartbeat
- Very fast, uneven or forceful heartbeat (palpitations)

Frequency unknown

- Skin rash caused by narrow or blocked blood vessels (called 'vasculitis')
- Being short 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.

These can be signs of inflammation of the liver (called 'hepatitis')

- Passing large amounts of urine, excessive thirst and having a dry mouth or skin. These may be signs of high blood sugar (hyperglycemia).
- Get sunburnt easier, and which may be more severe than in someone not taking Aldizem. You should use sun protection whilst taking this medicine.
- Breast enlargement in men

Tell your doctor as soon as possible if you have any of the following side effects:

Very common (affects more than 1 in 10 people)

- Swelling of the lower legs

Common (affects less than 1 in 10 people)

- Indigestion, stomach pain, constipation, and diarrhoea

Uncommon (affects less than 1 in 100 people)

- Feeling dizzy, light-headed or faint when you stand or sit up quickly (low blood pressure)

Rare (affects less than 1 in 1000 people)

- Dry mouth
- Itchy, lumpy rash (called 'urticaria')

Frequency unknown

- Swollen gums

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Common (affects less than 1 in 10 people)

- Headache
- Flushing (feeling of warmth)
- Feeling sick (nausea) or being sick (vomiting)
- General feeling of being unwell
- Weakness or tiredness
- Feeling dizzy
- Skin redness

Uncommon (affects less than 1 in 100 people)

- Difficulty sleeping

Frequency unknown

- Mood changes, including depression
- Bleeding or bruising under the skin

Blood tests

Aldizem can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ALDIZEM

Keep out of the sight and reach of children.

Do not use Aldizem after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in 12/2015