

DILZEM®

diltiazem hydrochloride

30 mg and 60 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking DILZEM.

This leaflet answers some common questions about DILZEM. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DILZEM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DILZEM is used for

DILZEM belong to a group of medicines called calcium channel blockers. DILZEM is used to treat (long term) and prevent angina pectoris. Diltiazem acts by relaxing the muscles around the blood vessels and so relaxes and widens the blood vessels. This makes it easier for the heart to do its work and allows more blood to flow to the heart, relieving angina (chest pain due to an inadequate blood supply to the heart). DILZEM also has an effect on the heart muscle itself, helping the heart to slow down and reduce the amount of work it is doing.

Your doctor may have prescribed DILZEM for another reason. **Ask your doctor if you have any questions about why DILZEM has been prescribed for you.**

This medicine is available only with a doctor's prescription.

Before you take DILZEM

When you must not take it

Do not take DILZEM if you have an allergy to:

- any medicine containing diltiazem hydrochloride or a class of medicines called calcium channel blockers.
- any of the ingredients listed at the end of this leaflet. DILZEM 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 medicine.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing.
- shortness of breath.
- swelling of the face, tongue, lips, or other parts of the body.
- hives on the skin, rash, or itching.

Do not take DILZEM if:

- you have heart disease or changes in the electrical activity of the heart. This includes having an uneven heartbeat (unless you have a pacemaker).
- you have a very low blood pressure.
- 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 have a very slow heartbeat – less than 40 beats per minute.
- you are having a medicine called dantrolene used for severe muscle spasms or severe fever.
- you are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

This is because a small amount of the active ingredient diltiazem hydrochloride passes into breast milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Do not give this medicine to children.

The safety and effectiveness of diltiazem in children has not been established.

Do not take it after the expiry date (EXP) printed on the back.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking DILZEM, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you are at risk of mood changes, including depression.
- you suffer from constipation or a history of blockages in the bowel.
- you have heart disease or changes in the electrical activity of the heart.
- you have allergies to:
 - Any other calcium channel blockers.
 - Any other substances, such as foods, preservatives or dyes.
- you are pregnant or intend to become pregnant.
- you are breastfeeding or planning to breastfeed.

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

- have liver or kidney problems.
- have diabetes.
- have ever had asthma.
- take any beta blocker medicines.
- are over 65 years old.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking DILZEM.

Some medicines may interfere with DILZEM. These include:

- beta-blockers such as metoprolol, propranolol, atenolol – medicines used to treat disorders of the heart and blood vessels such as high blood pressure, angina and cardiac arrhythmia.
- amiodarone and digoxin – medicines for an uneven heartbeat.
- dantrolene – medicine used for muscle spasms or severe fever.
- ivabradine used for the treatment of certain heart diseases.
- ciclosporin used to suppress the immune system.
- medicines for high blood pressure such as doxazosin, prazosin, tamsulosin, terazosin.
- rifampicin used to treat tuberculosis.
- methylprednisolone used for inflammation
- diazepam or triazolam or midazolam – medicines used for sleeplessness or anxiety.
- cimetidine and ranitidine – medicines for stomach ulcers.
- carbamazepine or phenytoin used for epilepsy.
- lithium used for some types of mental illness.
- theophylline used for breathing problems.
- glyceryl trinitrate or isosorbide trinitrate – medicines used for angina.
- simvastatin, atorvastatin – medicines used for high levels of cholesterol.
- aspirin
- medicines used to help prevent blood clots (antiplatelets)
- iodinated contrast media – used for tests involving x-rays.

- cilostazol used for intermittent cramp-like pain in your legs when you walk caused by insufficient blood supply in your legs.
- grapefruit juice – see *How to take DILZEM* section for further information.

These medicines or agents may be affected by DILZEM or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DILZEM.

How to take DILZEM

How much to take

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor will decide on the best dose for you taken in divided doses.

How to take it

DILZEM tablets should be taken with a full glass of water before meals as instructed by your doctor or pharmacist.

It is advisable to limit the amount of grapefruit juice you drink while taking DILZEM tablets 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.

When to take it

Take DILZEM before a meal, at about the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps you control your condition but does not cure it. Therefore, you must take it every day.

If you forget to take it

If you forget to take a dose, take one as soon as you remember. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking DILZEM

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking DILZEM.

If you are going to have surgery/general anaesthetic, tell the surgeon or anaesthetist that you are taking this medicine.

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

Things you must not do

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

Do not stop taking DILZEM or lower the dosage, without checking with your doctor. Your doctor may want you to gradually reduce the amount you are using before stopping completely. This may help reduce the possibility of withdrawal symptoms such as severe angina.

Things to be careful of

Be careful driving or operating machinery until you know how DILZEM affects you. It may cause dizziness or tiredness in some people, therefore make sure you know how you react to it before you drive a car, operate machinery, or do

anything else that could be dangerous if you feel dizzy or tired.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital if you think that you or anyone else may have taken too much DILZEM.

Do this even if there are no signs of discomfort or poisoning. An overdose may lead to severe low blood pressure leading to collapse, and a slow heartbeat which may be accompanied by changes in heart rhythm and conduction. You may need urgent medical attention.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

If you are over 65 years of age you may have an increased chance of getting side effects and therefore your doctor may adjust your dose accordingly.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Feeling dizzy, light-headed or faint when you stand or sit up quickly.
- weakness; tiredness.
- headache; nasal congestion
- indigestion; stomach pain; constipation.

- swelling of the lower legs; flushing (feeling hot suddenly)
- abnormal dreams; trouble sleeping.
- increased sensitivity to the sun.
- ringing or other persistent noise in the ears
- eye irritation.
- sexual difficulties.

Tell your doctor as soon as possible if you notice any of the following symptoms:

- slow or very fast; uneven or forceful heartbeat (palpitations).
- being short of breath, feeling tired along with swollen ankles and legs.
- high temperature, feeling tired, loss of appetite, stomach pain, feeling sick.
- passing large amounts of urine, excessive thirst and having a dry mouth or skin.
- loss of memory; hallucinations; mental depression.

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

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing; hives; fainting.
- you have difficulty breathing, wheezing, tightness in the chest.
- you get blistering or bleeding or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever.
- 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 are very serious side effects. If you have them, you may have had a serious allergic reaction to DILZEM. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After taking DILZEM

Storage

Keep your tablets in the bottle or blister pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Do not store DILZEM in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

DILZEM 30 mg Tablet is a white, circular, film-coated, biconvex tablet of approximately 6mm diameter embossed "D" one side.

DILZEM 60 mg Tablet is a white capsule shaped, film-coated tablet, 10mm in length and 5mm wide; with a breakline and 'DL60' engraved on one face.

DILZEM 30 mg & 60 mg tablets come in bottles of 100 tablets or blister packs of 30 tablets.

Not all strengths or pack sizes may be marketed.

Ingredients

Active ingredient:

Diltiazem hydrochloride

Other ingredients:

Aluminium hydroxide gel; hydrogenated castor oil; lactose monohydrate; magnesium stearate; methacrylic acid copolymer; opadry white Y-1R-7000B; purified talc

Sponsor details

DILZEM is supplied in New Zealand by:

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13 August 2020

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