

Package leaflet: Information for the user

DILZEM® XL 120 mg, 180 mg, 240 mg Prolonged-release Hard Capsules (Diltiazem hydrochloride)

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. 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 DILZEM XL is and what it is used for.
2. What you need to know before you take DILZEM XL.
3. How to take DILZEM XL.
4. Possible side effects.
5. How to store DILZEM XL.
6. Contents of the pack and other information.

1. What DILZEM XL is and what it is used for

DILZEM XL contains the active ingredient, diltiazem hydrochloride.

Diltiazem hydrochloride belongs to a group of medicines called calcium channel blockers (which interfere with the movement of calcium in heart muscle cells). These medicines work to lower blood pressure and ease anginal chest pain by preventing the narrowing of blood vessels.

DILZEM XL is designed to release the active ingredient, diltiazem hydrochloride, in a controlled manner throughout the whole day so that blood pressure and angina are treated for a full 24 hour period.

DILZEM XL is used to treat and control mild to moderately high blood pressure and to prevent and treat chest pain (angina pectoris) due to the narrowing of blood vessels in the heart, which is brought on by exercise.

2. What you need to know before you take DILZEM XL

Do not take DILZEM XL:

- if you are allergic to diltiazem hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman able to have children and not using contraception.
- if you are pregnant or think you may be pregnant or are breast-feeding.
- if you are currently in shock (reduced blood flow to vital organs).
- if you suffer from any serious heart problems such as heart failure with shortness of breath, a markedly slow heartbeat abnormal heart rhythm which may result in palpitation and do not have a pacemaker..
- if you have had a complicated heart attack.
- if you have a very low pulse rate or low blood pressure.
-
- if you are currently receiving an infusion of a muscle relaxant called dantrolene (this is only given in hospitals).
- if you are taking a medicine containing ivabradine for the treatment of certain heart diseases

Warnings and precautions

Talk to your doctor or pharmacist before taking DILZEM XL:

- if you have diabetes.
- if you have any liver or kidney problems or if you are 65 or over.
- if you have any heart problems, such as heart failure with shortness of breath, low pulse rate, abnormal heart rhythm which may result in palpitation.
- if you have a rare disease of the blood pigment called “porphyria”, or anyone in your family has it.
- if you have myasthenia gravis (a nervous condition which causes muscle weakness).
- if you suffer from constipation.

In some patients this medicine has caused mood changes, including depression. If you think you are affected in this way talk to you doctor.

If any of the above apply to you, please tell your doctor or pharmacist before taking DILZEM XL.

Children

This medicine is not recommended for use in children.

Other medicines and DILZEM XL

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

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

- Statins e.g. Simvastatin, or atorvastatin (used to treat high cholesterol)
- Lithium (used to treat mental health problems such as depression and manic disorder)
- Warfarin (used to thin the blood)
- Nitrate derivatives (usually used to treat angina or heart disease such as glyceryl trinitrate, isosorbide dinitrate)
- Theophylline (used to treat asthma or breathing problems)
- Alpha-blockers used to treat high blood pressure (such as hytrin and doxazosin). If you are taking Alpha-blockers your doctor should strictly monitor your blood pressure.
- Any medicine used to treat heart problems, including beta-blockers (such as propranolol), amiodarone or digoxin. If you are taking beta-blockers your doctor will monitor your heart rate at the beginning of treatment
- Methyldopa, nifedipine, diuretics ‘water tablets’ (such as bendrofluazide), ACE inhibitors (such as enalapril), or any other medicines used to treat high blood pressure
- Phenobarbital or carbamazepine (used to treat epilepsy, fits and stabilisation of mood) or rifampicin (used to treat bacterial infections and tuberculosis) Blood levels of carbamazepine may be raised in combination with DILZEM XL.
- Cimetidine or ranitidine (medicines used to treat stomach problems)
- Ciclosporin (which works by suppressing the body’s immune or defence system used to prevent your body from rejecting skin grafts, transplanted organs or bone marrow)
- Benzodiazepines (midazolam, triazolam) used for the treatment of mental illness
- Methylprednisolone (a corticosteroid-a hormone used to treat different types of diseases.)
- Any medicine which affects contractility of your heart muscle
- Ivabradine (for the treatment of certain heart diseases)
- Beta-blockers as it may lead to increased risk of depression.

If you are due to have surgery, or visit your dentist, tell the doctor or dentist that you are taking DILZEM XL as it may interact with anaesthetics and the effect of the anaesthetics on the function of your heart may be increased by DILZEM XL..

Pregnancy and breast-feeding

Do not take DILZEM XL if you are pregnant, think you may be pregnant, or if you are breast-feeding.

Driving and using machines

DILZEM XL should not affect your ability to drive or use machines. However, if you feel faint or dizzy, do not drive or operate any machines.

DILZEM XL contains sucrose

DILZEM XL contains sucrose. If you have been told that you have an intolerance to some sugars, contact your doctor before taking DILZEM XL.

3. How to take DILZEM XL

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

The recommended dose for adults is one 180 mg capsule a day.

Always swallow the capsules whole with water.

Do not suck or chew the capsule or remove the contents as this will affect the special release properties of the product.

Your doctor may increase the dose of DILZEM XL, depending on your response to the drug.

Elderly patients and those with kidney or liver problems may be started on a lower dose of 120 mg a day.

DILZEM XL is not recommended for children.

If you take more DILZEM XL than you should

If you accidentally take too many DILZEM XL capsules, tell your doctor immediately or go to the nearest hospital accident and emergency department. An overdose is likely to cause severe low blood pressure, collapse, and slow heart rate. Take along any capsules that are left, the container and this leaflet so that the hospital staff can easily tell what medicine you have taken.

If you forget to take DILZEM XL

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose (up to eight hours before), do not take the missed dose but take your next dose at your normal time.

Do not take a double dose to make up for the forgotten one.

If you stop taking DILZEM XL

Do NOT stop taking your medicine without talking to your doctor first even if you feel better.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following, **stop taking** DILZEM XL and contact your doctor **immediately** or go to the casualty department at your nearest hospital::

- An allergic reaction. The signs include: a red or lumpy rash, swallowing or breathing problems, swelling of the face, throat, lips, tongue or glands, sore throat and fever. This is a very serious side effect. You may need urgent medical attention or hospitalisation.
- Blistering or peeling of the skin around the lips, eyes, skin rash, blistering affecting the skin, mouth, eyes, genitals or anus, flu-like symptoms of fever. This could be an illness called “Stevens-Johnson syndrome”.

- 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, have a fever, chills or aching muscles. This could be an illness called “Toxic Epidermal Necrolysis”.
- Difficulty controlling movements and restlessness. This could be an illness called “Extrapyramidal syndrome”.

It is not known how often these side effects happen.

If you notice any of the following, **stop taking** DILZEM XL and contact your doctor **immediately**:

- Darkening of your urine.
- Pale stools.
- Yellowing of your skin or eyes.

As these may be signs of liver problems.

Other side effects include:

Very common (affects more than 1 in 10 people);

- Swelling of the ankles, feet or fingers

Common (affects less than 1 in 10 people)

- Headache, dizziness
- A heart problem called “atrioventricular block”, palpitations (feeling your heart beat)
- Flushing (Red face and redness of skin)
- Constipation, indigestion, chest pain due to stomach acidity, stomach pain, feeling sick (nausea)
- Oedema (swelling due to excess fluids), feeling of weakness, tiredness
- A heart problem called “atrioventricular block” (heart block), palpitations (abnormal or irregular heart beat).
- Rapid and irregular heart beat (Palpitation)
- Abdominal pain
- Feeling general discomfort.

Uncommon (affects less than 1 in 100 people)

- Nervousness, difficulty in sleeping
- Bradycardia (abnormally slow heart beat)
- Low blood pressure
- A fall in blood pressure on standing up which causes dizziness, light-headedness or fainting)
- Vomiting (being sick), diarrhoea
- Blood tests which show changes in the way the liver is working

Rare (affects less than 1 in 1000 people)

- Dry mouth, hives (lumpy, red, itchy skin)

Side effects with frequency not known:

- An allergic skin reaction
- Mood changes (including depression), change in personality
- Seeing, feeling or hearing things that are not there (hallucinations)
- Reduction in blood platelets, which increases risk of bleeding or bruising, high levels of white blood cells called eosinophils
- Shortness of breath or chest pains (angina)
- Feeling unsteady on your feet, fainting, memory loss, tingling or numbness, sleepiness, shaking
- A disease of the blood vessels called vasculitis (inflammation of the blood vessels, often with skin rash. Other symptoms of this may include: red face, headache, swollen lower limbs, weight loss, fever, red spots on skin, aching joints, mouth ulcer, abdominal pain, breathing difficulty.)
- Heart failure (Heart problems which can cause shortness of breath or ankle swelling)
- Leukocytoclastic Vasculitis. Symptoms of this may include: blisters on the skin, bleeding into the skin, small solid raised hives on skin etc
- Swollen, enlarged or bleeding gums
- Increased sensitivity to sunlight

- Red or brown lesions at sun exposed skin areas
- Sweating
- Swelling of the lymph nodes
- Swelling of breast tissue in men, loss of ability to have, or loss of interest in sex
- Lazy eye, eye irritation
- Nose bleed, blocked nose
- Loss of appetite, increased blood sugar levels
- Weight gain
- Increase of something called Creatine-Kinase (CK) in your blood, which may be a sign of muscle damage
- Increased need to pass urine or an increased volume of urine, especially at night
- Muscle weakness or pain in muscles, bones or joints
- Ringing or buzzing in the ears
- Widespread red, itchy and scaly skin
- Fever.
- Serious illness with blistering of the skin, mouth, eyes and genitals
- Serious illness with skin cell death
- Serious illness with detachment of top layer of skin from the lower layer

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DILZEM XL

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strips after EXP. The expiry date refers to the last day of that month.

If your doctor tells you to stop your treatment, return any left over capsules to the pharmacist.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What DILZEM XL contains

- The active substance is diltiazem hydrochloride.
- Each DILZEM XL capsule contains 120 mg, 180 mg or 240 mg of the active ingredient diltiazem hydrochloride.
- The other ingredients are: fumaric acid, talc, povidone, sugar spheres (containing sucrose and maize starch), ammonio methacrylate copolymer Type A, ammonio methacrylate copolymer Type B. The capsule shell contains gelatin, titanium dioxide (E171), black iron oxide (E172), shellac and propylene glycol (E1520).

What DILZEM XL looks like and contents of the pack

DILZEM XL capsules are white coloured capsules printed with e120, e180 or e240. They are supplied in blister packs of 28 capsules.

Marketing Authorisation Holder

Cephalon UK Limited,
Ridings Point,

Whistler Drive,
Castleford,
West Yorkshire,
WF10 5HX,
UK

Manufacturer

Alkermes Pharma Ireland Limited,
Monksland,
Athlone,
Co. Westmeath,
Ireland.

OR

TEVA UK LIMITED,
Brampton Road, Hampden Park, Eastbourne
East Sussex, BN22 9AG
United Kingdom

This leaflet was last revised in December 2020.