

PATIENT INFORMATION LEAFLET

DILTIAZEM HYDROCHLORIDE 60MG MODIFIED RELEASE TABLETS

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. See section 4.

In this leaflet:

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

1. What is diltiazem hydrochloride and what it is used for

- Diltiazem Hydrochloride is one of a group of medicines called calcium antagonists
- This medicine is for the prevention and treatment of angina pectoris (a heart problem) and to treat mild to moderate hypertension
- It works by reducing the amount of oxygen used by the heart muscle and increasing the ability to exercise

2. What you need to know before you take diltiazem hydrochloride

Do not take this medicine if you:

- are hypersensitive (allergic) to Diltiazem Hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- have marked bradycardia (a very slow heart rate)
- have sick sinus syndrome (a disorder of the heartbeat)
- have left ventricular failure (heart failure)
- have severe hypotension (low blood pressure)
- have second or third degree heart block (unless you have a working pacemaker fitted). If you have heart block, certain parts of the heart may beat at the wrong rate and, therefore, the heart does not pump the blood around your body well
- are being treated with dantrolene infusion (for severe muscle spasm)
- have an inherited disorder of the red blood pigment haemoglobin, causing skin blisters, abdominal pain and nervous system disorders (porphyria)
- are pregnant or are a woman of child bearing age
- are breast-feeding or planning to breast-feed

Warnings and precautions

Talk to your doctor or pharmacist before taking these tablets if you have:

- impaired **liver** function
- impaired **kidney** function
- **at risk of mood changes, including depression**
- are likely to have surgery which requires a general **anaesthetic**
- problems with your **stomach** or **intestines**
- **heart** problems apart from angina or the conditions described in the previous section
- **diabetes:** The treatment for your diabetes may need to be adjusted, as Diltiazem Hydrochloride tablets may impair glucose tolerance
- You have or ever had asthma
- You take any beta blocker medicines

Other medicines and Diltiazem Hydrochloride

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

- dantrolene given as an infusion for severe muscle spasms or severe fever
- medicines used to treat high blood pressure such as prazosin, hydralazine, minoxidil, nitroprusside, doxazosin, tamsulosin, atenolol, propranolol or acebutolol
- diuretics (water tablets, used in the treatment of hypertension, heart failure and liver or renal failure)

- antiarrhythmic drugs such as digoxin and amiodarone (used to treat an irregular heart beat)
- medicines such as ivabradine, glyceryl trinitrate or isosorbide trinitrate used to treat angina
- phenobarbital, phenytoin, primidone and carbamazepine (to treat epilepsy)
- ciclosporin, sirolimus and tacrolimus (used to suppress immune system)
- theophylline (used in breathing problems)
- lithium (used for mental health problems)
- midazolam or triazolam (used for sedation and anaesthesia)
- imipramine and other tricyclic antidepressants (used for depression)
- antipsychotics
- rifampicin (to treat tuberculosis)
- ranitidine and cimetidine used to treat stomach ulcers
- statins such as simvastatin, fluvastatin and atorvastatin (used to treat high cholesterol)
- methylprednisolone used to treat inflammation and allergic reactions
- levodopa to treat Parkinsons disease
- dutasteride used to treat an enlarged prostate gland
- baclofen and tizanidine used as muscle relaxants
- oestrogens used in hormone replacement therapy
- corticosteroids (to treat inflammation)
- carbenoxolone (to treat oesophageal ulceration and inflammation)
- asunaprevir used for the treatment of hepatitis C virus infection. Diltiazem may increase the concentration of the asunaprevir that may lead to an increase in the likelihood and severity of liver related side effects
- Antiplatelet medicines used to reduce the chance of blood clots forming, such as aspirin or clopidogrel.

Your doctor will be able to tell you which drugs you can take together.

If you are about to have an operation, tell the hospital staff that you are taking this medicine.

Treatment has been continued without problems in patients who have undergone an anaesthetic.

Pregnancy and breast-feeding

Do not take Diltiazem Hydrochloride tablets if you are pregnant, planning to become pregnant, are a woman of child bearing age or if you are breast feeding; this is because small amounts may pass into mother's milk. Speak to your doctor before taking any medicine.

Driving and using machines

Diltiazem tablets may cause dizziness or tiredness, therefore make sure you are not affected before driving or operating machinery.

Diltiazem Hydrochloride contains lactose and castor oil

Lactose - If a doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

Castor oil – may cause stomach upset and diarrhoea

Diltiazem Hydrochloride with food and drink

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

Tests

If you have impaired kidney or liver function, your doctor may want to monitor you by carrying out blood tests.

3. How to take diltiazem hydrochloride

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

The tablets should be swallowed whole with a glass of water. The exact dosage should be as directed by your doctor. Generally, the dose is one tablet three times daily.

For the elderly with liver or kidney problems, a dose of 60mg twice daily with monitoring of heart rate is recommended.

If necessary your doctor may increase the dose to:

- Two tablets (120mg) three times a day (360mg)
- Two tablets (120mg) four times a day (480mg)

Keep taking your medicine until your doctor tells you to stop.

This product is not recommended for children.

Your doctor may want to do regular checks on your blood, heart, liver and kidneys while taking this medicine.

If you take more tablets than you should

If you or anyone else has taken too many tablets, contact your nearest hospital casualty department or tell your doctor immediately. Take the container and any remaining tablets with you. An overdose may lead to severe low blood pressure leading to collapse, and a slow heart beat which may be accompanied by changes in heart rhythm and conduction. Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take Diltiazem Hydrochloride tablets

If you forget to take a dose, take the missed dose as soon as you remember and then go on as before. Do not take two doses at the same time to make up for a forgotten dose.

If you stop taking these tablets

If you suddenly stop taking this medicine it may cause the symptoms to come back so always follow your doctor's instructions carefully.

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

4. Possible side effects

Like all medicines, Diltiazem Hydrochloride 60mg Modified Release Tablets may cause side effects, although not everybody gets them.

Stop taking this medicine and contact your doctor or pharmacist immediately if:

- You have an allergic reaction. The signs include rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue.
- 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 where large areas of skin peel away leaving exposed areas of raw 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 lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. This may appear on the palms or on soles of the feet. This could be a sign of a condition called "erythema multiforme"
- Your asthma gets worse
- You have difficulty breathing, wheezing, tightness in the chest (called 'bronchospasm').

Tell your doctor straight away if you experience any of the following as you may need urgent medical treatment:

Common (may affect up to 1 in 10 people):

- slow or uneven heartbeat
- very fast, uneven or forceful heartbeat (palpitations)

Not known (frequency cannot be estimated from the available data):

- skin rash caused by narrow or blocked blood vessels (vasculitis)
- shortness of breath, feeling tired with swollen legs and ankles, this could be a sign of heart failure
- unusual movements of the tongue, muscle spasms of the 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 (hepatitis)
- passing large amounts of urine, excessive thirst and having a dry mouth or skin. These may be signs of high blood sugar (hyperglycemia)
- breast enlargement in men
- get sunburnt easier, and which may be more severe than in someone not taking Diltiazem Hydrochloride. You should use sun protection whilst taking this medicine

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

Very common (may affect more than 1 in 10 people):

- swelling of the lower limbs

Common (may affect up to 1 in 10 people):

- indigestion, stomach pain, constipation, diarrhoea

Uncommon (may affect up to 1 in 100 people):

- feeling dizzy, light-headed or faint when standing or sitting up quickly (low blood pressure)

Rare (may affect up to 1 in 1,000 people):

- dry mouth
- itchy, lumpy rash (urticaria)

Not known (frequency cannot be estimated from the available data):

- swollen gums
- a condition in which the body's defence system attacks normal tissue causing symptoms such as swollen joints, tiredness and rashes (called 'lupus-like syndrome')

Other side effects below have been reported. Tell your doctor or pharmacist if any of the following side effects get serious:

Common (may affect up to 1 in 10 people):

- headache
- flushing
- feeling sick (nausea) or being sick (vomiting)
- general feeling of being unwell
- weakness or tiredness
- feeling dizzy
- skin redness

Uncommon (may affect up to 1 in 100 people):

- difficulty sleeping

Frequency unknown (frequency cannot be estimated from the available data):

- mood changes
- bleeding or bruising under the skin
- rash that may occur on the skin or sores in the mouth (Lichenoid drug eruption)

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 at: 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 diltiazem hydrochloride

- Keep all medicines out of the sight and reach of children.
- Do not use any medicine after the expiry date printed after "EXP" on the carton and blister pack. The expiry date refers to the last day of that month.
- Keep your medicine below 25°C in a dry place.

Do not throw away any medicines via wastewater or household waste. 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 Diltiazem Hydrochloride contains

- The active substance is diltiazem hydrochloride. Each tablet contains 60mg of Diltiazem Hydrochloride in a modified release formulation.
- The other ingredients are: lactose monohydrate, hydrogenated castor oil, polyethylene glycol 6000, magnesium stearate. See end of section 2 for further information on lactose and castor oil.

What Diltiazem Hydrochloride look like and contents of the pack

- Diltiazem Hydrochloride tablets are off-white, engraved 'DTZ 60' on one side and 'PV' on the reverse.
- Pack sizes of the tablets are 28, 30, 56, 60, 84, 100 or 500 tablets in blister packs. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Product licence number: PL 04556/0059

Reference: 00590924/04

This leaflet was last revised in September 2024

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