

Diltiazem Hydrochloride 60mg tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any of the side effects or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- 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 symptoms are the same as yours.

In this leaflet:

- 1 What Diltiazem Hydrochloride tablets are and what they are used for**
- 2 Before you take Diltiazem Hydrochloride tablets**
- 3 How to take Diltiazem Hydrochloride tablets**
- 4 Possible side effects**
- 5 How to store Diltiazem Hydrochloride tablets**
- 6 Further information**

1 What Diltiazem Hydrochloride tablets are and what they are used for

Diltiazem Hydrochloride tablets belong to a group of medicines called calcium channel blockers. Diltiazem Hydrochloride tablets are used to:

- treat (long-term) and prevent angina pectoris
- treat mild to moderate high blood pressure.

2 Before you take Diltiazem Hydrochloride tablets

Do not take Diltiazem Hydrochloride tablets if you

- are **allergic** (hypersensitive) to diltiazem hydrochloride or any of the other ingredients in Diltiazem Hydrochloride tablets (see section 6).
- are **pregnant** or are a woman of **child bearing age**.
- have severe **low blood pressure**.
- have a **heart** condition such as; a severe slow heart beat (bradycardia), disturbances in heart rhythm causing palpitations or fainting (sick sinus syndrome) not requiring a pacemaker, heart failure with reduced blood flow, congestive heart failure, second or third degree heart block without a functioning pacemaker, narrowing of the opening of the aortic valve in the heart (aortic stenosis), shock caused by heart problems (cardiogenic shock),

- have an inherited disorder of the red blood pigment haemoglobin, causing skin blisters, abdominal pain and nervous system disorders (**porphyria**).

Check with your doctor or pharmacist before taking Diltiazem Hydrochloride tablets if you have

- impaired **liver** function.
- impaired **kidney** function
- **depression**
- are likely to have surgery which requires a general **anaesthetic**
- problems with your **stomach** or **intestines**
- **heart** problems including a slow heart beat, first degree heart block, a change in the electrical activity of the heart (prolonged PR interval).
- **diabetes**. The treatment for your diabetes may need to be adjusted, as Diltiazem Hydrochloride tablets may impair glucose tolerance.

Taking other medicines

Please **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 amiodarone (used to treat an irregular heart beat)
- ACE inhibitors e.g. lisinopril
- aldesleukin (used in some cancers)
- antihypertensives (used to lower blood pressure)
- antipsychotics
- lithium (used for mental health problems)
- 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 antagonists e.g. cimetidine (used to treat conditions caused by excess acid such as stomach ulcers)
- diuretics (water tablets)
- alpha blockers such as prazosin
- anaesthetics
- statins, e.g. simvastatin (used to treat high cholesterol)
- corticosteroids (used to treat inflammation).

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. 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.

Sugar intolerance

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.

Tests

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

3 How to take

Always take Diltiazem Hydrochloride tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Usual doses

Adult

The maintenance dose is one tablet (60mg) three times a day. Up to 8 tablets (480mg) a day may be used. Your doctor will decide on the best dose for you.

Elderly and those with impaired kidney function

Initially one tablet (60mg) twice a day. Your doctor may adjust the dose according to your response.

Children

Not recommended.

Taking the tablets

- Swallow the tablets whole with a little water.
- After all the drug has been released from the tablet, the empty shell may pass into the stools. This is normal and does not affect the action of the product.

If you take more Diltiazem Hydrochloride tablets than you should

Do not take more tablets than your doctor tells you to. If you take too many go to the nearest hospital casualty department or tell your doctor at once. 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.

If you forget to take Diltiazem Hydrochloride tablets

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

4 Possible side effects

Like all medicines, Diltiazem Hydrochloride tablets may cause side effects, although not everyone gets them.

Contact your doctor at once, if you have an allergic reaction such as swelling of the face, lips, tongue, mouth or throat, which may cause shortness of breath or difficulty swallowing.

Tell your doctor if you notice any of the following side effects.

Very common (occurs in more than 1 in 10 users): water retention causing swelling.

Common (occurs in less than 1 in 10 users): headache, dizziness, heart block, palpitations, flushing, constipation, indigestion, stomach pain, feeling sick, skin redness, feeling of general discomfort or illness.

Uncommon (occurs in less than 1 in 100 users): nervousness, difficulty sleeping, slow heart beat, feeling faint when getting up due to low blood pressure, being sick, diarrhoea, increase in liver enzymes (as seen in blood tests).

Rare (occurs in less than 1 in 1,000 users): dry mouth, itchy skin rash with pale or red irregular raised patches.

Not known: lowered number of platelets in the blood (as seen in blood tests), changes in mood (including depression), inflammation of the liver causing yellowing of the skin or eyes (hepatitis), heart failure, inflammation of the blood vessels, enlargement of the gums, sensitivity to light, sweating, enlarged breasts in men, tremor, slurred speech, restlessness, muscle spasm of neck, shoulders and body, anxiety, distress (extrapyramidal syndrome).

Rash and other severe skin reactions including - circular, severe skin rash (toxic epidermal necrolysis), severe form of skin rash with flushing, fever, blisters or ulcers (Steven-Johnson's syndrome), inflammation and scaling of skin (exfoliative dermatitis), irregular red patches of the skin of the hands and arms (erythema multiforme), boil-like inflammation of the skin (exanthematous pustulosis).

If you have any of the side effects, they get worse, or if you notice any side effects not listed, please tell your doctor or pharmacist.

5 How to store Diltiazem Hydrochloride tablets

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in the original container.

Keep the container tightly closed.

Do not use Diltiazem Hydrochloride tablets after the expiry date stated on the label/carton/bottle.

The expiry date refers to the last day of that month.

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.

6 Further information

What Diltiazem Hydrochloride tablets contain

- the active substance (the ingredient that makes the tablets work) is diltiazem hydrochloride. Each tablet contains 60mg of the active substance.
- the other ingredients are castor oil, lactose, magnesium stearate, polyethylene glycol.

What Diltiazem Hydrochloride tablets look like and contents of the pack

Diltiazem Hydrochloride tablets are white, uncoated, modified-release tablets.

Pack size is 84 and 100.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in – January 2011

