Diltiazem Hydrochloride 60mg 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, pharmacist or nurse.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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. Diltiazem Hydrochloride tablets and what they are used for
2. What you need to know 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. Contents of the pack and other information

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.

What you need to know 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, are a woman of child-bearing age or you are breast-feeding.
- 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).
- are already taking a medicine containing ivabradine for the treatment of certain heart diseases

Non-printing columns

Warnings and precautions

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

Other medicines and Diltiazem Hydrochloride tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:
- dantrolene infusion (a muscle relaxant)
- antithyroid drugs such as amiodarone (used to treat an irregular heart beat). 
- antihypertensives (used to lower blood pressure).
- lithium (used for mental health problems).
- nitrates such as glyceryl trinitrate or isosorbide mononitrate (used to treat angina).
- midazolam or triazolam (used for sedation and anaesthesia).
- rifampicin (used to treat tuberculosis).
- irinotecan and other topotecan antitumour agents (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).
- digoxin (used for 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.
- immunosuppressants.
- aspirin or clopidogrel (anti platelet medicines used to reduce the chance of blood clots forming).
- corticosteroids (used to treat inflammation).

Pregnancy, breast-feeding and fertility

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.
Diltiazem Hydrochloride tablets contain 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.

Diltiazem Hydrochloride tablets contain hydrogenated castor oil
Hydrogenated castor oil may cause stomach upset and diarrhoea.

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

3 How to take Diltiazem Hydrochloride tablets
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:
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.

Use in 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 a double dose to make up for a forgotten dose.

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

4 Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody 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: may affect up to 1 in 10 people:
• headache, dizziness, heart block, palpitations, flushing, constipation, indigestion, stomach pain, feeling sick, skin rash, red patches of the skin of the hands and arms, 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).

Common: may affect up to 1 in 100 people:
• dry mouth, itchy skin rash, nervousness, difficulty sleeping, slow heart beat, feeling faint when getting up due to low blood pressure, being sick, diarrhoea, increase in liver enzymes, heart failure, heart attack, inflammation of the blood vessels, enlargement of the gums, sensitivity to light, sweating, enlarged breasts in men, tremor, slurred speech, redness, muscle spasm of neck, shoulders and body, anxiety, distress (Steven-Johnsons syndrome).

Uncommon: may affect up to 1 in 1000 people:
• nervousness, difficulty sleeping, slow heart beat, feeling faint when getting up due to low blood pressure, being sick, diarrhoea, increase in liver enzymes.

Rare: may affect up to 1 in 10,000 people:
• dry mouth, itchy skin rash, nervousness, difficulty sleeping, slow heart beat, feeling faint when getting up due to low blood pressure, being sick, diarrhoea, increase in liver enzymes.

Not known: frequency cannot be estimated from the available data:
• 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, heart attack, inflammation of the blood vessels, enlargement of the gums, sensitivity to light, sweating, enlarged breasts in men, tremor, slurred speech, redness, muscle spasm of neck, shoulders and body, anxiety, distress (Steven-Johnsons syndrome).

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

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 tablets
Keep out of the sight and reach 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/bottle.
The expiry date refers to the last day of that month.
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 protect the environment.

6 Contents of the pack and other 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.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in May 2018

Continued top of front column
50949142 BBBA2095

Diltiazem Hydrochloride Tablets 60mg x 84s (UK)
JDE No.: 50949142
Dimensions: 130x210 (Reel Fed)
Component: Leaflet for Bottles
Pharmacode: 1999
Date sent: 22/05/18
Technologically Approved