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Ennogen

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diltiazem hydrochloride 60mg modified-release tablets

(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, 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 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 Diltiazem hydrochloride 60mg modified-release tablets are and what they are used for
2. What you need to know before you take Diltiazem hydrochloride 60mg modified-release tablets
3. How to take Diltiazem hydrochloride 60mg modified-release tablets
4. Possible side effects
5. How to store Diltiazem hydrochloride 60mg modified-release tablets
6. Contents of the pack and other information

1. WHAT DILTIAZEM HYDROCHLORIDE 60MG MODIFIED-RELEASE TABLETS ARE AND WHAT THEY ARE USED FOR

Diltiazem hydrochloride 60mg modified-release tablets contain the active substance diltiazem hydrochloride. It belongs to a group of medicines called calcium channel blockers. It works by making your blood vessels wider, which makes it easier for your heart to pump blood around the body. This helps to prevent the chest pain caused by angina.

Diltiazem hydrochloride 60mg modified-release tablets is used for:
- Angina (chest pain)
- Stopping you getting angina in the future.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DILTIAZEM HYDROCHLORIDE 60MG MODIFIED-RELEASE TABLETS

Do not take Diltiazem hydrochloride 60mg modified-release tablets if you:
- Are allergic to diltiazem hydrochloride or any of the other ingredients of this medicine (listed in section 6) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Are breast-feeding or planning to breast-feed (see section: 'Pregnancy and breast-feeding')
- Are taking a medicine called dantrolene used for severe muscle spasms or severe fever (see “Other medicines and Diltiazem hydrochloride 60mg modified-release tablets”)
- Have a very slow heartbeat - less than 50 beats per minute
- Have heart failure and problems with blood flow to your lungs. With these illnesses, you may feel out of breath and have swollen ankles
- Have any other serious problems with your heart. This includes having an uneven heartbeat (unless you have a pacemaker)
- Are already taking a medicine containing ivabradine for the treatment of certain heart diseases.
- Are already taking a medicine containing lomitapide used for the treatment of high cholesterol levels. (see section: 'Other medicines and Diltiazem hydrochloride 60mg modified-release tablets).
- Are already taking a medicine containing asunaprevir used for the treatment of hepatitis C virus infection. (see section: 'Other medicines and Diltiazem hydrochloride 60mg modified-release tablets).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Diltiazem hydrochloride 60mg modified-release tablets if you:
- Have a history of heart failure, new shortness of breath, slow heartbeat or low blood pressure. As cases of kidney injury in patients with such conditions have been reported, your doctor may need to monitor your kidney function.
- Have any other problem with your heart, apart from angina or those described in the previous section
- Are going to have an operation
- Are at risk of mood changes, including depression
- Are at risk of gut problems.
- Are taking blood thinners such as direct acting oral anti-coagulants (example: dabigatran, rivaroxaban, apixaban) along with Diltiazem hydrochloride 60mg modified-release tablets.

Your doctor will check you more closely particularly when you first start taking the tablets if you:
- Are over 65 years old
- Have liver or kidney problems
- Have diabetes
- Have or ever had asthma
- Take any beta blocker medicines.

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

Other medicines and Diltiazem hydrochloride 60mg modified-release tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Diltiazem hydrochloride 60mg modified-release tablets can affect the way some other medicines work. Also some medicines can affect the way Diltiazem hydrochloride 60mg modified-release tablets works.

Diltiazem hydrochloride 60mg modified-release tablets may lead to increase in level of Colchicine (drug used to treat gout) when administered concomitantly.

Diltiazem hydrochloride 60mg modified-release tablets may lead to increased risk of bleeding if taken along with blood thinners such as direct acting oral anti-coagulants (example: dabigatran, rivaroxaban, apixaban).

Diltiazem hydrochloride 60mg modified-release tablets may lead to QT prolongation (ECG changes such as changes in heart rate, rhythm along with symptoms of dizziness), when administered along with drugs with the potential/known for prolonging the QT interval.

In particular, do not take this medicine and tell your doctor if you are taking:
- Dantrolene (an infusion) used for severe muscle spasms or severe fever (called 'malignant hyperthermia')
- Medicines containing ivabradine used for the treatment of certain heart diseases.
- Medicines containing lomitapide used for the treatment of high cholesterol levels. Diltiazem may increase the concentration of the lomitapide that may lead to an increase in the likelihood and severity of liver related side effects.
- Medicines containing 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.

Diltiazem hydrochloride 60mg modified-release tablets may increase the effect of the following medicines:
- Medicines for high blood pressure such as doxazosin, tamsulosin, atenolol, propranolol or acebutolol
- Medicines used for an uneven heartbeat such as amiodarone and digoxin
- Medicines used for angina such as glyceryl trinitrate or isosorbide trinitrate
- Medicines used for high levels of cholesterol such as simvastatin, fluvastatin and atorvastatin
- Ciclosporin used to stop the rejection of organs after a transplant
- Phenytoin or carbamazepine used for epilepsy
- Antiplatelet medicines used to reduce the chance of blood clots forming, such as aspirin or clopidogrel
- Iodinated contrast media (used for tests involving X-rays)
- Theophylline used for breathing problems
- Lithium used for some types of mental illness
- Medicines used for sleeplessness or anxiety, such as triazolam or midazolam
- Methylprednisolone used for inflammation
- Cilostazol used for intermittent cramp-like pain in your legs when you walk caused by insufficient blood supply in your legs.

Diltiazem hydrochloride 60mg modified-release tablets may make the following medicine work less well:
- Rifampicin used for tuberculosis.

The following medicines can increase the effect of Diltiazem hydrochloride 60mg modified-release tablets:
- Medicines for stomach ulcers such as cimetidine and ranitidine.

Diltiazem hydrochloride 60mg modified-release tablets with food and drink
It is advisable to limit the amount of grapefruit juice you drink while taking Diltiazem hydrochloride 60mg modified-release tablets as it can increase the blood levels of the active substance diltiazem hydrochloride and may increase your chance of getting side effects. If you are concerned you should stop drinking grapefruit juice and consult your doctor.

Pregnancy and breast-feeding
You should not take Diltiazem hydrochloride 60mg modified-release tablets if you are pregnant, might become pregnant or think you may be pregnant. This is because Diltiazem hydrochloride 60mg modified-release tablets can cause problems for your baby. Talk to your doctor if you might be pregnant.

Do not breast-feed if you are taking Diltiazem hydrochloride 60mg modified-release tablets. This is because small amounts may pass into mother's milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Driving and using machines
You may feel dizzy while taking this medicine. If this happens, do not drive or use any tools or machines.

Diltiazem hydrochloride 60mg modified-release 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.

Diltiazem hydrochloride 60mg modified-release tablets contain hydrogenated castor oil
This may cause stomach upset and diarrhoea.

3. HOW TO TAKE DILTIAZEM HYDROCHLORIDE 60MG MODIFIED-RELEASE TABLETS

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

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Taking this medicine
For oral use. Swallow the tablets whole with a glass of water. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take
Adults:
- The recommended dose is one tablet three times a day.

If necessary, your doctor may increase this to:
- Two tablets three times a day or
- Two tablets four times a day.

Over 65 years or adults with liver or kidney problems:
- The recommended dose is one tablet twice a day.

Use in children
This medicine should not be given to children.

If you take more Diltiazem hydrochloride 60mg modified-release tablets than you should
If you take more tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling dizzy or weak, blurred vision, chest pain, shortness of breath, fainting, an unusually fast or slow heartbeat, slurred speech, confusion, decrease of kidney function, coma, and sudden death.

If you take more Diltiazem hydrochloride 60mg modified-release tablets than you should contact your doctor or nearest hospital straight away:
- Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If, in an emergency situation, the patient is treated quickly sudden death is not the only potential outcome.

If you forget to take Diltiazem hydrochloride 60mg modified-release tablets
If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Diltiazem hydrochloride 60mg modified-release tablets
Keep taking Diltiazem hydrochloride 60mg modified-release tablets until your doctor tells you to stop. Do not stop taking Diltiazem hydrochloride 60mg modified-release tablets just because you feel better. If you stop your illness may get worse.

Tests
Your doctor may do regular tests while you are taking this medicine. These might include a check on your heart and blood tests to check on your liver and kidneys.

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.

Stop taking these tablets and see a doctor or go to a hospital straight away if:
Frequency not known (cannot be estimated from the available data)
- You have an **allergic reaction**. The signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have a red or lumpy skin rash, swollen eyelids, face, lips, throat, or tongue, difficulty in swallowing
- Your asthma gets worse
- You have difficulty breathing, wheezing, tightness in the chest (called 'bronchospasm')
- 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 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 and have a fever, chills and aching muscles. This could be an illness called 'Toxic epidermal necrolysis'
- 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. This could be signs of a serious allergy to the medicine called 'erythema multiforme'.

Tell your doctor straight away if you notice any of the following serious side effects – 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).

Frequency not known (cannot be estimated from the available data)
- Skin rash caused by narrow or blocked blood vessels (called 'vasculitis')
- Being short of breath, feeling tired along with swollen ankles and legs. These could be signs of heart failure
- Unusual movements of the tongue, muscle spasms in your 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 (called 'hepatitis')
- Passing large amounts of urine, excessive thirst and having a dry mouth or skin. These may be signs of high blood sugar (hyperglycaemia)
- Get sunburnt easier, and which may be more severe than in someone not taking Diltiazem hydrochloride 60mg modified-release tablets. You should use sun protection whilst taking this medicine
- Breast enlargement in men.

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

Very common (may affect more than 1 in 10 people)
- Swelling of the lower legs.

Common (may affect up to 1 in 10 people)
- Indigestion, stomach pain, constipation, and diarrhoea.

Uncommon (may affect up to 1 in 100 people)
- Feeling dizzy, light-headed or faint when you stand or sit up quickly (low blood pressure).

Rare (may affect up to 1 in 1000 people)
- Dry mouth
- Itchy, lumpy rash (called 'urticaria').

Frequency not known (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').

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Common (may affect up to 1 in 10 people)
- Headache
- Flushing (feeling of warmth)
- 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 not known (cannot be estimated from the available data)
- Mood changes, including depression
- Bleeding or bruising under the skin.
- Rash that may occur on the skin or sores in the mouth (Lichenoid drug eruption).

Blood tests
Diltiazem hydrochloride 60mg modified-release tablets can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

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 60MG MODIFIED-RELEASE TABLETS

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Do not use this medicine if you notice any visible signs of deterioration.

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 60mg modified-release tablets contain
The active substance is diltiazem hydrochloride. Each tablet contains 60mg diltiazem hydrochloride.

The other ingredients are: lactose, hydrogenated castor oil, polyethylene glycol and magnesium stearate.

What Diltiazem hydrochloride 60mg modified-release tablets look like and contents of the pack
Diltiazem hydrochloride 60mg modified-release tablets are modified-release tablets and are white, circular, concave tablets with break line on one side and plain on other side, with an approximate diameter of 9mm.

The break line is not intended for breaking the tablet.

These tablets are available in packs of 28, 30, 50, 56, 60, 84, 90, 100, 112, 250 and 1,000.

Not all pack sizes may be marketed.

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