

Diltiazem hydrochloride Suerte 60mg modified release tablets

Your medicine is known by the above name, but will be referred to as Diltiazem Hydrochloride tablets throughout this leaflet.

Patient Information Leaflet

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 tablets are 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

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) What you need to know before you take Diltiazem Hydrochloride tablets

Do not take Diltiazem Hydrochloride 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 below: 'Pregnancy and breast-feeding')
- are taking a medicine called **dantrolene** used for severe muscle spasms or severe fever (see section below 'Other medicines and Diltiazem Hydrochloride 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
- are already taking a medicine containing **ivabradine** for the treatment of certain heart diseases
- 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 **lomitapide** used for the treatment of high cholesterol levels (see section below: 'Other medicines and Diltiazem Hydrochloride tablets')
- are already taking a medicine containing **asunaprevir** used for the treatment of hepatitis C virus infection (see section below: 'Other medicines and Diltiazem Hydrochloride 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 Diltiazem Hydrochloride tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Diltiazem Hydrochloride 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** (see Other medicines and Diltiazem Hydrochloride 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 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 Diltiazem hydrochloride tablets.

Other medicines and Diltiazem Hydrochloride 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 tablets can affect the way some other medicines work. Also, some medicines can affect the way Diltiazem Hydrochloride tablets work.

Diltiazem Hydrochloride tablets may lead to an increase in the level of Colchicine (used to treat gout) when administered concomitantly.

Diltiazem Hydrochloride tablets may lead to an increased risk of bleeding if taken along with blood thinners such as direct acting oral anti-coagulants, for example, dabigatran, rivaroxaban, apixaban.

Diltiazem Hydrochloride 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 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 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 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)
- carbamazepine used for epilepsy
- 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 tablets may make the following medicine work less well:

- rifampicin used to treat tuberculosis.

The following medicine can increase the effect of Diltiazem Hydrochloride tablets:

- medicines for stomach ulcers such as cimetidine and ranitidine.

Diltiazem Hydrochloride tablets with food and drink

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

Pregnancy, breast-feeding and fertility

- You should not take Diltiazem Hydrochloride tablets if you are pregnant, might become pregnant or think you may be pregnant. This is because the 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 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

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 you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Diltiazem Hydrochloride tablets contain 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:

Adults

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 liver or kidney problems

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

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 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, the patient is treated quickly, sudden death is not only the potential outcome.

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 stop taking Diltiazem Hydrochloride tablets

Keep taking Diltiazem Hydrochloride tablets until your doctor tells you to stop. Do not stop taking them just because you feel better. If you stop, your illness may get worse.

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 Diltiazem Hydrochloride tablets and see a doctor or go to a hospital straight away if:

Not known (frequency 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. These 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).

Not known (frequency 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 tablets. You should use sun protection whilst taking this medicine. Breast enlargement in men. 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 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 1,000 people):

Dry mouth. Itchy, lumpy rash (called 'urticaria').

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

Swollen gums.

Tell your doctor or pharmacist if any of the following side effects get serious or last 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.

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

Mood changes, including depression. Bleeding or bruising under the skin.

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 use after the expiry date printed on the carton or bottle label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.

- Store in the original package in order to protect from moisture.

- Keep the container in the outer carton.

- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

- 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) Contents of the pack and other information

What Diltiazem Hydrochloride tablets contain

The active substance is diltiazem hydrochloride. Each tablet contains 60mg diltiazem hydrochloride.

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, round, biconvex, uncoated, modified-release tablets marked "C" on one face, and "DU" on the reverse.

They are available in blister packs containing 90 and 100 tablets.

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Who makes and repackages your medicine?

Your medicine is manufactured by Actavis UK Ltd., Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK or Aurobindo Pharma BV, Baarnsche Dijk 1, 3741 LN, Baarn, The Netherlands or Generis-Farmaceutica, S.A., Rua Joao de Deus, n° 19, 2700-487, Venda Nova, Amadora, Portugal.

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For any information about this medicine, or to request for a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Ltd on 020 8839 3000.