

PACKAGE LEAFLET: INFORMATION FOR THE USER

CARDIL 120MG CONTROLLED RELEASE TABLET

(DILTIAZEM HYDROCHLORIDE)

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 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.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Cardil Tablets are and what they are used for
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1. What Cardil Tablets are and what they are used for

Cardil Tablets contain diltiazem hydrochloride, which belongs to a group of medicines called calcium channel blockers. Cardil Tablets are used in the treatment of:

- mild to moderate high blood pressure
- angina pectoris (a condition which causes chest pain sometimes on exertion)

2. How Cardil Tablets work

In high blood pressure, diltiazem hydrochloride works by widening the blood vessels. This creates less resistance to the blood flow, and results in lower blood pressure, which in turn reduces the strain on your heart.

In angina, diltiazem hydrochloride works by opening up the arteries supplying the heart muscle and this allows more blood and oxygen to reach the muscle, decreasing the chances of angina (chest pains) occurring when extra strain is placed upon the heart.

3. Before you take Cardil Tablets

Do not take Cardil Tablets if you:

- are allergic (hypersensitive) to diltiazem hydrochloride or any of the other ingredients of Cardil Tablets (see Section 7 Further Information)
- have a heart condition which results in an abnormal heart beat causing palpitations or fainting (sick sinus syndrome or second or third degree AV block) and do not have a functioning pacemaker
- have a heart condition called Wolff-Parkinson-White syndrome and a rapid, irregular heart beat (atrial fibrillation/flutter)
- have a very slow pulse – less than 40 beats per minute
- have heart failure with poor blood flow (causing breathlessness, tiredness and ankle swelling)
- have recently had a heart attack
- have very low blood pressure
- are a woman of child bearing age (see “Pregnancy and breast-feeding”)
- have taken too much of the medicine digitalis
- are going to be given a medicine called dantrolene used for severe muscle spasms or severe fever
- are pregnant or breast-feeding (see “Pregnancy and breast-feeding”)

Cardil Tablets are not recommended for use in children below 18 years of age.

Take special care with Cardil Tablets

Talk to your doctor if any of the following applies to you. Your doctor will take this into account during your treatment with Cardil Tablets:

- if you are diabetic and have kidney problems as your doctor may have to adjust your dose
- if you have any liver or kidney problems as your doctor may have to adjust your dose
- if you have a condition called porphyria
- if you are an elderly patient
- if you have any other problem with your heart, other than angina or those described above in Section 3 “Do not take Cardil Tablets if you”
- If you are going to have an operation as some of the medicines used as part of the general anaesthetic may interfere with the way Cardil Tablets work (see “Taking other medicines”)
- If you notice that your mood has changed or you have been feeling depressed
- If you suffer from any muscle weakness associated with the use of drugs called “statins” which are used to reduce cholesterol
- If you have been told by a doctor that you have an intolerance to certain kinds of sugar such as lactose and sucrose

Cardil Tablets contain castor oil which may cause stomach upset and diarrhoea.

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. In particular please tell your doctor if you are taking any of the following:

- other medicines for your blood pressure or irregular heart beats such as digoxin, nifedipine, amiodarone, moricizine, quinidine and any beta blockers such as propranolol, metoprolol. Your doctor may need to monitor your blood pressure and heart beat. Your doctor may alter the dose of your other medication to treat your blood pressure or irregular heart beat gradually
- beta blockers by injection such as propranolol, metoprolol, atenolol – do not take beta blockers by injection together with Cardil Tablets
- alpha blockers (e.g. doxazosin, prazosin) as you may need more frequent check ups with your doctor
- diuretics or “water” tablets
- medicines to lower cholesterol (called statins) such as simvastatin, atorvastatin or lovastatin because your doctor may need to monitor your condition
- dantrolene a medicine used for severe muscle spasms or severe fever – do not take this medicine together with Cardil Tablets (see Section 3 “Do not take Cardil Tablets if you”)
- medicines to treat anxiety such as triazolam, midazolam, alprazolam, diazepam or buspirone
- medicines for depression such as imipramine, nortriptyline or fluoxetine
- medicines used to treat heartburn or stomach ulcers such as cimetidine or ranitidine because your doctor may need to monitor your condition
- medicines used in the treatment of epilepsy such as carbamazepine, phenytoin and phenobarbitone
- medicines used to suppress the immune system such as ciclosporin, tacrolimus or sirolimus
- antibiotics such as azithromycin, clarithromycin, erythromycin or rifampicin because your doctor may need to monitor your condition
- HIV medicines such as ritonavir or nelfinavir
- medicines to treat fungal infections such as ketoconazole, miconazole or fluconazole

In addition to the above, you should tell your doctor if you are taking any of the following medicines:-

- theophylline used in the treatment of asthma
- tamoxifen used in the treatment of breast cancer
- methylprednisolone used as an anti-inflammatory medicine
- sildenafil used for erectile dysfunction
- cisapride used to treat acid reflux and constipation
- lithium used in the treatment of depression and other mental illnesses
- warfarin used to help prevent the blood from clotting

If you are going to have surgery let your doctor know that you are taking Cardil Tablets as some of the medicines used as part of a general anaesthetic may interfere with the way Cardil Tablets work.

Pregnancy and breast-feeding

Do not take Cardil Tablets if you are pregnant, think you might be pregnant, or are planning to become pregnant. Cardil Tablets should not be taken in women of child bearing age who are not using effective contraception.

Cardil Tablets should not be used whilst you are breast-feeding.

Speak to your doctor or pharmacist before taking any medicine.

Driving and using machines

Cardil Tablets may cause side effects such as dizziness, especially at the start of treatment. Do not drive or operate machinery if you experience this side effect.

Important information about some of the ingredients of Cardil Tablets

This medicine contains the sugars lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Cardil Tablets also contain castor oil which may cause stomach upset and diarrhoea.

4. How to take Cardil Tablets

Always take Cardil Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is 90mg twice daily or 60mg three times daily. Your doctor has decided on the dose which is suited to you and the length of your course of treatment. Cardil Tablets can be divided into equal halves. You should swallow the tablets with a drink of water.

Elderly or people with kidney or liver problems

The usual starting dose in these patients is 60mg twice daily.

Children below 18 years of age

The use of Cardil Tablets in children below the age of 18 years is not recommended.

If you take more Cardil Tablets than you should

If you or someone else takes too many Cardil Tablets, go to your nearest hospital emergency department straight away or tell your doctor immediately. Show the doctor your pack of tablets. The following effects may happen: feeling tired or drowsy, feeling dizzy or weak, blurred vision, chest pain, feeling cold, shortness of breath, fainting, feeling sick, an unusually fast or slow heartbeat, collapse and confusion.

If you forget to take Cardil Tablets

If you forget to take a tablet, take it as soon as you remember. If it is nearly time for your next dose, do not take the missed dose but take your usual dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cardil Tablets

Continue taking your medicine for as long as your doctor tells you to. If you stop taking your tablets too soon, your symptoms may return.

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

5. Possible side effects

Like all medicines, Cardil Tablets can cause side effects, although not everybody will experience them. If you experience any of the following side effects, stop taking Cardil Tablets and seek immediate medical attention:

- A serious allergic reaction (angioedema) which causes swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.
- Fever, chills, sore throat, fatigue and flu-like symptoms with ulcers in the mouth or genital area, or a severe blistering rash over the body (Stevens-Johnson syndrome or toxic epidermal necrolysis)
- 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 the feet (erythema multiforme).

These are very serious but rare side effects and require immediate medical attention.

Other possible side effects include: Very common (affecting more than 1 in 10 people):

- swelling of the lower leg (peripheral oedema)

Common (affecting less than 1 in 10 but more than 1 in 100 people)

- headache
- dizziness
- flushing (feeling warm)
- feeling sick (nausea), shortness of breath
- indigestion, stomach pain
- constipation
- generally feeling unwell
- very fast, uneven or forceful heartbeat (palpitations)

Uncommon (affecting less than 1 in 100 but more than 1 in 1,000 people)

- feeling more nervous than usual

- difficulty sleeping (insomnia)
- being sick (vomiting)
- diarrhoea
- feeling dizzy, light-headed or faint when you stand or sit up quickly (low blood pressure)
- slow or uneven heartbeat
- increase in the level of liver enzymes as shown in blood tests.

Rare (affecting less than 1 in 1,000 but more than 1 in 10,000 people)

- dry mouth
- itchy, lumpy rash (urticaria)

Frequency not known (cannot be estimated from the data available)

- mood changes including feeling low
- bruising easily (due to low blood clotting agents)
- unusual movements of the tongue, muscle spasms, trembling and slurred speech
- high temperature, feeling tired, loss of appetite, stomach pain, feeling sick. These can be signs of inflammation of the liver (hepatitis)
- swollen gums
- pain in joints
- being more sensitive to the sun than usual
- heart problems symptoms of which include shortness of breath especially on exertion, feeling tired along with swollen ankles and legs
- loss of consciousness or fainting (syncope)
- sweating
- skin rash caused by narrow or blocked blood vessels (vasculitis)
- breast enlargement in men
- weakness or tiredness

If any of the side effects become serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

6. Storage & Disposal

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not store above 25°C. 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.

7. Further information

What Cardil Tablets contain

Each Cardil 120mg Controlled Release Tablet contains 120mg diltiazem hydrochloride.

The other ingredients are lactose monohydrate, castor oil, hydrogenated, dried aluminium hydroxide gel, polyacrylate dispersion 30 per cent, talc, magnesium stearate, hypromellose, sucrose, glycerol (85 per cent), titanium dioxide (E171) and polysorbate 80.

What Cardil Tablets look like and contents of the pack

Cardil Tablets are white, film-coated, capsule-shaped and scored. Code DL 120. This is supplied in glass containers of 100 tablets.

MAL No: MAL19940235A

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