

Apo-Diltiazem CD

diltiazem hydrochloride

120mg, 180mg, 240mg and 300mg capsules

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Diltiazem CD.

This leaflet answers some common questions about Apo-Diltiazem CD. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Apo-Diltiazem CD against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Diltiazem CD is used for

Apo-Diltiazem CD contains the active ingredient diltiazem hydrochloride. Apo-Diltiazem CD is designed to release the active ingredient slowly so that it works over 24 hours and can be taken once a day (CD stands for “controlled delivery”).

This medicine belongs to a group of medicines called calcium channel blockers or calcium antagonists. They work by opening up blood vessels, which lowers blood pressure and lets more blood and oxygen reach the heart. They do not change the amount of calcium in your blood or bones.

Apo- Diltiazem CD capsules are used to:

- prevent angina
- or treat hypertension (high blood pressure).

Angina is a pain or uncomfortable sensation in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. The pain of angina is due to a shortage of oxygen to the heart.

High blood pressure can have many different causes, including kidney disease, hardening of the arteries and some hormone imbalances. However, the vast majority of people with high blood pressure have no identifiable cause for it. If left untreated,

high blood pressure can lead to serious health problems such as a stroke or heart attack.

Your doctor may have prescribed Apo-Diltiazem CD for another reason.

Ask your doctor if you have any questions about why Apo-Diltiazem CD has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you use Apo-Diltiazem CD

When you must not use it

Do not use Apo-Diltiazem CD if:

- **You have had any of the following medical conditions:**
 - certain types of abnormal heart rhythm
 - hypotension (low blood pressure)
 - heart attack or other heart-related complications
 - pulmonary congestion (fluid on the lungs)
- **You are currently taking any of the following medications:**
 - dantrolene (muscle relaxant)
 - ivabradine (an antiviral)
- **You have an allergy to:**
 - diltiazem hydrochloride or any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to this medicine may include:

- asthma, wheezing or shortness of breath
 - swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing
 - hives, itching or skin rash
 - fainting
- **You are pregnant, or intend to become pregnant.**

This medicine may affect your developing baby if they are taken during pregnancy.
 - **You are breastfeeding or intend to breastfeed.**

The active ingredient of this medicine passes into breast milk and may affect your baby.

- **The packaging is torn or shows signs of tampering or if capsules do not look quite right.**
- **The expiry date (EXP) printed on the pack has passed.**
If you take this medicine after the expiry date has passed, it may not work as well.

Do not give this medicine to a child.

The safety and effectiveness of this medicine have not been established in children.

If you are not sure whether you should start using Apo-Diltiazem CD, talk to your doctor.

Before you start to use it

Tell your doctor if:

If you have any allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

If you are pregnant or intend to become pregnant.

Apo-Diltiazem CD capsules should not be used during pregnancy.

If you are breastfeeding or plan to breastfeed.

Your doctor will discuss this situation with you. A decision will have to be made whether to discontinue breastfeeding or discontinue therapy taking into consideration the importance of the medicine.

If you have or have had any medical conditions, especially the following:

- abnormal heart beat rhythm
- hypotension (low blood pressure)
- heart attack or other heart-related complications
- impaired renal (kidney) or hepatic (liver) function
- diabetes
- asthma

If you have not told your doctor about any of the above, tell them before you start using Apo-Diltiazem CD.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Diltiazem CD.

Some medicines may interfere with Apo-Diltiazem CD. These include:

- dantrolene (a muscle relaxant)
- aspirin
- medications used to help prevent blood clots (antiplatelets)
- cilostazol (a medicine used to treat blockage of blood vessels to the legs)
- Some other medicines for your heart or high blood pressure (eg. beta blockers, digoxin, amiodarone, nitrates)
- cyclosporin, which you may have been given after an operation or because of rheumatoid arthritis
- rifampicin (an antibiotic)
- cimetidine or ranitidine (for ulcers or reflux)
- diazepam (for depression, alcohol withdrawal or anxiety)
- phenytoin (for epilepsy)
- carbamazepine (for bipolar disorder or epilepsy)
- lithium (for bipolar disorder)
- theophylline (for asthma and other breathing problems) certain drugs used to treat prostate problems
- ivabradine (an antiviral)
- inhaled anaesthetic agents such as halothane, isoflurane, enflurane (for surgery)
- drugs used to lower your blood cholesterol (including simvastatin, lovastatin)
- benzodiazepines or medicines used as sedatives or to treat anxiety such as midazolam, triazolam
- corticosteroids such as methylprednisolone, prednisone, cortisone
- antiarrhythmics or medicines used to treat irregular heart beats
- medicines used during scans to see images of your body

These medicines may be affected by Apo-Diltiazem CD, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Diltiazem CD.

How to use Apo-Diltiazem CD

How much to take

Apo-Diltiazem CD capsules can be taken once a day, preferably at the same time every day.

Your doctor will tell you how often and how much Apo-Diltiazem CD to take. Follow all directions given to you by your doctor and pharmacist carefully. Write them down if necessary.

If you do not understand the instructions on the packaging of this medicine, ask your doctor or pharmacist for help.

How to take it

Swallow the capsules with a glass of water. Do not chew them.

When to take it

Take this medicine at the same time(s) every day.

How long to take it

If you are not sure how long to take your medicine, talk to your doctor.

If you forget to take it

If you are taking this medicine for angina, do not suddenly stop taking them since this can cause severe angina for a day or two.

If you forget to take a dose and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your capsules as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are using Apo-Diltiazem CD

Things you must do

Take this medicine exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, you may not get relief from your attacks of angina, or your blood pressure may not be as well controlled as it could be.

If you are taking this medicine for angina, tell your doctor if you continue to have angina attacks or if they become more frequent.

Tell all your doctors, dentists and pharmacists that you are taking this medicine.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Diltiazem CD.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor says to.

Do not give Apo-Diltiazem CD to anyone else, even if they have the same condition as you.

As mentioned previously, if you are taking this medicine for angina, do not suddenly stop taking your medicine since this can cause severe angina for a day or two.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness and fainting in some patients, especially when you first start to use them. Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if this happens to you.

Be careful not to overdo physical activities when you first start using this medicine.

You may feel better when you start taking this medicine, but you will need time to improve your physical fitness.

Drinking grapefruit juice may increase the effects of Apo-Diltiazem CD.

Get up slowly when getting out of bed or standing up if you feel light-headed, dizzy or faint.

If this is a problem and it gets worse or continues, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Diltiazem CD.

Do this even if there are no signs of discomfort or poisoning.

If you take too much of this medicine, you may:

- feel continuously light-headed or dizzy
- notice your heart beating very slowly
- feel pain, which could be severe, in your left arm and chest.

If any of these occur, you should get medical attention immediately.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Diltiazem CD.

This medicine helps most people with angina and Apo-Diltiazem CD will help control most people's blood pressure, but they may have unwanted effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- swelling or flushing (feeling hot suddenly)
- headache
- nausea, vomiting, constipation, diarrhoea, indigestion, gastric pain
- dizziness
- confusion, hallucinations, abnormal dreams, mental depression or mood changes
- trouble sleeping
- nervousness, tremor
- ringing or other persistent noise in the ears
- loss of memory
- dry mouth
- loss of appetite
- weight increase
- increased sensitivity to the sun
- unusual movements or uncontrollable movements
- rash or an itchy, burning or prickly sensation
- small round, raised itchy areas on the skin
- weakness or tiredness

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- you feel continuously light headed or dizzy
- you notice your heart beating irregularly, slowly or very quickly
- you feel pain, which may be severe, in your left arm and chest
- you have blisters and bleeding in the lips, eyes, mouth, nose or genitals
- you have skin reactions such as red, painful or itchy spots, blisters or peeling of the skin
- you have difficulty breathing, wheezing or coughing

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Ask your doctor or pharmacist if you do not understand anything in this section.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Apo-Diltiazem CD

Storage

Keep this medicine in their container until it is time to take them. If you take the medicine out of its container it may not keep well.

Keep this medicine in a cool, dry place where it stays below 25°C. Protect from heat, light and moisture.

Do not store them, or any other medicine, in a bathroom or near a sink. Do not leave them in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking your Apo-Diltiazem CD medication, or it has passed its expiry date, ask your pharmacist what to do with any capsules that are left over.

Product description

What it looks like

120mg capsules: Light turquoise opaque body, light turquoise opaque cap, hard gelatin capsule. Imprinted APO 120.

180mg capsules: Light turquoise opaque body, light blue opaque cap, hard gelatin capsule. Imprinted APO 180.

240mg capsules: Light blue opaque body, light blue opaque cap, hard gelatin capsule. Imprinted APO 240.

300mg capsules: Light grey opaque body, light blue opaque cap, hard gelatin capsule. Imprinted APO 300.

Available in

- blister packs of 100 capsules
- bottles of 100 or 500 capsules.

*Not all presentations or strengths may be marketed.

Ingredients

Active ingredient:

- Each capsule contains 120mg, 180mg, 240mg or 300mg of the active ingredient diltiazem hydrochloride.

Inactive ingredients:

- Methacrylic acid copolymer dispersion (Eudragit RS30D)
- Methylcellulose
- Microcrystalline cellulose
- Polysorbate
- Purified talc
- Tributyl citrate
- Capsules (Capsugel):
 - 120mg, 180mg & 240mg – gelatin capsule shells which contains brilliant blue FCF and titanium dioxide as colouring agents.
 - 300mg – gelatin capsule shells which contains brilliant blue FCF, ferric oxide (black) and titanium dioxide as colouring agents.

This medicine is lactose and glucose free.

Sponsor Details

Apo-Diltiazem CD is supplied in New Zealand by:

Apotex NZ Ltd
32 Hillside Road
Glenfield
AUCKLAND 0627

Telephone: (09) 444 2073

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