

Diltiazem Sandoz®

diltiazem hydrochloride tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Diltiazem Sandoz.

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 taking this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT DILTIAZEM SANDOZ IS USED FOR

This medicine is used to prevent angina.

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms and neck, and sometimes the shoulders and back. This may be caused by too little blood and oxygen getting to the heart. Angina is usually brought on by exercise or stress.

It contains the active ingredient diltiazem hydrochloride.

Diltiazem belongs to a group of medicines called calcium channel blockers.

It works by opening up blood vessels, thereby increasing the

blood flow and allowing more blood (and oxygen) to reach the heart.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

BEFORE YOU TAKE DILTIAZEM SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- diltiazem hydrochloride, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under **PRODUCT DESCRIPTION**.

Some of the symptoms of an allergic reaction may include:

- asthma, wheezing or shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- fainting.

Do not take this medicine if you have or have had any of the following conditions:

- sick sinus syndrome (unless you have a working pacemaker)
- second or third degree AV block (unless you have a working pacemaker)

- low blood pressure (hypotension)
- severe congestive heart failure
- severe bradycardia (slow heart rate)
- heart attack
- pulmonary congestion (excessive amount of fluid in the lungs).

Do not take this medicine with ivabradine.

Combination with ivabradine may cause additional heart rate lowering effect of diltiazem to ivabradine.

Do not take this medicine if you are pregnant or intend to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Diltiazem Sandoz passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Diltiazem Sandoz should not be used during pregnancy.

Tell your doctor 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.

Tell your doctor if you have or have had any of the following medical conditions:

- abnormal heartbeat rhythm
- hypotension (low blood pressure)
- heart attack or other heart-related problems
- kidney or liver problems
- diabetes.

If you have not told your doctor about any of the above, tell him/her before you start taking Diltiazem Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Diltiazem Sandoz may interfere with each other. These include:

- beta-blockers, such as propranolol or atenolol, medicines used to treat high blood pressure or other heart problems
- certain medicines used to treat prostate problems
- medicines used to treat irregular heartbeats, such as amiodarone
- medicines used to treat reflux and stomach ulcers, such as cimetidine or ranitidine
- diazepam, a medicine used to treat anxiety, depression or alcohol withdrawal
- rifampicin, a medicine used to treat tuberculosis
- carbamazepine, a medicine used for a variety of conditions (such

as epilepsy, mania, bipolar mood disorder or trigeminal neuralgia)

- rimonabant, an appetite-reducing medicine
- lithium, a medicine used to treat some types of depression
- theophylline, a medicine used to treat asthma
- cyclosporin, a medicine used in patients who have received organ transplants or to treat certain problems with the immune system
- medicines used to treat high cholesterol, such as simvastatin or atorvastatin
- inhaled anaesthetics, such as isoflurane, enflurane or halothane (for surgery)
- dantrolene, a muscle-relaxant medicine.
- benzodiazepines or medicines used as sedatives or to treat anxiety, such as midazolam, triazolam
- corticosteroids, such as methylprednisolone, prednisone, cortisone.

These medicines may be affected by Diltiazem Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE DILTIAZEM SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Diltiazem Sandoz may not work as well and your problem may not improve.

Diltiazem Sandoz is usually taken three or four times daily.

How to take it

Swallow the tablets whole with a full glass of water. Do not chew them.

When to take Diltiazem Sandoz

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take Diltiazem Sandoz

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If you are taking this medicine for angina, do not suddenly stop taking it, as this can cause severe angina for one or two days.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Diltiazem Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- light-headedness
- dizziness
- slow or irregular heartbeat
- pain in the left arm and/or chest.

WHILE YOU ARE TAKING DILTIAZEM SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Diltiazem Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Diltiazem Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Stopping your medicine suddenly may bring on an angina attack.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how Diltiazem Sandoz affects you.

This medicine may cause dizziness or light-headedness in some people, especially after the first dose. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

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

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful not to overdo physical activities when you first start taking 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 diltiazem.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Diltiazem Sandoz.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist 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 are the more common side effects of the medicine. Mostly, these are mild.

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

- feeling 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.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

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

AFTER TAKING DILTIAZEM SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Diltiazem Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Diltiazem Sandoz 60mg - white, round, biconvex tablets with a score notch on one side.

Available in blisters and bottles of 90 tablets.

Ingredients

Active ingredients:

- Diltiazem Sandoz 60mg - 60mg diltiazem hydrochloride.

Inactive ingredients:

- hydrogenated castor oil
- lactose
- povidone
- macrogol 6000
- microcrystalline cellulose
- sodium starch glycollate
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- stearic acid
- titanium dioxide.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Diltiazem Sandoz is supplied in Australia by:

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road,
 Macquarie Park, NSW 2113
 Australia
 Tel: 1800 634 500

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Australian Register Number

60mg tablets: AUST R 60838 (blisters)
 60mg tablets: AUST R 62646 (bottles)