

Carvedilol Sandoz®

carvedilol tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Carvedilol 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 risk of you taking Carvedilol Sandoz against the benefits it is expected to 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 want to read it again.

What Carvedilol Sandoz is used for

The name of your medicine is Carvedilol Sandoz. It contains the active ingredient carvedilol.

Carvedilol Sandoz is used to treat heart failure.

Your doctor may have prescribed Carvedilol Sandoz for another reason.

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

How Carvedilol Sandoz works

Carvedilol Sandoz belongs to a group of medicines called beta-blockers.

It works by slowing down the heart rate and relaxing blood vessels if they are too tight. Additionally, it works as an antioxidant.

There is no evidence that Carvedilol Sandoz is addictive.

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

Before you take Carvedilol Sandoz

When you must not take it

Do not take this medicine if:

- you are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description. Symptoms of an allergic reaction may include an itchy skin rash, shortness of breath or swelling of the face or tongue.
- you are pregnant or breastfeeding, unless permitted by your doctor
- you have asthma or other conditions that cause difficulties in breathing
- you have allergic disorders including allergic asthma and/or allergic nose running/congestion
- you have or have had a very slow heart rate or uneven heartbeats
- you have certain other heart conditions
- you have problems with your liver including liver failure
- your blood pressure is very low
- it is past its expiry date or the packaging appears to have been tampered with.

Do not give Carvedilol Sandoz to people under 18 years of age.

Safety and effectiveness in children have not been established.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as carvedilol
- any other substances, including foods, preservatives or dyes.

Contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

Tell your doctor if you plan on becoming pregnant or will be breastfeeding while you are using Carvedilol Sandoz.

It passes into the breastmilk. Your doctor will discuss the risks and benefits of using Carvedilol Sandoz while being pregnant or breastfeeding.

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

- unstable angina, a condition of chest tightness or pain that might even occur when you are resting
- low blood pressure
- high blood pressure that also varies extremely
- peripheral vascular disease, a condition of poor blood circulation in your fingers and/or toes
- problems with your kidney
- conditions of your bronchial tubes such as chronic bronchitis or emphysema
- diabetes
- hypoglycaemia, a condition of suddenly dropping blood sugar levels
- problems with your thyroid
- severe allergic reactions causing swelling and/or difficulties in breathing
- pheochromocytoma, a rare cancer
- psoriasis, a skin disease.

Tell your doctor if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Carvedilol Sandoz.

Taking other medicines

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

In particular, tell your doctor if you take any of the following:

- rifampicin, used to treat tuberculosis (e.g. Rimycin, Rifadin)
- cimetidine, used to treat reflux or stomach ulcers (e.g. Tagamet, Cimehexal, Magicul, Sigmataidine)
- digoxin, used to treat heart failure (e.g. Lanoxin)
- monoamine-oxidase inhibitors (MAOIs) such as tranylcypromine (Parnate) and phenelzine (Nardil), used to treat depression
- clonidine, used to treat migraine, high blood pressure or menopausal symptoms (e.g. Catapres)
- diltiazem, used to treat high blood pressure or angina (e.g. Cardizem, Auscard, Cardcal, Coras, Diltahexal, Diltiamax, Dilzem, Vasocardol)

- verapamil, used to treat high blood pressure, angina or fast heart rate (e.g. Isoptin, Cordilox, Anpec, Verahexal)
- drugs used to correct irregular heartbeats such as disopyramide (Rythmodan, Norpace), quinidine (Kinidin), procainamide (Pronestyl), mexiletine (Mexitil), lignocaine, flecainide (Tambocor) and amiodarone (Corarone, Aratac).
- drugs to treat diabetes such as insulin injections, glibenclamide (Daonil, Glimel), metformin (Diabex, Diaformin, Glucohexal, Glucomet, Glucophage, NovoMet), chlorpropamide (Diabinese), gliclazide (Diamicon), glipizide (Minidiab, Melizide) and tolbutamide (Rastinon).
- cyclosporin, used to treat certain conditions related to the immune system (e.g. Neoral, Cicloral, Sandimmun)
- aspirin and other pain relievers or non-steroidal anti-inflammatory medicines such as ibuprofen (Nurofen) or naproxen (Naprosyn).
- medicines which may relieve asthma or help you breath better such as salbutamol (Ventolin) and salmeterol (Serevent/ Seretide)
- fluoxetine, a medicine used to treat depression and other conditions (e.g. Prozac)
- medicines that may help lower your blood pressure.

These medicines may be affected by Carvedilol Sandoz or may affect how well it works.

You may need to use different amounts of your medicine, or you may need to take different medicines.

Your doctor will advise you.

Your doctor or pharmacist have more information on medicines to avoid or be careful with while taking Carvedilol Sandoz.

How to take Carvedilol Sandoz

How much to take

Your doctor will tell you how many tablets you need to take each day.

Follow all directions given to you by your doctor carefully.

They might differ from the information contained in this leaflet.

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

The usual starting dose in heart failure is 3.125mg twice daily. The dose is usually increased every two weeks to 6.25mg twice daily, 12.5mg twice daily and then 25mg twice daily. If side effects occur, this might be done more slowly. If your heart rate is slowed down too much, you might go back down to the next lower dose.

Your doctor will monitor you carefully at each dose increase.

How to take it

The tablets should be swallowed whole or halved with a glass of water.

Do not crush or chew the tablets.

If you need to break Carvedilol Sandoz, hold tablet with both hands and snap along break line.

When to take it

Carvedilol Sandoz tablets should be taken with food at about the same time each day. This will minimize the risk of some side effects.

How long to take it

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

It is very important that Carvedilol Sandoz is not stopped suddenly. If you are to stop taking Carvedilol Sandoz your doctor will advise you to reduce the dose slowly over approximately two weeks.

If you forget to take your dose

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.

Do not take a double dose to make up for the dose 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 when 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) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Carvedilol Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose with Carvedilol Sandoz might include:

- low blood pressure leading to dizziness or fainting
- a very slow heart rate
- difficulties in breathing
- vomiting
- shock
- seizures.

While you are taking Carvedilol Sandoz

Things you must do

- **Always follow your doctor's instructions carefully**
- **Tell your doctor if you become pregnant while taking Carvedilol Sandoz**
- **If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Carvedilol Sandoz**
- **Tell all doctors, dentists and pharmacists that you are taking Carvedilol Sandoz.**
If you are having a surgery, also tell your surgeon and anaesthetist
- **Tell your doctor that you are taking Carvedilol Sandoz if you are having any laboratory tests**

- **Make sure to keep all appointments with your doctor.**
He may check your eyes, test your blood sugar level and kidney function from time to time
- **If you experience light-headedness, dizziness or fainting when getting up, get up slowly**
- **Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed**
- **Always make sure to drink enough water, especially during exercise or hot weather.**

Things you must not do

- **Do not stop taking Carvedilol Sandoz or change the dose without your doctor's permission. Do not let yourself run out of medicine over the weekend or on holidays.**
This medicine should only be stopped by gradually decreasing the dose over a two week period.
- **Do not use Carvedilol Sandoz to treat any other complaint unless your doctor says so.**
- **Do not give this medication to anyone else, even if their symptoms seem similar to yours.**

Things to be careful of

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

It may cause dizziness or light-headedness in some people, especially after the first dose or after your dose has been increased.

If you wear contact lenses you may experience that the amount of tear fluid in your eyes is reduced.

The amount of Carvedilol Sandoz absorbed by your body may be increased when taken with grapefruit juice.

Side effects

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

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- tiredness or drowsiness
- dizziness
- light-headedness
- abnormal or blurry vision
- slow heart rate
- diarrhoea
- nausea or vomiting
- bronchitis
- high blood sugar
- weight increase
- fluid retention
- unusual hair loss or thinning.

These are the more common side effects of Carvedilol Sandoz. Mostly, these are mild and short-lived.

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- itching, dark urine, loss of appetite, yellowing of skin or eyes, or feeling "flu-like" without a clear cause
- uneven heartbeats
- swelling of the feet or legs due to fluid retention
- bleeding or bruising more easily than usual.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

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

Tell your doctor if you notice any other effects.

Ask your doctor or pharmacist if you don't understand anything on this list.

After taking Carvedilol Sandoz

Storage

Keep Carvedilol Sandoz in the original packaging until you need to take it.

Store below 25°C in a dry place, out of the reach of children.

Keep your medicine where it is protected from light and moisture. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Do not store Carvedilol 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.

Disposal

Return any unused or out of date medicine to your pharmacist.

Product description

What Carvedilol Sandoz looks like

Carvedilol Sandoz 6.25mg tablets: a yellow, round, convex, scored tablet, coded C2 on one side.

Carvedilol Sandoz 12.5mg tablets: a red-brown, round, convex, scored tablet, coded C3 on one side.

Carvedilol Sandoz 25mg tablets: a white to almost white, round, convex, scored tablet, coded C4 on one side.

Carvedilol Sandoz is available in 60 tablet blister packs.

Ingredients

Active Ingredient

Each Carvedilol Sandoz 6.25mg tablet contains 6.25mg carvedilol.

Each Carvedilol Sandoz 12.5mg tablet contains 12.5mg carvedilol.

Each Carvedilol Sandoz 25mg tablet contains 25mg carvedilol.

Inactive Ingredients

Each Carvedilol Sandoz tablet also contains lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, colloidal anhydrous silica, magnesium stearate, iron oxide yellow (6.25 and 12.5mg) and iron oxide red (12.5mg).

Supplier

Carvedilol Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park
NSW 2113
Australia
Tel: 1800 726 369

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Australian Register Numbers:

Carvedilol Sandoz 6.25mg tablets: AUST R
104391 (blisters)

Carvedilol Sandoz 12.5mg tablets: AUST R
104396 (blisters)

Carvedilol Sandoz 25mg tablets: AUST R
104399 (blisters)