

## Consumer Medicine Information

# Carvedilol Sandoz<sup>®</sup>

carvedilol 6.25mg, 12.5mg and 25mg tablets, uncoated

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### WHAT IS IN THIS LEAFLET

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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 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.

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### WHAT CARVEDILOL SANDOZ IS USED FOR

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Carvedilol Sandoz is used to treat:

- high blood pressure
- angina (a type of severe chest pain)
- heart failure
- heart failure following a recent heart attack

Carvedilol Sandoz may be used in combination with other “heart” medicines. Carvedilol Sandoz is a long-term treatment.

Carvedilol Sandoz belongs to a group of medicines called beta blockers. These medicines work by relaxing tightened blood vessels and slowing the rate of heart beat. Carvedilol Sandoz is different from conventional beta blockers as it has additional effects of being an alpha blocker (which also relaxes and widens your blood vessels) and an antioxidant.

Heart failure occurs when the heart can no longer pump blood strongly enough for the body’s needs. Often the heart gets bigger to try to improve the blood flow, but this can make the heart failure worse. Symptoms of heart failure include shortness of breath and swelling of the feet and/or legs due to fluid build-up.

Carvedilol Sandoz, when used with other “heart” medicines, reduces the pressure that the heart has to pump against as well as controlling the heart rate. Over time this will reduce the size of an oversized heart and increase its efficiency.

Carvedilol Sandoz helps to stop heart failure getting worse and reduces the chances of you being admitted to hospital and/or dying from this disease.

Your doctor, however, may have prescribed Carvedilol Sandoz for another purpose.

**Ask your doctor if you have any questions about why Carvedilol Sandoz has been prescribed for you.**

There is not enough information to recommend the use of Carvedilol Sandoz for people under

the age of 18 years.

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

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## **BEFORE YOU TAKE CARVEDILOL SANDOZ**

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### ***When you must not take it***

**Do not take Carvedilol Sandoz if:**

- **you have had an allergic reaction to Carvedilol Sandoz or any ingredients listed at the end of this leaflet**
- **you have asthma, or a history of asthma**
- **you have wheeziness/difficulty in breathing or a history of lung disorders**
- **you have liver disease**
- **you have a history of a very slow heart rate (bradycardia) or uneven heart beating (heart block)**
- **you have very low blood pressure (hypotension)**
- **the package is torn or shows signs of tampering**
- **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.

**If you are not sure if you should be taking Carvedilol Sandoz, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor if:**

**1. you are pregnant or plan to become pregnant**

It is not known whether Carvedilol Sandoz is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take Carvedilol Sandoz when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

**2. you are breastfeeding or plan to breastfeed**

It is not known if Carvedilol Sandoz passes into breast milk. Breast feeding is not recommended if you are taking Carvedilol Sandoz.

**3. you have any other health problems, especially the following:**

- diabetes
- low blood pressure
- very poor circulation to your fingers and/or toes (called peripheral vascular disease or Raynaud's phenomenon)
- angina or chest pain/tightness which occurs even when you are at rest (called unstable angina)
- a history of poor kidney function
- thyroid disorders
- a history of severe allergic reactions causing swelling and/or difficulty breathing
- a history of psoriasis when taking beta-blockers
- a rare cancer called pheochromocytoma
- Lung disease (called chronic obstructive pulmonary disease)

**4. you are allergic to any other medicines, foods, dyes or preservatives**

**5. you plan to have surgery**

Your surgeon and anaesthetist should know well ahead of the date of your surgery so they can allow for your conditions and medications.

If you have not told your doctor about any of the above, you should do so before your start taking Carvedilol Sandoz.

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop:**

Some medicines may interfere with Carvedilol Sandoz. These medicines include:

- rifampicin (Rifadin®, Rifinah®)
- cimetidine (Apo-Cimetidine®, Cytine®)
- reserpine
- a group of medicines called monoamine oxidase inhibitors that includes moclobemide (Apo-moclobemide®), phenelzine (Nardil®) and tranylcypromine (Parnate®)
- cyclosporin (Neoral®, Sandimmun®)
- digoxin (Lanoxin®)
- diltiazem (Apo-Diltiazem®, Cardizem®, Dilcard®, Dilzem®)
- verapamil (Isoptin®, Verpamil®, Civicor®)
- clonidine (Catapres®, Dixarit®)
- medicines for diabetes including insulin injections, glibenclamide (Gliben®), metformin (Diabex®, Metomin®), gliclazide (Diamicron®, Apo-gliclazide®), glipizide (Minidiab®), tolbutamide (Diatol®), rosiglitazone (Avandia®), pioglitazone (Actos®)
- medicines for when your heart doesn't beat smoothly, including disopyramide (Rhythmodan®), quinidine, procainamide (Pronestyl®), mexiletine (Mexitil®), lignocaine, flecainide (Tambocor®), amiodarone (Aratac®, Cordarone X®) and propafenone (Rytmonorm®)
- 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 (Prozac®) and paroxetine

These medicines may be affected by Carvedilol Sandoz, or may affect how well it works. You may need to use different amounts of your medicines 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 Carvedilol Sandoz.**

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

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## **HOW TO TAKE CARVEDILOL SANDOZ**

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**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***

Take Carvedilol Sandoz exactly as your doctor has prescribed.

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

The usual dose for **hypertension (high blood pressure)** is 12.5 mg (one 12.5 mg tablet or half a 25 mg tablet) once a day for the first two days, then one 25 mg tablet once a day. If

necessary, after at least another two weeks, the dose may be increased to 50 mg per day, taken either as two 25 mg tablets at the same time once a day, or one 25 mg tablet taken in the morning and another 25 mg tablet taken in the evening.

The usual dose for **angina** is 12.5 mg (one 12.5 mg tablet or half a 25 mg tablet) twice a day for the first two days, then 25 mg twice a day (one 25 mg tablet in the morning and another 25 mg tablet in the evening). If necessary, after at least another two weeks, the dose may be increased to 50 mg (two 25 mg tablets) twice a day – a total of four 25 mg tablets per day.

The usual starting dose in **heart failure** is 3.125 mg (half a 6.25 mg tablet) twice daily. The dose is usually increased every two weeks to 6.25 mg twice daily (one 6.25 mg tablet in the morning and another 6.25 mg tablet in the evening), then 12.5 mg twice daily and then 25 mg twice daily. Some patients may require up to two 25 mg tablets (50 mg) twice daily. However, this dosage increase may be done more slowly if side effects occur. If the tablets slow your heart too much you may go back to a lower dose.

The usual starting dose for **heart failure following a recent heart attack** is 6.25 mg twice a day (one 6.25 mg tablet in the morning and another 6.25 mg tablet in the evening). If the 6.25 mg twice daily dose is well tolerated, the dose can be increased at intervals of 3 – 10 days to 12.5 mg twice daily and then up to a maximum of 25 mg twice daily. The final dose will be determined by how well you feel while taking Carvedilol Sandoz.

Your doctor will decide which dose is best for you and monitor you carefully each time the dose is increased or changed.

### ***How to take it***

**Swallow the tablets whole or halved with a glass of water.**

**Do not crush or chew the tablets.**

### ***When to take Carvedilol Sandoz***

**Take Carvedilol Sandoz during or immediately after a meal, at about the same times each day.**

If you take Carvedilol Sandoz on an empty stomach, it may increase the risk of some side effects.

### ***How long to take Carvedilol Sandoz***

Treatment with Carvedilol Sandoz is usually long term treatment.

**Continue taking Carvedilol Sandoz until your doctor tells you to stop.**

**It is very important that Carvedilol Sandoz treatment 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 it***

**Do not take an extra dose. Wait until the next dose and take your normal dose then.**

**Do not try to make up for the dose that you missed by taking more than one dose at a time.**

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

If you have trouble remembering your dose, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much Carvedilol Sandoz. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

The following are some symptoms which may or may not occur.

- low blood pressure causing dizziness or fainting
- a very slow heart rate
- difficulty breathing
- vomiting
- shock
- seizures

**Keep telephone numbers for these places handy.**

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

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## **WHILE YOU ARE TAKING CARVEDILOL SANDOZ**

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### ***Things you must do***

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

**Tell all doctors, dentists and pharmacists who are treating you that you are taking Carvedilol Sandoz. If you are having surgery be sure to tell your surgeon and anaesthetist that you are taking Carvedilol Sandoz.**

**Tell your doctor if you become pregnant while taking Carvedilol Sandoz.**

**Tell your doctor that you are taking Carvedilol Sandoz if you are going to have any laboratory tests.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.** Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

**Tell your doctor if you feel that the tablets are not helping your condition.**

**Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

Your doctor may examine your eyes, and test your blood glucose and kidney function from time to time.

### ***Things you must not do***

**Do not stop taking Carvedilol Sandoz or change the dose without first checking with your doctor.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

Carvedilol Sandoz should only be stopped by gradually reducing the amount you are taking as directed by your doctor.

**Do not give Carvedilol Sandoz to anyone else even if they have the same condition as you.**

**Do not use Carvedilol Sandoz to treat other complaints unless your doctor says to.**

**Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Carvedilol Sandoz affects you.** Carvedilol Sandoz may affect your ability to drive a car or operate machinery when you start taking it, or when the dosage is increased, or in combination with alcohol.

If you wear contact lenses you may also notice less tear fluid in your eyes. You may find you have to use your contact lenses less or switch to glasses.

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## **SIDE EFFECTS**

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

Carvedilol Sandoz helps most people but it may have unwanted side 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 side effects.

**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:**

- fatigue, dizziness, headache – these side effects often occur at the beginning of treatment
- feeling faint
- oedema (swelling)
- abnormal heart beat, including slow or fast heart beat
- nausea (feeling sick), vomiting, stomach pain, diarrhoea
- weight increase
- vision abnormalities
- dry or sore eyes
- lightheadedness on standing
- pain in your fingers and/or toes
- if you are diabetic, worsening control of your blood glucose levels
- unusual hair loss or thinning.

These are the more common side effects of Carvedilol Sandoz. Mostly these are mild.

**Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:**

- shortness of breath
- swelling of the mouth or tongue
- uneven heart beating
- swelling of the feet or legs due to fluid build-up
- bleeding or bruising more easily than normal
- cold extremities
- chest pain
- depressed mood
- sleep disturbances/nightmares
- loss of bladder control
- severe skin reactions - blisters and bleeding in the lips, eyes, mouth, nose and genitals

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

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.**

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

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

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## **AFTER TAKING CARVEDILOL SANDOZ**

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### ***Storage***

**Keep your tablets in the blister until it is time to take them.**

If you take the tablets out of the blister pack they may not keep well.

**Keep Carvedilol Sandoz in a cool dry place where the temperature stays below 25 °C.**

**Do not store it or any other medicine in a bathroom or near a sink or any other place where there is high humidity.**

**Do not leave it in the car or on windowsills.**

Heat and dampness can destroy some medicines.

**Keep Carvedilol Sandoz 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 Carvedilol Sandoz, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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## **PRODUCT DESCRIPTION**

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### ***What it looks like***

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

Carvedilol Sandoz 12.5 mg tablet: red/brown, round, convex, scored tablet, coded 'C3' on one side side.

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

Available in blister packs of 30 and 60 tablets.

### ***Active Ingredients***

Active ingredient: Carvedilol

### ***Inactive Ingredients***

**Lactose**, microcrystalline cellulose, crospovidone, povidone, colloidal anhydrous silica, magnesium stearate, iron oxide yellow (6.25 mg and 12.5mg), iron oxide red (12.5mg).

## ***Supplier/Distributor***

Sandoz New Zealand Limited  
12 Madden Street  
Auckland 1010  
New Zealand

Tel: 0800 726 369

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