

# Dicarz™

contains the active ingredient carvedilol

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Dicarz.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Dicarz against the benefits he/she expects it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.**

You may need to read it again.

### What Dicarz is used for

Dicarz is used to treat:

- heart failure
- high blood pressure (hypertension)
- Dicarz belongs to a group of medicines called beta-blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. Dicarz also slows your heart rate, which in turn increases the efficiency of your heart. Dicarz has the additional effect of being an antioxidant.

#### **Heart Failure:**

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working. Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

Dicarz can help to reduce the number of heart failure episodes needing hospital admission and also the risk of sudden death.

Dicarz is often used with other medicines to treat heart failure.

#### **Hypertension:**

All people have blood pressure. This pressure helps to push blood all around your body. Your blood pressure changes during the day, depending on how busy you are or how you are feeling.

You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

Regular blood pressure checks are the only way of knowing that you have hypertension. There are usually no symptoms of hypertension and you may feel fine. If hypertension is not treated, serious health problems such as stroke, heart disease and kidney failure may occur.

Dicarz helps to lower your blood pressure.

Your doctor, however, may have prescribed Dicarz for another reason. Ask your doctor if you have any questions about why Dicarz has been prescribed for you.

Dicarz is not recommended for use in children, as the safety and efficacy in children have not been established.

It is available only with a doctor's prescription.

### Before you take Dicarz

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

**Do not take Dicarz if you are allergic to:**

- any medicine containing carvedilol
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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.

**Do not take Dicarz if you have:**

- asthma or other condition that makes you short of breath from time to time.
- a history of allergic problems, including hayfever. Symptoms of an allergy may include: rash, itching, watery eyes or sneezing.
- a history of a very slow heart rate or uneven heart beating.
- very low blood pressure.

- certain other heart conditions. Your doctor will know what these conditions are.
- liver problems, including liver failure.

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

**Tell your doctor if you are pregnant or plan to become pregnant.**

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

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

Dicarz is not recommended while you are breastfeeding as it passes into breast milk. Your doctor will discuss the risks and benefits of taking Dicarz when breastfeeding.

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

- angina or chest pain/tightness which occurs even when you are at rest (also known as unstable angina)
- low blood pressure
- high blood pressure which varies widely
- very poor circulation to your fingers and/or toes (also called peripheral vascular disease)
- a history of poor kidney function
- chronic bronchitis or emphysema causing breathing difficulties
- diabetes

- sudden low blood sugar levels (also known as hypoglycaemia)
- thyroid disorders
- severe allergic reactions causing swelling and/or difficulty breathing
- a rare cancer of the adrenal gland called phaeochromocytoma which is not being treated with other medicines.
- psoriasis, a skin disease with thickened patches of red skin, often with silvery scales.

Your doctor may want to take special care if you have any of these conditions.

**Tell your doctor if you plan to have surgery.**

The surgeon and anaesthetist must be told that you are taking Dicarz well ahead of the date of your surgery, in order to allow for your condition and medications.

**If you have not told your doctor about any of the above, tell them before you start taking Dicarz.**

### *Taking other medicines*

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

Some medicines may be affected by Dicarz, or may affect how well it works. These include:

- rifampicin, a medicine used to treat tuberculosis
- cimetidine, a medicine used to treat stomach ulcers or reflux
- digoxin, medicine used to treat heart failure
- monoamine oxidase inhibitors, medicines used to treat depression (e.g. phenelzine, tranylcypromine)
- clonidine, a medicine used to treat high blood pressure, migraine or menopausal symptoms
- diltiazem, a medicine used to treat high blood pressure or angina

- verapamil, a medicine used to treat high blood pressure, angina or fast heart rate
- cyclosporin, a medicine used to treat certain problems with the immune system
- anti-arrhythmic drugs used to treat irregular or abnormal heartbeat (e.g. disopyramide, flecainide, amiodarone, quinidine, procainamide, mexiletine and lignocaine)
- insulin injections, glibenclamide, metformin, gliclazide, or glipizide, medicines used for the treatment of diabetes
- aspirin and other pain relievers or non-steroidal anti-inflammatory medicines such as ibuprofen or naproxen medicines which may relieve asthma or help you breathe better such as salbutamol and salmeterol
- fluoxetine, a medicine used to treat depression and other conditions
- other medicines that may help lower your blood pressure.

Your doctor can tell you what to do if you are taking any of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

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

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## How to take Dicarz

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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.

## *How much to take*

### **Take Dicarz exactly as your doctor has prescribed.**

Your doctor will tell you how many Dicarz tablets to take each day. This depends on your condition and whether or not you are taking other medicines.

### **Heart Failure**

The usual starting dose in heart failure is 3.125 mg twice daily. The dose is usually increased every two weeks to 6.25 mg twice daily, 12.5 mg twice daily and then 25 mg twice daily. However, this 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.

### **High Blood Pressure**

Adults: The recommended dose for initiation of therapy is 12.5 mg a day for the first two days.

Thereafter, the recommended dosage is 25 mg once a day.

If necessary, the dosage may be increased every two weeks up to the recommended maximum daily dose of 50 mg given once a day or in divided doses (twice daily).

Elderly: The recommended dose for initiation of therapy is 12.5 mg once daily, which has provided satisfactory control in some patients. If the response is inadequate, the dose may be increased every two weeks up to the recommended maximum daily dose.

Your doctor will monitor your blood pressure, heart rate and other vital signs carefully after you start treatment with Dicarz.

## *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 it*

**Take Dicarz during or immediately after food at about the same time each day.**

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

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

## *If you forget to take it*

**If 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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

**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 your dose, ask your pharmacist for some hints.**

## *How long to take it for*

**Continue taking Dicarz until your doctor tells you to stop.**

Make sure you have enough to last over weekends and holidays.

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

## *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 the nearest hospital, if you think you or anyone else may have taken too much Dicarz. 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.

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## **While you are taking Dicarz**

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### *Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking Dicarz.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Dicarz.**

**Make sure you drink enough water during exercise and hot weather when you are taking Dicarz, especially if you sweat a lot.**

**Tell your doctor if you become pregnant while taking Dicarz.**

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

**If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Dicarz.**

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

Your doctor may check your eyes, kidney function, and blood glucose levels from time to time.

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Your doctor may think it is not working effectively and change your treatment unnecessarily.

### *Things you must not do*

**Do not stop taking Dicarz, or lower the dose, without checking with your doctor.**

Stopping Dicarz suddenly may cause your condition to worsen or other heart complications may occur.

**Dicarz should only be reduced gradually over a period of about two weeks before stopping completely.**

**Do not use Dicarz to treat any other conditions unless your doctor tells you to.**

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

**Do not give Dicarz to children. The safety and effectiveness of Dicarz in this group have not been proven.**

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

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Dicarz affects you.**

Dicarz may cause tiredness, dizziness or light-headedness in some people, especially after the first dose or when the dosage is increased. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful getting up from a sitting or lying position.**

Dizziness, light-headedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

If you wear contact lenses you may also notice a reduction in the amount of tear fluid in your eyes.

When taken with grapefruit juice the amount of Dicarz absorbed by your body may be increased.

### *Lifestyle measures that help reduce heart disease risk*

**By following these simple measures, you can further reduce the risk from heart disease.**

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
  - eating plenty of vegetables and fruit;
  - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor. Do this before starting any exercise programme.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

**Know warning signs of heart attack and what to do:**

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

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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 Dicarz.**

Dicarz helps most people with heart failure, but it may have unwanted side effects in some 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.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**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:**

- headache (this is usually mild and happens at the start of your treatment)
- tiredness, drowsiness
- low blood pressure. The signs include feeling dizzy or light headed especially after you stand up
- abnormal or blurry vision
- slow heart rate
- diarrhoea
- nausea or vomiting
- bronchitis
- loss of control of blood sugar in diabetics

- weight increase
- fluid retention. The signs include overall swelling of parts of your body such as your hands, feet, ankles and legs
- unusual hair loss or thinning.

These are the more common side effects of Dicarz. Most of them are mild and usually occur at the beginning of therapy, often disappearing within 1 to 2 weeks.

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

- itching, dark urine, loss of appetite, yellowing of skin or eyes, or feeling "flu-like" with no clear cause
- shortness of breath or swelling of the mouth or tongue
- irregular heart beat
- swelling of the feet or legs due to fluid build up
- bleeding or bruising more easily than normal
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

These are very serious but uncommon side effects. You may need urgent medical attention or hospitalisation.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

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## After taking Dicarz

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### Storage

**Keep Dicarz 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.

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

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

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

**Do not store Dicarz or any other medicine in the bathroom or near a sink.**

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

Heat and dampness can destroy some medicines.

### Disposal

**If your doctor tells you to stop taking Dicarz, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### What it looks like

Dicarz is available in three tablet strengths:

- Dicarz 6.25 mg - White, oval shaped, film-coated tablets, with break line on both sides imprinted "6.25" on one side. Available in blister pack of 60.
- Dicarz 12.5 mg - White, oval shaped, film-coated tablets, with break line on both sides, imprinted "12.5" on one side. Available in blister pack of 60.
- Dicarz 25 mg - White, oval shaped, film-coated tablets, with break line on both sides, imprinted "25" on one side. Available in blister pack of 60.

### Ingredients

The active ingredient in Dicarz is carvedilol.

The tablets also contain:

- cellulose-microcrystalline
- lactose

- crospovidone
- povidone
- silica-colloidal anhydrous
- magnesium stearate
- opadry II white YS-22-18096

The tablets are gluten free.

### Supplier

Dicarz is supplied by:

**Alphapharm Pty Limited**

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

Medical Information Phone:

1800 028 365

**Australian Registration Numbers:**

Dicarz 6.25 mg - Blister packs AUST R 124079

Dicarz 12.5 mg - Blister packs AUST R 124081

Dicarz 25 mg - Blister packs AUST R 101742

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