

# Dicarz™

contains the active ingredient carvedilol

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## CONSUMER MEDICINE INFORMATION

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### 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.

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### What Dicarz is used for

Dicarz is used to treat heart failure.

#### **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 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.

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.

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.

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### Before you take Dicarz

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

**Do not take Dicarz if you are allergic to medicines containing carvedilol or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause

difficulty in swallowing or breathing, wheezing or shortness of breath.

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

- asthma or other condition that makes you short of breath from time to time.
- allergic disorders, including allergies which cause asthma or nose running/congestion. See above for description of the possible symptoms of an allergic reaction.
- 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).
- a history of poor kidney function
- chronic bronchitis or emphysema causing breathing difficulties.
- sudden low blood sugar levels (also known as hypoglycaemia).
- Prinzmetal angina or variant angina.
- low blood pressure.
- high blood pressure which varies widely.
- any blood vessel disorder causing poor circulation in the arms and legs
- diabetes.
- asthma.
- psoriasis, a skin disease with thickened patches of red skin, often with silvery scales.
- thyroid disorders.
- severe allergic reactions causing swelling and/or difficulty breathing.
- liver problems.
- pheochromocytoma, a rare tumour of the adrenal gland.

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 anaesthetist must be told that you are taking Dicarz before 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.
- monoamine oxidase inhibitors, medicines used to treat depression (eg. phenelzine, tranylcypromine).
- cimetidine, a medicine used to treat stomach ulcers or reflux.
- calcium antagonists, medicines used to treat high blood pressure and angina (eg. diltiazem, verapamil).
- clonidine, a medicine used to treat high blood pressure, migraine or menopausal symptoms.
- cyclosporin, a medicine used to treat certain problems with the immune system.
- anti-arrhythmic drugs used to treat irregular or abnormal heartbeat (eg. disopyramide, flecainide, amiodarone, quinidine, procainamide, mexiletine and lignocaine).
- insulin and oral drugs for diabetes
- anaesthetic agents used in surgery
- digoxin, medicine used to treat heart failure.

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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### ***How much to take***

The usual starting dose to treat heart failure is 3.125 mg twice daily for two weeks. If well tolerated, your doctor will gradually increase dose to 6.25 mg, 12.5 mg and then 25 mg twice daily at two weeks intervals. Based on how well you tolerate, your doctor will tell you how many Dicarz tablets to take each day.

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

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

### ***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 times each.**

This will lessen the chance of 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.**

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

**If you have any questions about this, check with your doctor or pharmacist.**

### ***How long to take it for***

To properly control your condition, Dicarz must be taken every day, usually as long-term treatment.

**Keep taking Dicarz for as long as your doctor recommends.**

It is very important that you do not stop taking Dicarz suddenly. If you are to stop taking Dicarz, your doctor will advise you to gradually reduce the dose 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.

If you take too much Dicarz, you may feel dizzy, have a very slow heart rate, have difficulty breathing and go into shock.

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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.**

**If you become pregnant while taking Dicarz, tell your doctor.**

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

**Visit your doctor regularly so he/she can check on your progress.**

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.

**If you are to have any medical tests, tell your doctor that you are taking Dicarz.**

### ***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. 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.

### ***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:**

- tiredness, exhaustion.
- dizziness.
- light-headedness.
- abnormal or blurry vision.
- slow heart rate.
- nausea or vomiting.
- diarrhoea, constipation.
- high blood sugar.
- weight increase.
- bronchitis.
- fluid retention.

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:**

- swelling of the face, lips, tongue or throat which may cause difficulty breathing or swallowing.
- signs of worsening heart failure such as shortness of breath, sometimes with tiredness or weakness, swelling of the feet or legs due to fluid build up.
- chest tightness, wheezing, rattly breathing.
- yellowing of the skin or eyes, dark coloured urine, itching, generally feeling unwell
- constant "flu-like" symptoms such as fever, sore throat, lack of energy
- irregular heart beating.

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)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

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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