

# APO-Carvedilol

Contains the active ingredient, carvedilol

## Consumer Medicine Information

**For a copy of a large print leaflet, Ph 1800 195 055**

### What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about carvedilol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on the medicine may be available.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with the medicine. You may need to read it again

### What this medicine is used for

The name of your medicine is APO-Carvedilol. It contains the active ingredient, carvedilol.

It is used to treat high blood pressure and, together with other medicines, to help treat congestive heart failure.

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

Your doctor may have prescribed this medicine for another reason.

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

#### How it works

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

These medicines work by relaxing tightened blood vessels and slowing the heart rate. Carvedilol has the additional effect of being an antioxidant.

Heart failure occurs when the heart can no longer pump blood strongly enough for the body's needs. Often the heart grows in size 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 or legs due to fluid build-up.

Carvedilol reduces the pressure that the heart has to pump against as well as controlling your heart rate. Over 6 months or more, this will reduce the size of an oversized heart and increase its efficiency.

Carvedilol reduces the chances of you being admitted to hospital for this condition.

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

There is no evidence that the medicine is addictive.

#### Use in children

There is not enough information to recommend using this medicine for children.

### Before you take this medicine

#### When you must not take it

Do not take this medicine if:

- **you have or have had a very slow heart rate or uneven heart beating or certain other heart problems such as 2nd or 3rd degree AV block. Carvedilol is not suitable for people with these types of heart problem**
- **you have a very serious type of heart failure (with swelling of your hands, ankles and feet) which is being treated by medicines given into your veins (intravenously)**
- **you have liver problems**
- **you have very low blood pressure**
- **you have been told that you are suffering from shock**
- **you have a problem with the acid levels in your blood ('metabolic acidosis')**
- **you have asthma, wheezing or other conditions which make you short of breath from time to time**

- it has passed the expiry date (EXP) printed on the pack.
- the packaging is torn, shows signs of tampering or it does not look quite right.
- you have allergic disorders, including allergies which cause asthma or nose running/congestion
- you are intolerant or allergic to lactose. This medicine contains lactose.
- you have had an allergic reaction to carvedilol or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash itching or hives on the skin, fainting or hayfever-like symptoms.

**If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

**Do not give this medicine to people under 18 years of age.**

Safety and effectiveness in children have not been established.

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

**Before you start taking this medicine, tell your doctor if:**

#### **1. You have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes.

#### **2. You have or have had any medical conditions, especially the following:**

- a growth on one of your adrenal glands ('phaeochromocytoma')
- angina or chest pain/tightness which occurs even when you are at rest (also called unstable angina or Prinzmetal's variant angina)
- slow heart rate (bradycardia)

- low blood pressure
- high blood pressure which varies widely or which is due to a different medical problem
- very poor circulation to your fingers and/or toes (also called peripheral vascular disease or Raynaud's phenomenon)
- poor kidney function
- heart problems
- liver problems
- chronic bronchitis, asthma, wheezing or emphysema causing breathing difficulties
- diabetes, or sudden low blood sugar levels (also called hypoglycaemia)
- thyroid problems, especially hyperthyroidism
- severe allergic reactions (e.g. sudden swelling, causing difficulty breathing or swallowing, swelling of the hands, feet and ankles or a severe rash)
- skin disease such as psoriasis (hardened patches of red skin), or a previous history of developing psoriasis when taking beta-blockers

#### **3. You are pregnant or plan to become pregnant**

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

#### **4. You are breast-feeding or plan to breast-feed**

Carvedilol passes into breast milk. Your doctor will discuss the risks and benefits of taking carvedilol if you are breast-feeding.

#### **5. You wear contact lenses**

You may not produce as many tears, so wearing contact lenses may be more difficult. Consider using artificial tears if this happens.

#### **6. You are intolerant or allergic to lactose**

This medicine contains lactose.

#### **7. 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 condition and medications.

#### **8. You are currently receiving or are planning to receive dental treatment**

#### **9. You are taking or are planning to take any other medicines, This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop**

Some medicines may interact with carvedilol.

These include:

- rifampicin, a medicine used to treat tuberculosis (e.g. Rimycin®, Rifadin®)
- cimetidine, a medicine used to treat stomach ulcers or reflux
- digoxin, a medicine used to treat heart failure
- medicines used to treat depression, such as monoamine-oxidase inhibitors (MAOIs), e.g. phenelzine (Nardil®), tranylcypromine (Parnate®), and reserpine; or SSRIs such as fluoxetine and paroxetine.
- other monoamine oxidase inhibitors
- clonidine, a medicine used to treat high blood pressure, migraine or menopausal symptoms (e.g. Catapres®)
- medicines used to treat blood pressure or heart problems, such as beta-blockers or diltiazem, disopyramide, quinidine, procainamide, mexiletine, lignocaine, flecainide, amiodarone, tocainide, propafenone and verapamil
- drugs for diabetes, including tablets, and insulin injections,
- cyclosporin, a medicine used to treat certain problems with the immune system or after organ

transplants to protect against rejection

- drugs used during anaesthetics, such as ether, cyclopropane and trichloroethylene
- medicines usually inhaled to treat asthma called beta agonists. These include salbutamol, terbutaline and salmeterol
- anti-inflammatory medicines for treating pain and inflammation, such as ibuprofen, naproxen, aspirin and diclofenac.

If you are taking any of these you may need a different dose or you may need to take different medicines or you may need to be closely monitored for side effects.

Other medicines not listed above may also interact with carvedilol.

Grapefruit juice may also affect your blood levels of carvedilol.

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## How to take this medicine

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Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

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

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any 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**

The usual starting dose in high blood pressure is once daily.

- **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 subsequently be increased at intervals of at least 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 titrated at intervals of at least two weeks up to the recommended maximum daily dose.

Your doctor will monitor you carefully each time the dose is increased.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

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

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

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

### ***When to take it***

**Take this medicine during or immediately after a meal, at about the same time each day.**

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

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

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

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

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

It is very important that you do not suddenly stop taking carvedilol. If you are to stop taking it, your doctor

will advise you to reduce the dose slowly over approximately two weeks.

### ***If you forget to take it***

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember, and then go back to taking your medicine as you would normally.

**Do not take a double dose to make up for missed doses.**

This may increase the chance of unwanted side effects.

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

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

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.**

**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 (fits).

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## While you are taking this medicine

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you become pregnant or plan to breastfeed
- you are going to have surgery (tell your surgeon and anaesthetist)
- you develop a very slow heart rate
- you develop low blood pressure (light-headedness, fainting); this is most likely to happen when you first start taking carvedilol or when you increase the dose.
- you develop dark urine, jaundice and/or you have pain in your upper right side of your abdomen.
- you develop kidney problems

Your doctor may occasionally do blood or urine tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

**Monitor your blood glucose levels regularly if you are diabetic, especially when you start or stop taking this medicine or increase the dose.**

**Have regular eye examinations from your eye doctor.**

**Tell all doctors, dentists and pharmacists who are treating you that you take this medicine.**

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

**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 the tablets are not helping your condition.**

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

**Do not:**

- Give this medicine to anyone else even if their symptoms seem similar to yours

- **take your medicine to treat any other condition unless your doctor or pharmacist tells you to**
- **stop taking your medicine, or change the dosage, without first checking with your doctor. Carvedilol should only be discontinued gradually over two weeks**
- **let yourself run out of medicine over the weekend or on holidays.**

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

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

Carvedilol may affect your ability to drive a car or operate machinery when started or when the dosage is increased, or when it is taken with alcohol.

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

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

Consider using artificial tears to wet the eye if this happens.

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

If you need to stop taking carvedilol, follow your doctor's instructions and gradually discontinue it over 2 weeks. During this time limit the amount of exercise you do and tell your doctor if your blood pressure or heart failure symptoms get worse.

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## **Possible 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 or if you have any questions or concerns.**

Carvedilol helps most people with heart failure but it may have

unwanted side effects in a few people.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor or pharmacist if you notice any of the following and they worry you.**

This list includes the more common side effects. Mostly, these are mild:

- tiredness, sleepiness, weakness, drowsiness or feeling lethargic
- dizziness or giddiness
- wind
- loss of appetite
- indigestion
- problems sleeping or getting to sleep
- problems concentrating
- headache (this is usually mild and happens at the start of your treatment)
- problems with sight (abnormal or blurry vision) or hearing
- diarrhoea, nausea, stomach pain or vomiting
- constipation
- pain in your back, muscles or joints
- muscle weakness
- stuffy nose
- mild rash
- leg or muscle cramps
- numbness or tingling in your fingers
- sore throat
- inflamed gums
- bruising
- hair loss
- memory loss
- dry mouth, increased sweating
- increase sensitivity to touch, sight or smell
- weight increase

- increase in cholesterol levels (shown by a blood test)
- being unable to get an erection (erectile dysfunction) or lacking sex drive

**Tell your doctor as soon as possible if you notice any of the following.**

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- feeling depressed
- problems with blood circulation in your arms and legs. The signs include cold hands and feet, whiteness, tingling and pain in your fingers and a pain in your leg which gets worse when you walk
- problems with your heart when increasing the dose. The signs include chest pains, tiredness, shortness of breath and swelling of your arms and legs
- breathing problems or coughing or chest infection such as bronchitis
- fever
- migraine
- thinking strange thoughts or feeling paranoid or emotionally unstable
- moderate skin rashes, feeling itchy and dry skin patches
- excessive sunburn-type rash after only a short time in the sun
- low numbers of all types of white blood cells. The signs include infections of the mouth, gums, throat and lungs
- low number of platelets in your blood. The signs include bruising easily and nose bleeds
- changes in your blood shown up by a blood test
- hyperkalaemia (too much potassium in your blood)
- anaemia
- high blood pressure (sometimes this can only be measured, but you may have a headache)
- fast,, slow or irregular heart rate

- low blood pressure The signs include feeling dizzy or light-headed, in particular after you stand up.
- fainting
- stuffy nose, wheezing and flu-like symptoms
- sore eyes
- pain when passing urine, blood in the urine or changes in how often or how much urine you pass
- black tarry stools
- high blood sugar levels or developing the signs of diabetes or having trouble controlling your blood sugar if you have diabetes
- some women may have difficulty with bladder control (urinary incontinence). This normally will get better when treatment is stopped.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- itching, dark urine, loss of appetite, yellowing of skin or eyes, or feeling "flu-like" for no known reason
- convulsions or fits
- shortness of breath
- chest pain or tightness
- uneven or slow heart beating or other heart problems
- swelling of the feet or legs due to fluid build up
- serious rashes which cover much of your body and may have blisters or flaking patches of skin
- sudden onset of the symptoms of stroke - such as being unable to smile, having droopy mouth and/or eyes, problems speaking or understanding, confusion and/or unconsciousness.

Other side effects not listed above may occur in some patients.

## **Allergic reactions**

**If you think you are having an allergic reaction to carvedilol, stop taking this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

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## **Storage and disposal**

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### **Storage**

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place, where the temperature will stay below 25°C. Protect it from light and moisture.**

**Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking the tablets or it**

has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### ***What APO-Carvedilol looks like***

#### **3.125 mg tablets:**

White oval shaped, film-coated tablets, imprinted with "P" logo on one side and plain on the other side.

Blister packs of 30 tablets.

Bottles of 30 tablets

Not all strengths, pack types and/or pack sizes may be available.

#### **6.25 mg tablets:**

White oval shaped, film-coated tablets, imprinted "6.25" on one side and "P" logo on the other side.

Blister packs of 30 and 60 tablets.

Bottles of 30 and 60 tablets.

Not all strengths, pack types and/or pack sizes may be available.

#### **12.5 mg tablets:**

White oval shaped, film-coated tablets, imprinted "12.5" on one side and "P" logo on the other side.

Blister packs of 60 tablets.

Bottles of 60 tablets

Not all strengths, pack types and/or pack sizes may be available.

#### **25 mg tablets:**

White oval shaped, film-coated tablets, imprinted "25" on one side and "P" logo on the other side.

Blister packs of 60 tablets.

Bottles of 60 tablets.

Not all strengths, pack types and/or pack sizes may be available.

### ***Ingredients***

Each tablet contains 3.125 mg, 6.25 mg, 12.5 mg or 25 mg of carvedilol as the active ingredient.

It also contains the following inactive ingredients:

- cellulose microcrystalline
- lactose
- crospovidone
- povidone
- silica-colloidal anhydrous
- magnesium stearate
- opadry II complete film coating system YS-22-18096 white.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

### ***Australian Registration Numbers***

APO-Carvedilol 3.125 mg tablets

Blister pack: AUST R 123823.

APO-Carvedilol 3.125 mg tablets

Bottle: AUST R 123825.

APO-Carvedilol 6.25 mg tablets

Blister pack: AUST R 123828.

APO-Carvedilol 6.25 mg tablets

Bottle: AUST R 123833.

APO-Carvedilol 12.5 mg tablets

Blister pack: AUST R 123836.

APO-Carvedilol 12.5 mg tablets

Bottle: AUST R 123837.

APO-Carvedilol 25 mg tablets

Blister pack: AUST R 123840.

APO-Carvedilol 25 mg tablets

Bottle: AUST R 123841.

### ***Sponsor***

Apotex Pty Ltd

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