

APO-CARVEDILOL

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-CARVEDILOL ?

APO-CARVEDILOL contains the active ingredient carvedilol. APO-CARVEDILOL is used to treat heart failure and high blood pressure (hypertension)

For more information, see Section [1. Why am I using APO-CARVEDILOL?](#) in the full CMI.

2. What should I know before I use APO-CARVEDILOL?

Do not use if you have ever had an allergic reaction to carvedilol or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-CARVEDILOL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-CARVEDILOL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-CARVEDILOL?

- Take APO-CARVEDILOL exactly as your doctor has prescribed.
- Your doctor will tell you how many APO-CARVEDILOL tablets to take each day. This depends on your condition and whether or not you are taking other medicines.

More instructions can be found in Section [4. How do I use APO-CARVEDILOL?](#) in the full CMI.

5. What should I know while using APO-CARVEDILOL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist, surgeon, or anesthetist you visit that you are using APO-CARVEDILOL, especially if you are going to have any laboratory tests or surgery.• Drink enough water during exercise and hot weather.• Tell your doctor if you haven't taken your medicines or if you feel it is not helping your condition.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not change the dose without first checking with your doctor• Do not run out of medicine over the weekend or on holidays
Driving or using machines	<ul style="list-style-type: none">• APO-CARVEDILOL may affect your ability to drive a car or operate machinery when started or when dosage is increased.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister pack until its time to take them• Store it in a cool place below 30°C away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using APO-CARVEDILOL?](#) in the full CMI.

6. Are there any side effects?

Shortness of breath, swelling of the mouth or tongue, fluid retention, severe blisters & bleeding in the lips, eyes, mouth, nose and genitals, itching dark urine, loss of appetite, yellowing of skin or eyes, feeling "flu-like" with no clear cause, bleeding or bruising more easily, slow heart rate, irregular heartbeat, chest pain, feeling dizzy or lightheaded, headache, tiredness, drowsiness, abnormal or blurry vision, diarrhoea, nausea or vomiting, bronchitis, weight increase, unusual hair loss or thinning.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-CARVEDILOL

Active ingredient(s): *carvedilol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-CARVEDILOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-CARVEDILOL.**

Where to find information in this leaflet:

- [1. Why am I using APO-CARVEDILOL?](#)
- [2. What should I know before I use APO-CARVEDILOL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-CARVEDILOL?](#)
- [5. What should I know while using APO-CARVEDILOL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-CARVEDILOL?

APO-CARVEDILOL contains the active ingredient **carvedilol**.

Carvedilol belongs to a group of medicines called betablockers. These medicines work by relaxing tightened blood vessels and slowing the heart rate.

Carvedilol has an additional effect of being an antioxidant

Carvedilol is used to treat:

- **Heart failure**
- **High blood pressure, which is called hypertension**

Heart Failure

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.

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 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 high blood pressure. There are usually no symptoms of high blood pressure, and you may feel fine. If high blood pressure is not treated, serious health problems such as stroke, heart disease and kidney failure may occur.

Carvedilol helps to lower your blood pressure.

There is no evidence that the medicine is addictive.

2. What should I know before I use APO-CARVEDILOL?

Warnings

Do not use APO-CARVEDILOL if:

- you are allergic to carvedilol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are under 18 years of age.
- you have asthma or other conditions which make you short of breath from time to time.
- you have a history of allergic problems, including hay fever. Symptoms of an allergy may include rash, itching, watery eyes or sneezing.
- you have a history of a very slow heart rate or uneven heart beating.
- you have certain other heart conditions.
- you have liver problems including liver failure.
- you have very low blood pressure.
- the package is torn or shows signs of tampering.
- the expiry date (EXP) printed on the pack has passed or if the tablets appear damaged in some way.

Do not give APO-CARVEDILOL to people under 18 years of age. Safety and effectiveness in children have not been established.

Check with your doctor if you have any other medical conditions, especially:

- angina or chest pain/tightness which occurs even when you are at rest (also called 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 called hypoglycemia)
- thyroid disorders
- severe allergic reactions causing swelling and/or difficulty breathing
- a history of severe anaphylactic reactions (a whole body allergic reaction), as the effect of medicinal product used for treatment might be reduced
- a rare cancer of the adrenal gland called pheochromocytoma which is not being treated with other medicines
- skin disease such as psoriasis (hardened patches of red skin).

Check with your doctor if you take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

It is not known whether APO-CARVEDILOL is harmful to an unborn baby when taken by a pregnant woman. Your doctor will discuss the risks and benefits of using APO-CARVEDILOL during your pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Surgery

Check with your doctor if you plan to have surgery

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

3. What if I am taking other medicines?

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

Some medicines may interfere with APO-CARVEDILOL and affect how it works. These medicines include:

- rifampicin, a medicine used to treat tuberculosis
- cimetidine, a medicine used to treat stomach ulcers or reflux
- digoxin, a medicine used to treat heart failure
- monoamine-oxidase inhibitors (MAOIs) such as phenelzine and tranylcypromine, medicines used to treat depression

- 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
- ciclosporin or tacrolimus, medicines used to treat certain problems with the immune system
- aspirin and other pain relievers or non-steroidal anti-inflammatory medicines such as ibuprofen or naproxen medicines which may relieve asthma or help you breath better such as salbutamol and salmeterol
- fluoxetine or paroxetine, medicines used to treat depression and other conditions
- drugs for when your heart doesn't beat smoothly, including disopyramide, mexiletine, lignocaine, flecainide, and amiodarone
- drugs for diabetes, including insulin injections, glibenclamide, metformin, gliclazide, glipizide
- other medicines that may help lower your blood pressure.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-CARVEDILOL.

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 has more information on medicines to be careful with or avoid while taking APO-CARVEDILOL.

4. How do I use APO-CARVEDILOL?

How much to take / use

- Take APO-CARVEDILOL exactly as your doctor has prescribed.
- Your doctor will tell you how many APO-CARVEDILOL 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 (half a 6.25 mg tablet) 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 you carefully each time the dose is increased.
- Follow the instructions provided and use APO-CARVEDILOL until your doctor tells you to stop.

When to take / use APO-CARVEDILOL

- APO-CARVEDILOL should be taken during or immediately after a meal, 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 APO-CARVEDILOL on an empty stomach, it may increase the risk of some of the side effects.

How to take APO-CARVEDILOL

- Swallow the tablets whole or halved with a glass of water.
- Do not crush or chew the tablets.

How long to take APO-CARVEDILOL

- Continue taking APO-CARVEDILOL until your doctor tells you to stop.
- Make sure you have enough to last over weekends and holidays.
- It is very important that APO-CARVEDILOL is not ceased suddenly. If you are to stop taking APO-CARVEDILOL your doctor will advise you to reduce the dose slowly over approximately two weeks.

If you forget to use APO-CARVEDILOL

APO-CARVEDILOL should be used regularly at the same time each day.

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 it as soon as you remember then go back to taking your medicine 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 use too much APO-CARVEDILOL

If you think that you have used too much APO-CARVEDILOL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

The following are some symptoms, which may or may not occur because of taking too much APO-CARVEDILOL:

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

5. What should I know while using APO-CARVEDILOL?

Things you should do

Make sure you drink enough water during exercise and hot weather when you are taking APO-CARVEDILOL, especially if you sweat a lot

Tell your doctor that you are taking APO-CARVEDILOL if you are going to have any laboratory tests.

Remind any doctor, dentist, or pharmacist you visit that you are using APO-CARVEDILOL. You should tell your surgeon or anaesthetist if you are having surgery.

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.

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.

Call your doctor straight away if you:

- feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
- become pregnant while taking APO-CARVEDILOL

Things you should not do

- Do not stop using this medicine suddenly.
- Do not stop taking APO-CARVEDILOL or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
APO-CARVEDILOL should only be stopped by gradually reducing the amount over a two-week period.
- Do not give APO-CARVEDILOL to anyone else if they have the same condition as you.
- Do not use APO-CARVEDILOL to treat other complaints unless your doctor says so.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Contact lenses

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

Drinking grapefruit juice

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-CARVEDILOL affects you.

APO-CARVEDILOL may affect your ability to drive a car operate machinery when started or when the dosage is increased.

Drinking alcohol

Tell your doctor if you drink alcohol.

Talk to your doctor about drinking alcohol before taking APO-CARVEDILOL.

Alcohol can change how the medicine affects your condition. Your doctor may advise you to limit your alcohol intake.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
If you take the tablets out of the blister pack they may not keep well. APO-CARVEDILOL tablets are known to fade when exposed to light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
---------------------------	------------

<ul style="list-style-type: none"> • Headache (this is usually mild and happens at the start of the treatment) • Tiredness, drowsiness • Low blood pressure • These signs include feeling dizzy or lightheaded especially after you stand up • Faintness • Abnormal or blurry vision • Slow heart rate • Diarrhoea • Nausea or vomiting • Bronchitis • Loss of control of blood sugar in diabetics • Weight increase • Fluid retention • These signs include overall swelling of parts of your body for example your hands, feet, ankles and legs. • Unusual hair loss or thinning • Dry or irritated eyes • Indigestion • Stomach pain or discomfort • Unusual weakness • General pain or discomfort, pain in extremities • Frequent need to urinate • Difficulty or pain when passing urine • Depression • Hallucination • Asthma • Excessive sweating <p>These are the more common side effects of APO-CARVEDILOL. Most of these are mild and will decrease as you get used to your medicine.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
--	---

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 heartbeat, slow heartbeat or heartbeat pauses/stops, especially in older people or people with other heart conditions • swelling of the feet or legs due to fluid build up • bleeding or bruising more easily than normal 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals • fever, chills, shortness of breath and a cough which produces yellow-green phlegm and occasionally blood • difficulty breathing, or breathlessness which usually worsens on lying down • chest tightness 	
--	--

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-CARVEDILOL contains

Active ingredient (main ingredient)	Carvedilol
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • lactose monohydrate • crospovidone • povidone • colloidal anhydrous silica • magnesium stearate • opadry II complete film coating system YS-22-18096 white (USA).
Potential allergens	This medicine contains sugars as lactose

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

Do not take this medicine if you are allergic to any of these ingredients.

What APO-CARVEDILOL looks like

3.125 mg tablets: AUST R 123823

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

Blister packs of 30 tablets. **AUST R 123823**

Bottles of 30 tablets **AUST R 123825.**

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. **AUST R 123828.**

Bottles of 30 and 60 tablets. **AUST R 123833.**

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. **AUST R 123836**

Bottles of 60 tablets **AUST R 123837**

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. **AUST R 123840.**

Bottles of 60 tablets. **AUST R 123841**

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

Who distributes APO-CARVEDILOL

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in April 2024.