Karvea® Tablets

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Karvea?

Karvea contains the active ingredient irbesartan. Karvea is used to treat high blood pressure and is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes. For more information, see Section 1. Why am I taking Karvea? in the full CMI.

2. What should I know before I take Karvea?

Do not take if you have ever had an allergic reaction to Karvea 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 take Karvea? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Karvea 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 take Karvea?

- Your doctor will tell you how many tablets to take each day. The standard dose is one 150 mg tablet per day. This dose may be increased to a 300 mg tablet per day.
- Swallow the table whole with a glass of water and take Karvea at about the same time each day.
  More instructions can be found in Section 4. How do I take Karvea? in the full CMI.

5. What should I know while taking Karvea?

Things you should do	• Remind any doctor or dentist you visit that you are taking Karvea. • If you become pregnant or plan to breastfeed while taking Karvea tell your doctor immediately. • Before you start on any new medicine, tell your doctor and pharmacist you are taking Karvea. • If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Karvea. • Make sure you drink enough water during exercise and hot weather when you are taking Karvea. • If you have excessive vomiting and/or diarrhoea while taking Karvea, tell your doctor. • If you feel lightheaded or dizzy after your dose is increased, tell your doctor immediately.
Things you should not do	• Do not stop taking Karvea, or lower the dosage, without checking with your doctor.
Driving or using machines	• Be careful driving or operating machinery until you know how Karvea affects you. Karvea may cause dizziness or light- headedness in some people. If this occurs do not drive.
Drinking alcohol	• If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	• Keep Karvea tablets in a cool dry place where the temperature stays below 25°C. • Keep your tablets in the packaging until it is time to take them.

For more information, see Section 5. What should I know while taking Karvea? in the full CMI.

6. Are there any side effects?

Common side effects: headache, dizziness or light-headedness, unusual tiredness or weakness, fatigue, nausea/vomiting. Serious side effects: swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing; severe and sudden onset of pinkish, itchy swellings on the skin (hives or nettle rash). Common side effects: headache; dizziness or light-headedness (vertigo); unusual tiredness or weakness, fatigue; nausea/vomiting. 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.

Karvea® Tablets

Active ingredient(s): irbesartan

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I taking Karvea?
2. What should I know before I take Karvea?
3. What if I am taking other medicines?
4. How do I take Karvea?
5. What should I know while taking Karvea?
6. Are there any side effects?
7. Product details

1. Why am I taking Karvea?

Karvea contains the active ingredient irbesartan. Karvea is belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin II is a substance produced in the body that causes blood vessels to narrow. Karvea blocks angiotensin-II and therefore widens your blood vessels, making it easier for your heart to pump blood throughout your body. This helps to lower your blood pressure. Karvea also slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Karvea is used to treat high blood pressure, which doctors call hypertension. Karvea is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes.

2. What should I know before I take Karvea?

Warnings

Do not take Karvea if:

- you are allergic to irbesartan, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- you are pregnant (or think you may be pregnant) or are planning to become pregnant.
- you are breast-feeding. It is not known if Karvea passes into breast milk, therefore it is recommended that you not take it while you are breast-feeding
- you have diabetes or have kidney problems and are being treated with medicines that lower blood pressure such as an ACE inhibitor, any medicines containing aliskiren or medicines that belong to a group of medicines known as Angiotensin-II receptor antagonists (medicines also used to treat high blood pressure)

Check with your doctor if you:

- have any other medical conditions
- have had recent excessive vomiting or diarrhoea
- have kidney problems, or you have had a kidney transplant or dialysis
- have heart problems
- have liver problems, or have had liver problems in the past
- have diabetes
- have high levels of potassium in your blood
- are strictly restricting your salt intake
- take any medicines for any other condition
- are pregnant or intend to become pregnant
- if you are breast feeding or plan to breastfeed
- plan to have surgery (even at the dentist) that needs a general anaesthetic
- have allergies to any substances, such as foods, preservatives or dyes.

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?

Use in children

Karvea should not be given to children.

Pregnancy and breastfeeding

- Check with your doctor if you are pregnant or intend to become pregnant. Do not take Karvea if you are pregnant or intend to become pregnant.
- Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not take Karvea if you are breastfeeding.

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.

Tell your doctor if you are taking or plan to take any of the following:

- other medicines to treat high blood pressure
- potassium supplements or, potassium-containing salt substitutes (you may need to have regular blood tests
- diuretics
- medicines containing lithium (you may need to have regular blood tests)
- non-steroidal anti- inflammatory medicine such as diclofenac, ibuprofen) and COX- 2 inhibitors (for example celecoxib). These medicines may be used to relieve pain, swelling and other symptoms of inflammation including arthritis. Taking Karvea and an

anti-inflammatory medicine alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect Karvea has on lowering blood pressure.
- medicines taken to treat diabetes such as repaglinide. Karvea might lower your blood glucose levels.

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

4. How do I take Karvea?

How much to take

- The usual starting dose is 150 mg tablet once a day. However, some patients may need a lower starting dose. Your doctor will tell you if this is necessary. The full blood pressure lowering effect of Karvea should be reached about 4 to 6 weeks after starting treatment.
- Depending on how your blood pressure responds, your daily dose of Karvea may need to be increased. Most patients take either 150 mg or 300 mg once a day.
- In patients with high blood pressure and type 2 diabetes, 300 mg once a day is the preferred maintenance dose for slowing the progression of associated kidney disease.
- Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.
- Follow the instructions provided and take Karvea until your doctor tells you to stop.

When to take Karvea

- Take Karvea at about the same time each day.

How to take Karvea

- Swallow the tablet whole with a glass of water. It does not matter whether you take Karvea tablets before or after food.
- Continue taking Karvea until your doctor tells you to stop.
- Karvea tablets are supplied in a Calendar pack with the foil backing marked with the days of the week. This is just a way to help you to remember to take your tablets. All of the tablets in the pack are the same.
- When you start a new strip of tablets, take the tablet marked "START" at the end of the blister strip. On the next day, take the tablet marked with the relevant day of the week. Continue taking your tablets each day until all of the tablets are taken. Commence the next strip at "START" and continue as before.

If you forget to take Karvea

Karvea should be used regularly at the same time each day. If you miss your dose at the usual time.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

Otherwise, take it as soon as you remember, and go back to taking your tablets as you would normally.

If you take too much Karvea

If you think that you have used too much Karvea, you may need urgent medical attention. If you take too many Karvea tablets you will probably feel lightheaded or dizzy.

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.

If you take too many Karvea tablets you will probably feel lightheaded or dizzy.

5. What should I know while taking Karvea?

Things you should do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Karvea
- Tell your doctor immediately if you become pregnant while taking Karvea
- Have your blood pressure checked when your doctor tells you to, to make sure Karvea is working
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Karvea
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Karvea. Your blood pressure may drop suddenly
- Make sure you drink enough water during exercise and hot weather when you are taking Karvea, especially if you sweat a lot. If you do not drink enough water while taking Karvea, you may faint or feel light-headed or sick. This is because your body does not have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.
- Tell your doctor if you have excessive vomiting and/or diarrhoea while taking Karvea. You may lose too much water and salt and your blood pressure may drop too much.
- Tell your doctor immediately If you feel lightheaded or dizzy after taking your first dose of Karvea, or when your dose is increased.
- Tell your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Karvea. Your doctor will decide on further treatment. Do not stop taking Karvea on your own.

Things you should not do

- Do not give Karvea tablets to anyone else, even if they have the same condition as you

- Do not take Karvea to treat any other complaints unless your doctor or pharmacist tells you to
- Do not stop taking Karvea, or lower the dosage, without checking with your doctor

Things to be careful of

- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
- Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Karvea affects you.

As with many other medicines used to treat high blood pressure, Karvea may cause dizziness or light- headedness in some people. If this occurs do not drive.

Make sure you know how you react to Karvea before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

- Keep Karvea tablets in a cool dry place where the temperature stays below 25°C
- Keep your tablets in the blister pack until it is time to take them

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
- do not store it in the car or on window sills.

Do not take this medicine after the expiry date.

Keep it where young children cannot reach it.

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.

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
• headache • dizziness or light-headedness (vertigo) • unusual tiredness or weakness, fatigue • nausea/vomiting • low blood glucose levels • decreased number of red blood cells (anaemia – symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale)	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **They are generally mild and do not normally require treatment to be interrupted.**

Serious side effects

Serious side effects	What to do
• skin rash or itchiness. • aching muscles, not caused by exercise • muscle pain or weakness • blood tests may show raised levels of an enzyme that measures the breakdown of muscle (creatine phosphokinase) • a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea • buzzing, ringing or other persistent noise in the ear • symptoms that may indicate kidney disease, such as passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness • symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm • symptoms that may indicate liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine • yellowing of the skin and/or eyes, also called jaundice • symptoms that may indicate low platelet count such as easy or excessive bruising, bleeding from gums or nose, prolonged	**Call your doctor straight away, you may need medical attention**

Serious side effects	What to do
bleeding from cuts and blood in urine or stools.	
Allergy-related symptoms: • swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing • severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash	**Stop taking Karvea and 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.**

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 Karvea contains

Active ingredient (main ingredient)	Each tablet contains 150 mg or 300 mg of irbesartan
Other ingredients (inactive ingredients)	• carnauba wax • croscarmellose sodium • hypromellose • lactose monohydrate • magnesium stearate • microcrystalline cellulose • silicon dioxide • OPADRY II complete film coating system 32F38977 WHITE
Potential allergens	Sugars (as lactose monohydrate)

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

What Karvea looks like

Karvea 150 mg tablets: white, oval film-coated tablets with a heart shape imprinted on one side and "2872" engraved on the other side. Pack size: 30 tablets (Aust R 101706)

Karvea 300 mg tablets: white, oval film-coated tablets with a heart shape imprinted on one side and "2873" engraved on the other side. Pack size: 30 tablets (Aust R 101708).

Who distributes Karvea

Distributed by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

This leaflet was prepared in April 2026.

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