

Karvea(R)

Irbesartan

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking Karvea.

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

Do not throw this leaflet away.

You may need to refer to it again later.

Always follow the instructions that your doctor and pharmacist give you about Karvea. If you have any concerns about taking Karvea, ask your doctor or pharmacist.

What is Karvea

Karvea is a trade name (manufacturer's name) for the medicine, irbesartan. This medicine is in the tablets your doctor has prescribed for you.

What Karvea is used for

Karvea lowers high blood pressure, which doctors call hypertension.

Your doctor measured your blood pressure and found it to be too high. Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure)

that means your blood pressure stays high, even when you are calm and relaxed.

There are usually no symptoms of high blood pressure. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. This may lead to heart attacks, heart or kidney failure, strokes, or blindness. There are usually no symptoms of high blood pressure before damage occurs, so your doctor needs to measure your blood pressure to see if it is too high.

High blood pressure can be treated and controlled with medicines such as Karvea. Your doctor may also have recommended that you adjust your lifestyle to help to lower your high blood pressure (losing weight, avoiding smoking, reducing alcohol consumption and restricting the amount of salt in the diet). Your doctor may also have encouraged the practice of regular, mild (not strenuous) exercise such as walking, swimming, etc.

Karvea is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes.

What Karvea does and how it works

Karvea 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 tighten.

Karvea blocks angiotensin-II and therefore relaxes your blood vessels. This helps to lower your blood pressure.

Karvea slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Your doctor may have prescribed Karvea for another use. If you want more information, ask your doctor.

When you must not take Karvea

Do not take Karvea if:

- * **you are pregnant (or think you may be pregnant) or are planning to become pregnant;** Your baby may absorb this medicine in the womb and there is a possibility of harm to the baby;
- * **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 are allergic to irbesartan or to any of the ingredients listed under Product Description at the end of this leaflet;**
- * **the packaging is torn or shows signs of tampering;**
- * **the expiry date on the pack has passed;**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure if you should start taking Karvea, talk to your doctor.

Karvea should not be given to children.

Before you start to take Karvea

Tell your doctor if:

- * **you are or intend to become pregnant or plan to breast-feed;**
Karvea should not be used during pregnancy or while breast-feeding;
- * **you have recently had excessive vomiting or diarrhoea;**
- * **you suffer from any medical conditions especially kidney or heart problems, liver problems, or have had liver problems in the past;**
- * **you are strictly restricting your salt intake;**
- * **you are lactose intolerant or have had any allergies to any other medicine or any other substances, such as foods, preservatives or dyes.**

Be sure you tell your doctor about any of these things before you take any Karvea.

Taking Karvea with other medicines

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

Some medicines may affect the way others work. Also, some other medicines used to treat high blood pressure may have an additive effect with Karvea in lowering blood pressure. This may happen with diuretics (fluid tablets). As a result you may need different amounts of your medicines.

It may be necessary to have blood tests done regularly if you take potassium supplements, potassium-containing salt substitutes or some medicines such as diuretics (fluid tablets).

It may also be necessary to have blood tests done regularly if you take a medicine containing lithium while you are taking Karvea.

In general Karvea has been shown not to interfere with other medicines. However it is important to tell your doctor and pharmacist about any medicines you are taking or plan to take.

How to take Karvea

The tablets should be taken regularly as directed by your doctor. They should be swallowed with a glass of water.

How much to take

Your doctor will tell you how many tablets to take each day.

Usually patients start with one 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 4-6 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 each day.

In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for the treatment of associated kidney disease.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

You should try to take your daily dose of Karvea at about the same time each day.

Taking your Karvea tablets at the same time each day will have the best effect. It does not matter whether you take Karvea tablets before or after food. The tablets should be swallowed with a drink of water.

How long to take it

Continue taking Karvea until your doctor tells you to stop.

Karvea helps to control your high blood pressure, but it does not cure it. Therefore Karvea must be taken every day.

To help you remember to take your tablets each day, 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 miss a dose

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, and go back to taking your tablets as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too much Karvea (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone: 13 11 26) or go to the Emergency Department at your nearest hospital, if you or anyone else may have taken too much Karvea. Do this even if there are no signs of discomfort or poisoning.

If you take too many Karvea tablets you will probably feel light-headed or dizzy.

While you are using Karvea

Things you must do

If you become pregnant while taking Karvea tell your doctor immediately.

Have your blood pressure checked when your doctor tells you to, to make sure Karvea is working.

If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking Karvea.

Get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy while taking Karvea, especially if you are also taking a diuretic (fluid tablet). This may become worse if you stand up quickly as your blood pressure may fall. 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. This problem is not common. If it occurs, talk to your doctor.

If you plan to have surgery (even at the dentist) 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, 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.

If you have excessive vomiting and/or diarrhoea while taking Karvea, tell your doctor.

This can also mean that you are losing too much water and your blood pressure may become too low.

Things you must not do

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

Things to be careful of

Be careful driving or operating machinery 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. 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.

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

Side effects

Karvea helps most people with high blood pressure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Karvea.

Tell your doctor if you notice any of the following and they worry you:

- * headache;

- * dizziness or light-headedness;
- * unusual tiredness or weakness, fatigue;
- * nausea/vomiting.

These are common side effects. They are generally mild and do not normally require treatment to be interrupted.

Tell your doctor immediately if you notice any of the following:

- * skin rash or itchiness;
- * aching muscles, not caused by exercise;
- * muscle pain, weakness or paralysis of muscles;
- * buzzing, ringing or other persistent noise in the ear;
- * yellowing of the skin and/or eyes, also called jaundice;
- * 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.

These are serious side effects. Skin rash and itchiness may be symptoms of an allergic reaction. You may need medical attention.

These side effects are not common.

If any of the following happen, stop taking Karvea and tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- * 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 nettlerash.

These are serious side effects. If you have them, you have had a serious allergic reaction to Karvea. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Other side effects not listed above may occur in some patients. If you notice any other unwanted effects, you should tell your doctor or pharmacist and ask for their advice.

After using Karvea

Storage

Keep your Karvea 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.

Keep Karvea tablets in a cool dry place where the temperature stays below 25 degrees C. Do not store Karvea or any other medicine in the bathroom or near a sink. Do not leave them near a radiator, in a car on hot days or on a window sill.

Heat and dampness can destroy some medicines.

Keep all medicines out of the reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

Starting from February 2006 the manufacturer will be supplying a new formulation of Karvea tablets with some different inactive ingredients. Therefore, until all stocks of the original formulation have been used up, your pharmacist may give you either the original formulation or the new one. There is only a slight difference between the appearance of the original and the new tablets (see below).

There is no difference between the two formulations in the active ingredient or how well Karvea tablets work.

Original formulation

Karvea 75 mg tablets: white to off-white, oval tablets with a heart shape on one side and "2771" on the other. Pack size: 30 tablets. AUST R 63088.

Karvea 150 mg tablets: white to off-white, oval tablets with a heart shape on one side and "2772" on the other. Pack size: 30 tablets. AUST R 63090.

Karvea 300 mg tablets: white to off-white, oval tablets with a heart shape on one side and "2773" on the other. Pack size: 30 tablets. AUST R 63089.

New formulation

Karvea 75 mg tablets: white to off-white, oval film-coated tablets with a heart shape on one side and "2871" on the other. Pack size: 30 tablets. AUST R 101702.

Karvea 150 mg tablets: white to off-white, oval film-coated tablets with a heart shape on one side and "2872" on the other. Pack size: 30 tablets. AUST R 101706.

Karvea 300 mg tablets: white to off-white, oval film-coated tablets with a heart shape on one side and "2873" on the other. Pack size: 30 tablets. AUST R 101708.

Active ingredients

Karvea 75 mg tablets: 75 mg irbesartan per tablet.

Karvea 150 mg tablets: 150 mg irbesartan per tablet.

Karvea 300 mg tablets: 300 mg irbesartan per tablet.

Other Ingredients

Original formulation

Karvea tablets also contain microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate, silicon dioxide, pregelatinised maize starch, and poloxamer 188.

New formulation

Karvea tablets also contain carnauba wax, croscarmellose sodium, hypromellose, lactose, macrogol 3000, magnesium stearate, microcrystalline cellulose, silicon dioxide, and titanium dioxide

Manufacturer

Karvea is supplied in Australia by: sanofi-aventis australia Pty ltd
12-24 Talavera Road
Macquarie Park, NSW 2113.

This leaflet was prepared in September 2006.

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