

## Karbesat

contains the active ingredient irbesartan

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about KARBESAT.

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 KARBESAT against the benefits they expect 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.

#### What KARBESAT is used for

KARBESAT lowers high blood pressure, also called hypertension.

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) which 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 KARBESAT. 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.

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

KARBESAT belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which causes blood vessels to tighten. KARBESAT blocks angiotensin-II and therefore relaxes your blood vessels. This helps to lower your blood pressure.

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

Your doctor may have prescribed KARBESAT for another reason.

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

KARBESAT is not recommended for use in children.

KARBESAT is available only with a doctor's prescription.

#### Before you take KARBESAT

*When you must not take it*

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

**Do not take KARBESAT if you are pregnant.** KARBESAT may harm your developing baby if you take it during pregnancy.

**Do not take KARBESAT if the expiry date (Exp.) printed on the pack has passed.**

**Do not take KARBESAT if the packaging is torn or shows signs of tampering.**

*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 breastfeeding or wish to breastfeed.**

Your doctor will discuss the risks and benefits of taking KARBESAT when breastfeeding.

**Tell your doctor if you plan to become pregnant.**

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- kidney problems
- heart problems
- liver problems
- recent excessive vomiting or diarrhoea.

**Tell your doctor if you are restricting salt intake in your diet.**

**If you have not told your doctor about any of the above, tell them before you start taking KARBESAT.**

*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 KARBESAT, or may affect how well it works. These include:

- other medicines for high blood pressure
- fluid tablets or diuretics
- lithium or lithium containing medicines (for example Lithicarb)
- potassium tablets (for example Span-K, Slow-K, Mag-K)
- potassium containing salt substitutes (for example Pressor-K)
- anti-inflammatory medicines, used to relieve pain, swelling and other symptoms of inflammation, including arthritis. These include nonsteroidal anti-inflammatory agents - NSAIDs (for example Voltaren, Indocid) and COX-2 inhibitors (for example Celebrex).

Taking a combination of KARBESAT with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.

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 KARBESAT.

#### How to take KARBESAT

*How much to take*

The dose varies from patient to patient.

The usual starting dose is one 150 mg tablet once a day, although a lower dose may be needed in some patients.

Depending on how your blood pressure responds, your daily dose of KARBESAT may need to be increased. The full blood pressure lowering effect of KARBESAT should be reached about 4-6 weeks after starting treatment.

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 and pharmacist carefully.**

*How to take KARBESAT*

**Swallow the tablets with a glass of water.**

**Take your daily dose of Karbesat at about the same time each day.**

Taking your KARBESAT tablets at the same time each day will have the best effect.

To help you remember to take your tablets each day, KARBESAT 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 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". 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.

It does not matter whether you take KARBESAT tablets before or after food.

*If you forget to take KARBESAT*

**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.**

*How long to take KARBESAT for*

KARBESAT helps control your high blood pressure but does not cure it. To properly control your condition, KARBESAT must be taken every day.

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

*If you take too much KARBESAT (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 KARBESAT. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much KARBESAT, you may feel dizzy or lightheaded.

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## While you are taking KARBESAT

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### *Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking KARBESAT.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking KARBESAT.**

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

**If you plan to have surgery, including dental surgery, that needs a general anaesthetic, tell your doctor or dentist that you are taking KARBESAT.**

**Visit your doctor regularly so they can monitor your blood pressure and ensure that KARBESAT is working for you.**

### *Things you must not do*

**Do not use KARBESAT to treat any other conditions unless your doctor tells you to.**

**Do not give KARBESAT 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 KARBESAT affects you.** KARBESAT may cause drowsiness, dizziness or light-headedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

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

**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. This problem can be more common if you are also taking a diuretic (fluid tablets). 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.

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

If you do not drink enough water while taking KARBESAT, 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 KARBESAT, tell your doctor.**

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

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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 KARBESAT.**

Like all other medicines, KARBESAT may have unwanted side effects in some people. 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:**

- 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 or aching joints, not caused by exercise
- muscle pain
- buzzing, ringing or other persistent noise in the ears
- 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 and change in heart rhythm.

These are uncommon but serious side effects.

Skin rash and itchiness may be symptoms of an allergic reaction. You may need medical attention.

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

- swelling to 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.

These are very rare but serious side effects. If you have them you have had a serious allergic reaction to KARBESAT. 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 using KARBESAT

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### *Storage*

**Keep KARBESAT 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 a cool dry place where the temperature stays below 25°C.**

**Do not store KARBESAT or any other medicine in the bathroom or near a sink.**

**Do not leave KARBESAT in the car or on window sills.**

Heat and dampness can destroy some medicines.

### *Disposal*

**If your doctor tells you to stop taking KARBESAT, 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*

KARBESAT comes in 3 strengths of tablets:

- KARBESAT 75 - White, oval shaped coated tablet with 'IS' on one side and ">" on the other side
- KARBESAT 150 - White, oval shaped coated tablet with 'IS 150' on one side and ">" on the other side
- KARBESAT 300 - White, oval shaped coated tablet with 'IS 300' on one side and ">" on the other side.

Each pack contains 30 tablets.

### *Ingredients*

The active ingredient in KARBESAT is irbesartan.

- each KARBESAT 75 tablet contains 75 mg of irbesartan
- each KARBESAT 150 tablet contains 150 mg of irbesartan
- each KARBESAT 300 tablet contains 300 mg of irbesartan.

The tablets also contain:

- microcrystalline cellulose
- lactose
- crospovidone
- hydroxypropylcellulose
- purified talc
- sodium stearyl fumarate
- Opadry II 8F18378 White.

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

### *Supplier*

**Aspen Pharma Pty Ltd**  
34-36 Chandos Street  
St. Leonards NSW 2065  
Australia

**Australian registration numbers:**  
KARBESAT 75 - AUST R 171460  
KARBESAT 150 - AUST R 171462  
KARBESAT 300 - AUST R 171458

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