

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 SEVIKAR?

SEVIKAR contains the active ingredient olmesartan medoxomil and amlodipine besilate. SEVIKAR is used to treat high blood pressure.

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

2. What should I know before I use SEVIKAR?

Do not use if you have ever had an allergic reaction to SEVIKAR 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 SEVIKAR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SEVIKAR 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 SEVIKAR?

- Follow all directions given to you by your doctor or pharmacist carefully. Your doctor will tell you which SEVIKAR tablet you will need to take each day.
- Swallow SEVIKAR whole with a full glass of water.
- Take your tablets at the same time each day.

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

5. What should I know while using SEVIKAR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SEVIKAR.• If you become pregnant while taking SEVIKAR, tell your doctor immediately.• Go to your doctor regularly for a check-up.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly, or lower the dosage, or take it to treat any other complaints, unless your doctor tells you to.• Do not give SEVIKAR to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how SEVIKAR affects you.• SEVIKAR may cause dizziness, light-headedness or tiredness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Your doctor may advise you to limit your alcohol intake.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the box until it is time to take them.• Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects may include dizziness, feeling light-headed, cough, headache, feeling nauseous, vomiting, diarrhoea, tiredness, 'flu-like' symptoms, sore throat, difficulty swallowing, back pain, swelling of the face or body and urinary infection.

Serious side effects may include swelling of the face, lips tongue or throat which causes difficulty swallowing or breathing and muscle pain.

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.

SEVIKAR

Active ingredient(s): olmesartan medoxomil and amlodipine besilate

Consumer Medicine Information (CMI)

This leaflet provides important information about using SEVIKAR. **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 SEVIKAR.**

Where to find information in this leaflet:

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

1. Why am I using SEVIKAR?

SEVIKAR contains the active ingredient olmesartan medoxomil and amlodipine besilate.

SEVIKAR is used to treat high blood pressure which is sometimes called hypertension.

Everyone has blood pressure. This pressure helps push blood all around your body. Your blood pressure changes at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

How SEVIKAR works

SEVIKAR contains olmesartan medoxomil, which 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. SEVIKAR blocks the action of angiotensin-II and therefore relaxes your blood vessels. This helps lower your blood pressure.

SEVIKAR also contains amlodipine besilate, a calcium channel blocker. This reduces the movement of calcium into the cells of the heart and blood vessels. This also helps to lower blood pressure as it relaxes the blood vessels and increases the supply of blood and oxygen to the heart.

Your doctor may have prescribed SEVIKAR for another reason. Ask your doctor if you have any questions about why SEVIKAR has been prescribed for you.

SEVIKAR is not addictive.

2. What should I know before I use SEVIKAR?

Warnings

Do not use SEVIKAR if:

- you are allergic to:
 - olmesartan,
 - amlodipine besilate, medicines belonging to a group of chemicals called dihydropyridines used to treat blood pressure and other heart problems,
 - or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to SEVIKAR may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.

- you have serious problems with your kidneys
- you have serious problems with your liver
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- you have had recent serious heart problems
- you have low potassium or sodium levels in the blood
- you are pregnant or breast-feeding
- the expiry date on the pack has passed or if the packaging is torn or shows signs of tampering

Tell your doctor if:

- you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- you have or have had any other medical conditions, especially the following:
 - Kidney problems
 - liver problems
 - heart problems
 - diabetes
 - excessive vomiting or diarrhoea recently
 - high levels of potassium in your blood.
 - Problems with your adrenal glands (small glands above the kidneys)
- you are following a very low salt diet
- you are or intend to become pregnant or plan to breastfeed.
- you are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or other medicines that may increase serum potassium (e.g., trimethoprim-containing products)

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

Do not take SEVIKAR if you are pregnant or breastfeeding.

SEVIKAR may enter your womb or it may pass into the breast milk and there is the possibility that your baby may be affected.

If pregnancy is discovered SEVIKAR should be discontinued as soon as possible.

Use in children

The safety and effectiveness of SEVIKAR in children has not been established.

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 and SEVIKAR may interfere with each other. These include:

- other medicines to treat high blood pressure
- any medicines that contain aliskiren
- medicines used to treat angina, such as diltiazem
- non-steroid anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis
- potassium supplements or potassium-containing salt substitutes
- other medicines that may increase serum potassium (e.g., trimethoprim-containing products)
- lithium or antidepressant medicines
- some antibiotics, such as erythromycin or rifampicin
- some antifungals, such as ketoconazole or itraconazole
- anti-proteases, medicines used to treat HIV infection such as ritonavir
- medicines which lower your immune system, such as ciclosporin and tacrolimus
- St John's Wort
- Grapefruit or grapefruit juice
- any medicines that contain colesevelam.

These medicines may be affected by SEVIKAR, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

4. How do I use SEVIKAR?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you which SEVIKAR tablet you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

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

How much to take

- The dose of SEVIKAR is one tablet to be taken once a day.

How to take SEVIKAR

- **Swallow SEVIKAR whole with a full glass of water.**
- Do not chew the tablets.

When to take SEVIKAR

- **Take SEVIKAR at about the same time each day, with or without food.**

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets. It does not matter whether you take it with or without food.

How long to take SEVIKAR

SEVIKAR helps control your condition, but does not cure it. Therefore you must take SEVIKAR every day. Continue taking your medicine for as long as your doctor tells you.

If you forget to take SEVIKAR

SEVIKAR 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 and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you take too much SEVIKAR (overdose)

If you think that you have used too much SEVIKAR, 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.

Keep telephone numbers for these places handy.

If you take too much SEVIKAR, you may feel light-headed, dizzy, or you may faint. You may also have a fast heartbeat.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

5. What should I know while using SEVIKAR?

Things you should do

- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking SEVIKAR.
- Have your blood pressure checked when your doctor says, to make sure SEVIKAR is working.
- Go to your doctor regularly for a check-up. Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.
- 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.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking SEVIKAR. Your blood pressure may suddenly drop.
- If you are about to have any blood tests, tell your doctor that you are taking SEVIKAR. SEVIKAR may interfere with the results of some tests.

Call your doctor straight away if you:

- **have excess vomiting and/or diarrhoea while taking SEVIKAR.**
You may lose too much water and salt and your blood pressure may drop too much.
- **feel light-headed or dizzy after taking your first dose of SEVIKAR, or when your dose is increased.**
- **become pregnant while taking SEVIKAR.**

Remind any doctor, dentist or pharmacist you visit that you are using SEVIKAR.

Things you should not do

- Do not give SEVIKAR to anyone else, even if they have the same condition as you.
- Do not take SEVIKAR to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking SEVIKAR, or lower the dosage, without checking with your doctor.

Things that would be helpful for your blood pressure

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.
- Diet - eat a healthy diet which includes plenty of fresh vegetables, fruit, bread (preferably wholegrain),

cereals and fish. Also eat less sugar and fat (especially saturated fat) which includes sausages, fatty meats, full cream dairy products, biscuits, cakes, pastries, chocolates, chips and coconut. Monounsaturated and polyunsaturated fats from olive oil, canola oil, avocado and nuts are beneficial in small quantities.

- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table and avoid cooked or processed foods containing high sodium (salt) levels.
- Exercise - regular exercise, maintained over the long term, helps to reduce blood pressure and helps get the heart fitter. Regular exercise also improves your blood cholesterol levels, helps reduce your weight and stress levels, and improves your sleep, mood and ability to concentrate. However, it is important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- Smoking - your doctor may advise you to stop smoking or at least cut down. There are enormous benefits to be gained from giving up smoking. There are many professionals, organisations and strategies to help you quit. Ask your doctor or pharmacist for further information and advice.

Driving or using machines

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

As with other medicines in this class, SEVIKAR may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to SEVIKAR before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Your doctor may advise you to limit your alcohol intake.

Looking after your medicine

- **Keep your tablets in the box until it is time to take them.**
If you take the tablets out of the box they will not keep well.
- **Keep your tablets in a cool dry place where the temperature stays below 25°C.**

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.

Heat and dampness can destroy some medicines.

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking SEVIKAR 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.

SEVIKAR helps most people with high blood pressure, but it may have unwanted side effects in a few people. If you are over 65 years of age you may have an increased chance of getting side effects.

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
<p>Head and nervous system-related:</p> <ul style="list-style-type: none"> feeling light-headed, dizzy or faint headache <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> diarrhoea feeling sick (nausea) or vomiting <p>Respiratory-related:</p> <ul style="list-style-type: none"> bronchitis Cough <p>General conditions:</p> <ul style="list-style-type: none"> swelling of the face, hands, feet or ankles sore throat and discomfort when swallowing (pharyngitis) back pain unusual tiredness or weakness, fatigue 'flu-like' symptoms <p>Urinary system-related:</p> <ul style="list-style-type: none"> urinary tract infection 	<p>These are common side effects and are generally mild. 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"> skin rash or itchiness aching, tender or weak muscles not caused by exercise painful joints fast heartbeat shortness of breath or tightness in the chest swelling of the face, hands, feet or ankles yellowing of the whites of the eyes, dark urine and itching of the skin. symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm. 	<p>Call your doctor as soon as possible, if you notice any of these serious side effects. You may need medical attention.</p>
<ul style="list-style-type: none"> swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing 	<p>Stop taking SEVIKAR and call your doctor immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Serious side effects are rare.

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 SEVIKAR contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> SEVIKAR 20/5 - 20 mg olmesartan medoxomil and 5 mg amlodipine besilate
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	<ul style="list-style-type: none"> • SEVIKAR 20/10 - 20 mg olmesartan medoxomil and 10 mg amlodipine as besilate. • SEVIKAR 40/5 - 40 mg olmesartan medoxomil and 5 mg amlodipine besilate • SEVIKAR 40/10 - 40 mg olmesartan medoxomil and 10 mg amlodipine besilate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • colloidal anhydrous silica • pregelatinised maize starch • croscarmellose sodium • magnesium stearate • polyvinyl alcohol • macrogol 3350 • titanium dioxide • purified talc • and iron oxides in SEVIKAR 40/5 and 40/10.

SEVIKAR does not contain sucrose, tartrazine or any other azo dyes.

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

What SEVIKAR looks like

SEVIKAR tablets come in four strengths and each has a different appearance:

- SEVIKAR 20/5 is a white round tablet, approximately 6mm in diameter, with C73 debossed on one side. (AUST R 157565)
- SEVIKAR 20/10 is a round tablet, approximately 8 mm in diameter, greyish-orange in colour with C74 debossed on one side. (AUST R 157564)*
- SEVIKAR 40/5 is a cream round tablet, approximately 8mm in diameter, with C75 debossed on one side. (AUST R 157563)
- SEVIKAR 40/10 is a brownish red round tablet, approximately 8mm in diameter, with C77 debossed on one side. (AUST R 157562)

The product is presented in blister packs of 10* or 30 film-coated tablets.

*Not currently available in Australia

Who distributes SEVIKAR

Organon Pharma Pty Ltd
Level 5, 66 King St
Sydney NSW 2000.
AUSTRALIA

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