

SEVIKAR®

Olmesartan medoxomil and amlodipine besilate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SEVIKAR.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SEVIKAR against the benefits he/she expects it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your tablets.

You may need to read it again.

What SEVIKAR is used for

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.

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

Before you take SEVIKAR

When you must not take it

Do not take SEVIKAR if you have an allergy 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.

Do not take SEVIKAR if:

- 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

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.

Do not take SEVIKAR after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking SEVIKAR, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any 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 must also tell your doctor if 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)

If you have not told your doctor about any of the above, tell him/her before you start taking SEVIKAR.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any 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.

Other medicines not listed above may also interfere with SEVIKAR. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Use in children

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

How to take 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 it

Swallow SEVIKAR whole with a full glass of water.

Do not chew the tablets.

When to take it

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 it

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 it

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 are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (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 that you or anyone else may have taken too much SEVIKAR. 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 heart beat.

While you are using SEVIKAR

Things you must do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking SEVIKAR.

If you have excess vomiting and/or diarrhoea while taking SEVIKAR, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

If you feel light-headed or dizzy after taking your first dose of SEVIKAR, or when your dose is increased, tell your doctor immediately.

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 drop suddenly.

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

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.

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.

Things you must 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 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.

Be careful driving or operating machinery 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. If you drink alcohol, dizziness or light-headedness may be worse.

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.

Side effects

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

SEVIKAR 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. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

The following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

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

- feeling light-headed, dizzy or faint
- cough
- headache
- feeling sick (nausea) or vomiting
- diarrhoea

- unusual tiredness or weakness, fatigue
- 'flu-like' symptoms
- bronchitis
- sore throat and discomfort when swallowing (pharyngitis)
- back pain
- urinary tract infection
- swelling of the face, hands, feet or ankles

These are common side effects. They are generally mild.

Tell your doctor as soon as possible if you notice any of the following:

- skin rash or itchiness
- aching, tender or weak muscles not caused by exercise
- painful joints
- fast heart beat
- shortness of breath or tightness in the chest
- swelling of the face, hands, feet or ankles
- symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm.

These may be serious side effects. You may need medical attention.

Serious side effects are rare.

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

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

These are very serious side effects. 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. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using SEVIKAR

Storage

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.

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

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

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

Product description

What it 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.

SEVIKAR 20/10 is a round tablet, approximately 8 mm in diameter, greyish-orange in colour with C74 debossed on one side. (Not currently available in Australia)

SEVIKAR 40/5 is a cream round tablet, approximately 8mm in diameter, with C75 debossed on one side.

SEVIKAR 40/10 is a brownish red round tablet, approximately 8mm in diameter, with C77 debossed on one side.

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

Ingredients

Active ingredients:

SEVIKAR 20/5 - 20 mg olmesartan medoxomil and 5mg amlodipine besilate

SEVIKAR 20/10 - 20 mg olmesartan medoxomil and 10 mg amlodipine as besilate.

SEVIKAR 40/5 - 40 mg olmesartan medoxomil and 5mg amlodipine besilate

SEVIKAR 40/10 - 40 mg olmesartan medoxomil and 10mg amlodipine besilate

Other ingredients:

- 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.

Supplier

SEVIKAR is supplied in Australia by:

Organon Pharma Pty Ltd

Building A, 26 Talavera Road,

Macquarie Park NSW 2113

Australian Registration Numbers

SEVIKAR 20/5 AUST R 157565

SEVIKAR 20/10 AUST R 157564

SEVIKAR 40/5 AUST R 157563

SEVIKAR 40/10 AUST R 157562

This leaflet was prepared in January 2021

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