

SEVIKAR HCT®

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 HCT?

SEVIKAR HCT contains the active ingredients olmesartan medoxomil, amlodipine (as besilate) and hydrochlorothiazide. SEVIKAR HCT is used to treat high blood pressure.

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

2. What should I know before I use SEVIKAR HCT?

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

3. What if I am taking other medicines?

Some medicines may interfere with SEVIKAR HCT 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 HCT?

- Follow all directions given to you by your doctor or pharmacist carefully. Your doctor or pharmacist will tell you which SEVIKAR HCT tablet you will need to take each day.
- Swallow SEVIKAR HCT 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 HCT?](#) in the full CMI.

5. What should I know while using SEVIKAR HCT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SEVIKAR HCT.• If you become pregnant while taking SEVIKAR HCT, 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 HCT 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 HCT affects you.• SEVIKAR HCT 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 HCT?](#) in the full CMI.

6. Are there any side effects?

Common side effects may include dizziness, light-headedness, cough, headache, nausea, vomiting, stomach pain, diarrhoea, tiredness, 'flu-like' symptoms, runny/ blocked nose, sore throat, difficulty swallowing, back pain, blurred vision, sleep or mood disturbances, skin rash/ flushing, swelling of the face or body and urinary infection. Serious side effects may include skin rash, yellowing of the eyes, dry mouth, swelling of the face, lips tongue or throat causing difficulty swallowing or breathing, muscle pain or weakness and chest 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 HCT

Active ingredient(s): *olmesartan medoxomil, amlodipine (as besilate) and hydrochlorothiazide*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using SEVIKAR HCT?

SEVIKAR HCT contains the active ingredients **olmesartan medoxomil, amlodipine (as besilate) and hydrochlorothiazide**.

SEVIKAR HCT 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 HCT works

SEVIKAR HCT 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 HCT blocks the action of angiotensin-II and therefore relaxes your blood vessels. This helps lower your blood pressure.

SEVIKAR HCT 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.

SEVIKAR HCT also contains hydrochlorothiazide, a diuretic which reduces the amount of fluid in the body. This also helps to lower blood pressure.

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

SEVIKAR HCT is not addictive.

2. What should I know before I use SEVIKAR HCT?

Warnings

Do not use SEVIKAR HCT 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,
 - hydrochlorothiazide, a diuretic,
 - or any of the ingredients listed at the end of this leaflet or other sulfonamide-derived drugs.

Symptoms of an allergic reaction to SEVIKAR HCT 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 had recent serious heart problems
- you have low potassium or sodium levels in the blood
- you have high calcium or uric acid levels in the blood.
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- 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)
 - systemic lupus erythematosus, a disease affecting the skin, joints and kidneys
 - gout
- 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)
- you have skin cancer or if you develop a new skin lesion during treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Discuss with your doctor how to protect your skin from sun exposure, and avoid artificial tanning.

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 HCT if you are pregnant or breastfeeding.

SEVIKAR HCT 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 HCT should be discontinued as soon as possible.

Use in children

The safety and effectiveness of SEVIKAR HCT 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 HCT may interfere with each other. These include:

- other medicines to treat high blood pressure
- digitalis glycosides, medicines used to treat heart problems
- medicines used to treat angina, such as diltiazem
- antiarrhythmics which treat irregular heartbeats
- non-steroid anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis
- antacids, medicines used to treat heartburn and indigestion
- simvastatin, a medicine used to help lower cholesterol levels
- potassium supplements or potassium-containing salt substitutes
- other medicines that may increase serum potassium (e.g., trimethoprim-containing products)
- calcium-containing supplements
- 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
- other diuretics, also known as fluid or water tablets
- insulin and tablets used to treat diabetes
- medicines which lower your immune system, such as corticosteroids, ciclosporin, tacrolimus and cytotoxic medicines used to treat cancer (including radiation therapy)
- alcohol
- laxatives, medicines used to treat constipation
- medicines used to relieve pain
- medicines used to treat epilepsy
- muscle relaxants
- cholestyramine and colestipol, used to treat high cholesterol
- St John's Wort
- grapefruit or grapefruit juice
- medicines used to treat gout, such as allopurinol
- medicines used to treat Parkinson's Disease, such as amantadine
- any medicines that contain aliskiren
- any medicines that contain colessevelam.

These medicines may be affected by SEVIKAR HCT, 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 HCT.

4. How do I use SEVIKAR HCT?

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 HCT 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 HCT is one tablet to be taken once a day.

How to take SEVIKAR HCT

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

When to take SEVIKAR HCT

- **Take SEVIKAR HCT 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 HCT

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

If you forget to take SEVIKAR HCT

SEVIKAR HCT 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 HCT (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 HCT, you may feel light-headed, dizzy, or you may faint. You may also have nausea, drowsiness, muscle spasm and 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 HCT?

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 HCT.
- Make sure you drink enough water during exercise and hot weather when you are taking SEVIKAR HCT, especially if you sweat a lot.
If you do not drink enough water while taking SEVIKAR HCT, you may feel light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

- 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 HCT. Your blood pressure may suddenly drop.
- If you are about to have any blood tests tell your doctor that you are taking SEVIKAR HCT. SEVIKAR HCT may interfere with the results of some tests.
- Tell your doctor if photosensitivity reaction occurs during your treatment.
- Have your blood pressure checked when your doctor says, to make sure SEVIKAR HCT 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.

Call your doctor straight away if:

- **You have excess vomiting and/or diarrhoea while taking SEVIKAR HCT.**
You may lose too much water and salt and your blood pressure may drop too much. You may also have dry mouth, weakness, drowsiness, confusion, muscle pain or cramps and seizures. Tell your doctor immediately if you experience any of these symptoms.
- **You feel light-headed or dizzy after taking your first dose of SEVIKAR HCT, or when your dose is increased.**
- **You become pregnant while taking SEVIKAR HCT.**
- **You experience acute onset of decreased visual acuity or ocular pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking SEVIKAR HCT. This can lead to permanent vision loss, if not treated.**
- **you experience any fever, severe shortness of breath, breathing faster than normal, difficulty breathing, slightly blue fingertips and lips after taking SEVIKAR HCT. Stop the medication and seek medical attention immediately.**

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

Things you should not do

- Do not give SEVIKAR HCT to anyone else, even if they have the same condition as you.
- Do not take SEVIKAR HCT to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking SEVIKAR HCT, 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 HCT affects you.

As with other medicines in this class, SEVIKAR HCT may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to SEVIKAR HCT 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.

Your doctor may advise you to limit your alcohol intake.

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

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 HCT 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 HCT 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>Eye-related:</p> <ul style="list-style-type: none"> blurred vision <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> diarrhoea feeling sick (nausea) or vomiting stomach pain or discomfort <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 flushing 'flu-like' symptoms <p>Liver and biliary-related:</p> <ul style="list-style-type: none"> jaundice <p>Psychiatric-related:</p> <ul style="list-style-type: none"> sleep disturbance depression <p>Respiratory-related:</p> <ul style="list-style-type: none"> bronchitis Cough Runny or blocked nose, or sneezing <p>Skin-related:</p> <ul style="list-style-type: none"> skin rashes or eczema <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. symptoms that may indicate water and salt imbalance such as dry mouth, weakness, drowsiness, confusion, muscle pain or cramps and seizures. Hydrochlorothiazide increases sensitivity of the skin to the sun and may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma). 	<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"> fever, severe shortness of breath, breathing faster than normal, difficulty breathing, slightly blue fingertips and lips. swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing chest pain 	<p>Stop taking SEVIKAR HCT 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>

Serious side effects are rare.

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 SEVIKAR HCT contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • SEVIKAR HCT 20/5/12.5 mg contains 20 mg olmesartan medoxomil, 5 mg amlodipine as besilate and 12.5 mg hydrochlorothiazide. • SEVIKAR HCT 40/5/12.5 mg contains 40 mg of olmesartan medoxomil, 5 mg amlodipine as besilate and 12.5 mg hydrochlorothiazide. • SEVIKAR HCT 40/5/25 mg contains 40 mg of olmesartan medoxomil, 5 mg amlodipine as besilate and 25 mg hydrochlorothiazide. • SEVIKAR HCT 40/10/12.5 mg contains 40 mg of olmesartan medoxomil, 10 mg amlodipine as besilate and 12.5 mg hydrochlorothiazide. • SEVIKAR HCT 40/10/25 mg contains 40 mg of olmesartan medoxomil, 10 mg amlodipine as besilate and 25 mg hydrochlorothiazide.
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 (as following): <ul style="list-style-type: none"> ○ SEVIKAR HCT 20/5/12.5 mg tablet contains iron

	oxide yellow, red and black. <ul style="list-style-type: none"> ○ SEVIKAR HCT 40/5/12.5 mg tablet and SEVIKAR HCT 40/5/25 mg tablet contains iron oxide yellow. ○ SEVIKAR HCT 40/10/12.5 mg tablet and SEVIKAR HCT 40/10/25 mg tablet contains iron oxide red and yellow.
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SEVIKAR HCT 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 HCT looks like

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

- SEVIKAR HCT 20/5/12.5 mg is an orange white round tablet, approximately 8 mm in diameter, with C51 debossed on one side. (AUST R 198998)
- SEVIKAR HCT 40/5/12.5 mg is a light yellow round tablet, approximately 9.5 mm in diameter, with C53 debossed on one side. (AUST R 199006)
- SEVIKAR HCT 40/5/25 mg is a light yellow oval tablet, approximately 15 x 7 mm, with C54 debossed on one side. (AUST R 199007)
- SEVIKAR HCT 40/10/12.5 mg is a round greyish red tablet, approximately 9.5 mm in diameter, with C55 debossed on one side. (AUST R 199005)
- SEVIKAR HCT 40/10/25 mg is a greyish red oval tablet, approximately 15 x 7 mm, with C57 debossed on one side. (AUST R 199000)

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

*Not available in Australia

Who distributes SEVIKAR HCT

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

This leaflet was prepared in April 2025.

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