SEVIKAR® HCT

Olmesartan medoxomil, amlodipine (as besilate) and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SEVIKAR HCT. 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 HCT against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What SEVIKAR HCT is used for

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.

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

The safety and effectiveness of SEVIKAR HCT in children and teenagers under the age of 18 years have not been established.

SEVIKAR HCT is not addictive.

Before you take SEVIKAR HCT

When you must not take it

Do not take SEVIKAR HCT 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,**
- **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.

Do not take SEVIKAR HCT if:

- **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.**

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.

Do not take SEVIKAR HCT 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 HCT, 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)
- systemic lupus erythematosus, a disease affecting the skin, joints and kidneys
- gout

You must also tell your doctor if you:

- are following a very low salt diet
- 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.

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

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 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 colesevelam.

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.

Other medicines not listed above may also interfere with SEVIKAR HCT. 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 HCT in children have not been established.

How to take 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 it

Swallow SEVIKAR HCT whole with a full glass of water.

Do not chew the tablets.

When to take it

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 it

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 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 HCT. 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.

While you are using SEVIKAR HCT

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

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.

If you feel light-headed or dizzy after taking your first dose of SEVIKAR HCT, 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 HCT.

Your blood pressure may drop suddenly.

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

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.

Tell your doctor immediately in case of acute onset of decreased visual acuity or ocular pain.

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.

Things you must 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 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 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. 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 HCT.

SEVIKAR HCT 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.

Hydrochlorothiazide, a component of this medicine, 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).

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
- stomach pain or discomfort
- diarrhoea
- unusual tiredness or weakness, fatigue
- 'flu-like' symptoms
- runny or blocked nose, or sneezing
- bronchitis
- sore throat and discomfort when swallowing (pharyngitis)
- back pain
- urinary tract infection
- jaundice

- blurred vision
- skin rashes or eczema
- sleep disturbance
- depression
- swelling of the ankles, feet, face or hands
- flushing

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
- symptoms that may indicate water and salt imbalance such as dry mouth, weakness, drowsiness, confusion, muscle pain or cramps and seizures.

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 HCT 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
- chest pain

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 HCT

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 HCT 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 HCT 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 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.

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.

SEVIKAR HCT 40/5/25 mg is a light yellow oval tablet, approximately 15 x 7 mm, with C54 debossed on one side.

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.

SEVIKAR HCT 40/10/25 mg is a greyish red oval tablet, approximately 15 x 7 mm, with C57 debossed on one side.

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

Ingredients

Active ingredients:

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:

- microcrystalline cellulose
- colloidal anhydrous silica
- pregelatinised maize starch
- croscarmellose sodium
- magnesium stearate
- polyvinyl alcohol,
- macrogol 3350,
- titanium dioxide,
- purified talc,

- and iron oxides (see below).

SEVIKAR HCT 20/5/12.5 mg tablet contains iron oxide yellow, red and black.

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.

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

Supplier

SEVIKAR HCT is supplied in Australia by:

Organon Pharma Pty Ltd

Building A, 26 Talavera Road,

Macquarie Park NSW 2113

Australian Registration Numbers

SEVIKAR HCT 20/5/12.5 AUST R 198998

SEVIKAR HCT 40/5/12.5 AUST R 199006

SEVIKAR HCT 40/10/12.5 AUST R 199005

SEVIKAR HCT 40/5/25 AUST R 199007

SEVIKAR HCT 40/10/25 AUST R 199000

This leaflet was prepared in June 2021.

® Registered trademark of Daiichi Sankyo Company Ltd