

## **Package leaflet: Information for the user**

**SEVIKAR HCT 20 mg/5 mg/12.5 mg Film-Coated Tablets**  
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**SEVIKAR HCT 40 mg/5 mg/25 mg Film-Coated Tablets**  
**SEVIKAR HCT 40 mg/10 mg/25 mg Film-Coated Tablets**

**olmesartan medoxomil/amlodipine/hydrochlorothiazide**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### **What is in this leaflet**

1. What Sevika HCT is and what it is used for
2. What you need to know before you take Sevika HCT
3. How to take Sevika HCT
4. Possible side effects
5. How to store Sevika HCT
6. Contents of the pack and other information

### **1. What Sevika HCT is and what it is used for**

Sevika HCT contains three active substances: (i) olmesartan, (ii) amlodipine and (iii) hydrochlorothiazide. All three substances help to control high blood pressure.

- Olmesartan belongs to a group of medicines called “angiotensin-II receptor antagonists” that lower blood pressure by relaxing blood vessels.
- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine also lowers blood pressure by relaxing blood vessels.
- Hydrochlorothiazide is one of a group of medicines called thiazide diuretics (“water tablets”). It lowers blood pressure by helping the body to get rid of extra fluid by making your kidneys produce more urine.

Sevika HCT is used to treat high blood pressure in subjects who are already taking either (a) a fixed-dose combination of olmesartan medoxomil and amlodipine (b) a fixed-dose combination of olmesartan medoxomil and hydrochlorothiazide plus the amlodipine as a single tablet or (c) a fixed-dose combination of olmesartan medoxomil and amlodipine plus hydrochlorothiazide as a single tablet.

## 2. What you need to know before you take Sevikar HCT

Do not take Sevikar HCT if:

- you are allergic to olmesartan, to amlodipine, to hydrochlorothiazide, to substances related to any of the 3 components or to any of the other ingredients of this medicine listed in section 6 of this leaflet.  
If you think you may be allergic to the components of Sevikar HCT talk to your doctor before taking Sevikar HCT.
- you have severe kidney problems.
- you have low potassium, low sodium, high calcium or high uric acid (with symptoms of gout or kidney stones) levels in your blood that have not got better when treated.
- you are more than 3 months pregnant. (It is also better to avoid Sevikar HCT in early pregnancy - see section “Pregnancy and breast-feeding”).
- you have severe liver problems, if bile secretion is impaired or drainage of bile from the gall bladder is blocked (e.g. by gallstones), or if you are jaundiced (yellowing of the skin and eyes).
- you have very low blood pressure.
- the blood flow from your heart is impaired. This may happen if the blood vessel or valve that takes blood away from your heart becomes narrow (aortic stenosis).
- you have heart failure. Heart failure may make you feel short of breath or cause swelling in your feet and ankles.

Do not take Sevikar HCT if any of the above applies to you.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Sevikar HCT. **Tell your doctor** if you have any of the following health problems:

- Kidney problems or a kidney transplant.
- Liver disease.
- Heart failure or problems with your heart valves or heart muscle.
- Severe vomiting, diarrhoea, treatment with high doses of “water tablets” (diuretics) or if you are on a low salt diet.
- Increased potassium in your blood.
- Problems with your adrenal glands
- Diabetes.
- Lupus erythematosus (an autoimmune disease).
- Allergies or asthma.
- Skin reactions such as sunburn or rash after being in the sun or using a sunbed.

As with any medicine that reduces blood pressure, an excessive drop in blood pressure may lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.

Sevikar HCT may cause a rise in blood cholesterol and uric acid (the cause of gout – painful swelling of the joints). Your doctor may request blood tests to check.

Sevikar HCT may also affect your body’s salt balance. Your doctor may request blood tests to check. Possible symptoms include thirst, dryness of the mouth, muscle

pain or cramps, tired muscles, low blood pressure, feeling weak, sluggish, tired, sleepy or restless, nausea, vomiting, less need to pass urine, a rapid heart rate. Tell your doctor if you notice these symptoms.

If you are due to have tests for parathyroid function you should stop taking Sevikar HCT before these tests are carried out.

You must tell your doctor if you think that you are (or might become) pregnant. Sevikar HCT is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see section “Pregnancy and breast-feeding”).

### **Children and adolescents (under 18)**

Sevikar HCT is not recommended for children and adolescents under the age of 18.

### **Other medicines and Sevikar HCT**

Tell your doctor or pharmacist if you are taking or have recently taken any of the following:

- Lithium (a medicine used to treat mood swings and some types of depression), used at the same time as Sevikar HCT may increase the toxicity of lithium. If you have to take lithium your doctor will measure your lithium blood levels.
- Diltiazem, verapamil, used for heart rhythm problems and high blood pressure.
- Rifampicin, erythromycin, clarithromycin, used for tuberculosis and other infections.
- St. John’s wort (*Hypericum perforatum*), a herbal remedy for treatment of depression.
- Cisapride, used to increase food movement in the stomach and gut.
- Diphemanil, used to treat a slow heartbeat or reduce sweating.
- Halofantrine, used for malaria.
- Vincamine IV, used to improve circulation to the nervous system.
- Amantadine, used for Parkinson’s disease.
- Potassium supplements, salt substitutes containing potassium, “water tablets” (diuretics), heparin (for thinning the blood and prevention of blood clots), ACE inhibitors (for blood pressure lowering), laxatives, steroids, adrenocorticotrophic hormone (ACTH), carbenoxolone (a medicine used to treat mouth and stomach ulcers), penicillin, an antibiotic, certain pain killers such as aspirin or salicylates. Using these medicines at the same time as Sevikar HCT may alter the concentration of potassium in your blood.
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis), used at the same time as Sevikar HCT may increase the risk of kidney failure. The effect of Sevikar HCT can be decreased by NSAIDs. In case of high dosages of salicylate the toxic effect on central nervous system may be increased.
- Sleeping tablets, sedatives and anti-depressant medicines as using these medicines together with Sevikar HCT may cause a sudden drop in blood pressure when standing up.
- Certain antacids (indigestion or heartburn remedies) as the effect of Sevikar HCT can be slightly decreased.

- Other blood pressure lowering medicines as the effect of Sevikar HCT in lowering blood pressure can be increased.
- Certain muscle relaxing medicines such as baclofen and tubocurarine.
- Anticholinergic agents such as atropine and biperiden.
- Calcium supplements.
- Dantrolene (infusion for severe body temperature abnormalities).
- Simvastatin, used to lower levels of cholesterol and fats (triglycerides) in the blood.
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Also, tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines to:

- Treat certain mental health problems such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, amisulpride, pimozide, sultopride, tiapride, droperidol or haloperidol.
- Treat low blood sugar (e. g. diazoxide) or high blood pressure (e. g. beta-blockers, methyldopa) as Sevikar HCT can affect how these drugs work.
- Treat heart rhythm problems such as mizolastine, pentamidine, terfenadine, dofetilide, ibutilide or erythromycin injections.
- Treat HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir)
- Treat fungal infections (e. g. ketoconazole, itraconazole, amphotericin).
- Treat heart problems such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, bepridil or digitalis.
- Treat cancers such as amifostine, cyclophosphamide or methotrexate.
- Increase blood pressure (such as noradrenaline) and slow heart rate
- Treat infections such as the antibiotics called tetracyclines or sparfloxacin.
- Treat gout such as probenecid, sulfinpyrazone and allopurinol.
- Lower blood fat levels such as colestyramine and colestipol.
- Stop rejection of organ transplants such as ciclosporin.
- Lower blood sugar such as metformin or insulin.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Sevikar HCT with food and drink  
Sevikar HCT can be taken with or without food.

Grapefruit juice and grapefruit should not be consumed by people who are taking Sevikar HCT. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Sevikar HCT.

Take care when drinking alcohol while you are taking Sevikar HCT as some people feel faint or dizzy. If this happens to you, do not drink any alcohol.

#### Elderly patients

If you are over 65 years of age your doctor will regularly check your blood pressure at any dose increase, to make sure that your blood pressure does not become too low.

#### Pregnancy and breast-feeding

##### Pregnancy

You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Sevikar HCT before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Sevikar HCT. Sevikar HCT is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant as it may cause serious harm to your baby if used after the third month of pregnancy.

If you become pregnant during therapy with Sevikar HCT please inform and see your physician without delay.

##### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Sevikar HCT is not recommended for mothers, who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Driving and using machines

You may feel sleepy, sick or dizzy or get a headache while being treated for your high blood pressure. Do not drive or use machines whilst you have symptoms. Ask your doctor for advice.

### **3. How to take Sevikar HCT**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose of Sevikar HCT is one tablet per day.
- The tablet can be taken with or without food. Swallow the tablet with some fluid (such as a glass of water). The tablet should not be chewed. Do not take the tablet with grapefruit juice.
- If possible, take your daily dose at the same time each day, for example at breakfast time.

#### **If you take more Sevikar HCT than you should**

If you take more tablets than you should you may experience low blood pressure with symptoms such as dizziness, fast or slow heart beat.

If you take more tablets than you should or if a child accidentally swallows some go to your doctor or nearest emergency department immediately and take your medicine pack or this leaflet with you.

**If you forget to take Sevikar HCT**

If you forget to take a dose take your normal dose the following day as usual. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Sevikar HCT**

It is important to continue to take Sevikar HCT unless your doctor tells you to stop.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them

The following side effects are important and will require immediate action if you experience them. You should stop taking Sevikar HCT and see your doctor immediately if the following symptoms occur:

Common, affecting less than 1 in 10 people:

- angina (heart pain)

Rare, affecting less than 1 in 1000 people:

- anaemia causing shortness of breath or looking pale
- blood clots
- severe, extensive, blistering skin rash
- a sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure
- inflamed pancreas, causing abdominal pain and vomiting

Very rare, affecting less than 1 in 10,000 patients

- heart attack
- swelling of the face, tongue and windpipe which can cause great difficulty in breathing
- flaccid gut, causing vomiting and abdominal distension
- increased susceptibility to infection causing, for example, fever, sore throat or mouth ulcers

The following side-effects have also been reported:

Common, affecting less than 1 in 10 people:

- Upper airways infection, bronchitis / urinary infection / gastroenteritis
- Awareness of heartbeat

- Dizziness, headache, , tiredness, flu-like symptoms, sleepiness, confusion, weakness
- Nausea, vomiting, diarrhoea, constipation, abdominal discomfort or pain
- Accumulation of gas in intestines, heartburn
- Swollen joints, joint pains, muscle spasms, aches and pains
- Low blood pressure
- Frequent need to pass urine, blood in urine
- Fluid retention causing swollen limbs or face
- Changes in blood test results that report on how the kidneys, liver and muscles are working
- Changes in blood test results of salt balance
- Raised blood sugar (may affect diabetes status)
- Excess glucose in urine

Uncommon, affecting less than 1 in 100 people:

- Dizziness on standing, fainting, spinning sensation (vertigo)
- Reduced number of a type of blood cells known as platelets, which can result in bruising easily or a prolonged bleeding time
- Anaphylactic reactions, skin rash, allergic inflammation of the skin, redness of skin, skin discolouration or flushing, red itchy bumps (hives), sweating, itch, increased sensitivity of skin to light causing sunburn, rash and discomfort, swelling of the face
- Fast heartbeat
- Difficulty sleeping sleep disturbances, mood change, irritability
- Cough, dry mouth, breathlessness
- Abnormally reduced appetite, weight decrease (or increase)
- Tremor
- Visual disturbance (including blurred vision), worsening of shortsightedness
- Ringing in ears (tinnitus)
- Altered sense of taste
- Palpitations
- Altered or decreased sensation of touch
- Breast enlargement
- Decreased sex drive, inability to gain erection in males
- Exhaustion

Rare, affecting less than 1 in 1000 people:

- Restlessness
- Convulsions (fits)
- Decreased tear production (important if using contact lenses)
- Fever
- Fluid accumulation in the lungs, pneumonia
- Jaundice, inflamed gall bladder
- Inflamed salivary glands
- Kidney problems that may become severe, acute kidney failure

Very rare, affecting less than 1 in 10000 people:

- Inflamed blood vessels
- High muscle tension
- Allergy

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

## 5. How to store Sevikar HCT

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Sevikar HCT contains

The active substances are olmesartan medoxomil, amlodipine (as amlodipine besilate) and hydrochlorothiazide.

Each film-coated tablet contains 20 mg olmesartan medoxomil, 5 mg amlodipine (as amlodipine besilate) and 12.5 mg hydrochlorothiazide.

Each film-coated tablet contains 40 mg olmesartan medoxomil, 5 mg amlodipine (as amlodipine besilate) and 12.5 mg hydrochlorothiazide.

Each film-coated tablet contains 40 mg olmesartan medoxomil, 10 mg amlodipine (as amlodipine besilate) and 12.5 mg hydrochlorothiazide.

Each film-coated tablet contains 40 mg olmesartan medoxomil, 5 mg amlodipine (as amlodipine besilate) and 25 mg hydrochlorothiazide.

Each film-coated tablet contains 40 mg olmesartan medoxomil, 10 mg amlodipine (as amlodipine besilate) and 25 mg hydrochlorothiazide.

Other ingredients are:

*Tablet core:* pregelatinized maize starch, silicified microcrystalline cellulose (microcrystalline cellulose and silica colloidal anhydrous), croscarmellose sodium, magnesium stearate

*Film coat:* polyvinyl alcohol, macrogol 3350, talc, titanium dioxide (E 171), iron (III) oxide yellow (E 172), iron (III) oxide red (E 172) (20 mg/5 mg/12.5mg, 40 mg/10 mg/12.5 mg, 40 mg/10 mg/25mg film coated tablets only), iron (II, III) oxide black (E°172) (20 mg/5 mg/12.5 mg film coated tablets only)

### What Sevikar HCT looks like and contents of the pack

Sevikar HCT 20 mg/5 mg/12.5 mg film-coated tablets of 8 mm are light orange, round with C51 debossed on one side.



Sevikar HCT 40 mg/5 mg/12.5 mg film-coated tablets of 9.5 mm are light yellow, round with C53 debossed on one side.

Sevikar HCT 40 mg/10 mg/12.5 mg film-coated tablets of 9.5 mm are greyish red, round with C55 debossed on one side.

Sevikar HCT 40 mg/5 mg/25 mg film-coated tablets of 15 x 7 mm are light yellow, oval with C54 debossed on one side.

Sevikar HCT 40 mg/10 mg/25 mg film-coated tablets of 15 x 7 mm are greyish red, oval with C57 debossed on one side.

Sevikar HCT film-coated tablets are available:

- in blister packs of 14, 28, 30, 56, 84, 90, 98 and 10 x 28, 10 x 30 film-coated tablets
- in packs with perforated unit dose blisters of 10, 50 and 500 film-coated tablets.
- Sevikar HCT in HDPE-bottles in packs of 7, 30 and 90 film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### *Marketing Authorisation Holder*

DAIICHI SANKYO UK Limited  
Chiltern Place  
Chalfont Park  
Gerrards Cross  
Buckinghamshire  
SL9 0BG  
UK

#### *Manufacturer*

DAIICHI SANKYO EUROPE GmbH  
Luitpoldstrasse 1  
85276 Pfaffenhofen  
Germany

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#### **UK:**

Sevikar HCT 20mg/5mg/12.5mg

Sevikar HCT 40mg/5mg/12.5mg

Sevikar HCT 40mg/10mg/12.5mg

Sevikar HCT 40mg/5mg/25mg

Sevikar HCT 40mg/10mg/25mg

Film-coated Tablets: The following pack sizes are currently marketed: 28 film-coated tablets.

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Please be ready to give the following information:

Product Name: Sevikar HCT 20mg/5mg/12.5mg Film-Coated Tablets  
Reference Number: PL 08265/0031

This is a service provided by the Royal National Institute of Blind People.