1.3.1.3 TEXT PROPOSED FOR THE PACKAGE LEAFLET

Sevikar 20 mg/5 mg
Sevikar 40 mg/5 mg
Sevikar 40 mg/10 mg
Film-Coated Tablets

Variation application NL/H/1113/001-003/IA/051

Attached please find:

Proposed IE Package leaflet - proposed clean

Package leaflet: Information for the user

Sevikar 20 mg/5 mg
Sevikar 40 mg/5 mg
Sevikar 40 mg/10 mg
Film-Coated Tablets
olmesartan medoxomil/amlodipine

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 (see section 4).

What is in this leaflet:

1. What Sevikar is and what it is used for

Sevikar contains two substances called olmesartan medoxomil and amlodipine (as amlodipine besilate). Both of these substances help to control high blood pressure.

- Olmesartan medoxomil belongs to a group of medicines called “angiotensin-II receptor antagonists” which lower blood pressure by relaxing the blood vessels.

- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening thereby also reducing blood pressure.

The actions of both these substances contribute to stopping the tightening of blood vessels, so that blood vessels relax and blood pressure decreases.

Sevikar is used for the treatment of high blood pressure in patients whose blood pressure is not controlled enough with either olmesartan medoxomil or amlodipine alone.

2. What you need to know before you take Sevikar

Do not take Sevikar

- if you are allergic to olmesartan medoxomil or to amlodipine or a special group of calcium channel blockers, the dihydropyridines, or to any of the other ingredients of this medicine (listed in section 6).
  If you think you may be allergic, talk to your doctor before taking Sevikar.
- if you are more than 3 months pregnant (It is also better to avoid Sevikar in early pregnancy - see section "Pregnancy and breastfeeding".).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have severe liver problems, if bile secretion is impaired or drainage of bile from the gallbladder is blocked (e.g. by gallstones), or if you are experiencing any jaundice (yellowing of the skin and eyes).
- if you have very low blood pressure.
- if you are suffering from insufficient blood supply to your tissues with symptoms like e.g. low blood pressure, low pulse, fast heartbeat (shock, including cardiogenic shock). Cardiogenic shock means shock due to severe heart troubles.
- if the blood flow from your heart is obstructed (e.g. because of the narrowing of the aorta (aortic stenosis)).
- if you suffer from low heart output (resulting in shortness of breath or peripheral swellings) after a heart attack (acute myocardial infarction).

Warnings and precautions

Talk to your doctor or pharmacist before using Sevikar.

Tell your doctor if you are taking any of the following medicines used to treat high blood pressure:

- an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems,
- aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Sevikar".

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 levels of potassium in your blood.
- Problems with your adrenal glands (hormone-producing glands on top of the kidneys).

Contact your doctor if you experience diarrhoea that is severe, persistent and causes substantial weight loss. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

As with any medicine which reduces blood pressure, an excessive drop in blood pressure in patients with blood flow disturbances of the heart or brain could lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.

You must tell your doctor if you think that you are (or might become) pregnant. Sevikar 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 is not recommended for children and adolescents under the age of 18.

Other medicines and Sevikar
Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- **Other blood pressure lowering medicines**, as the effect of Sevikar can be increased. Your doctor may need to change your dose and/or to take other precautions:
  If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Sevikar " and "Warnings and precautions").
- **Potassium supplements**, **salt substitutes containing potassium**, **"water tablets"** (diuretics) or **heparin** (for thinning the blood and prevention of blood clots.). Using these medicines at the same time as Sevikar may raise the levels of potassium in your blood.
- **Lithium** (a medicine used to treat mood swings and some types of depression) used at the same time as Sevikar may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.
- **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 may increase the risk of kidney failure. The effect of Sevikar can be decreased by NSAIDs.
- **Colesevelam hydrochloride**, a drug that lowers the level of cholesterol in your blood, as the effect of Sevikar may be decreased. Your doctor may advise you to take Sevikar at least 4 hours before colesevelam hydrochloride.
- **Certain antacids** (indigestion or heartburn remedies), as the effect of Sevikar can be slightly decreased.
- **Medicines used for HIV/AIDS** (e.g. ritonavir, indinavir, nelfinavir) **or for the treatment of fungal infections** (e.g. ketoconazole, itraconazole).
- **Diltiazem, verapamil**, (agents used for heart rhythm problems and high blood pressure).
- **Rifampicin**, **erythromycin, clarithromycin (antibiotics),** agents used for tuberculosis or other infections.
- **St. John's wort** (Hypericum perforatum), a herbal remedy.
- **Dantrolene** (infusion for severe body temperature abnormalities).
- **Simvastatine**, an agent used to lower levels of cholesterol and fats (triglycerides) in the blood.
- **Tacrolimus, sirolimus, temsirolimus, everolimus and cyclosporine**, used to control your body's immune response, enabling your body to accept the transplanted organ.

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

Sevikar with food and drink
Sevikar can be taken with or without food. Swallow the tablet with some fluid (such as one glass of water). If possible, take your daily dose at the same time each day, for example at breakfast time.
Grapefruit juice and grapefruit should not be consumed by people who are taking Sevikar. 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.

Elderly
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.

Black patients
As with other similar drugs the blood pressure lowering effect of Sevikar can be somewhat less in black patients.

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 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Sevikar. Sevikar 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, please inform and see your physician without delay.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Amlodipine has been shown to pass into breast milk in small amounts. Sevikar 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. If this happens, do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3. How to take Sevikar

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 is one tablet per day.
- The tablets 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 them 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 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.

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

If you forget to take Sevikar

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

If you stop taking Sevikar

It is important to continue to take Sevikar 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. If they do occur, they are often mild and do not require treatment to be stopped.

Although not many people may get them, the following side effects can be serious:

Allergic reactions, that may affect the whole body, with swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with Sevikar. **If this happens stop taking Sevikar and talk to your doctor immediately.**

Sevikar can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. This could cause severe light-headedness or fainting. **If this happens stop taking Sevikar, talk to your doctor immediately and lie down flat.**

Frequency not known: If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Sevikar longer time ago, **contact your**

doctor immediately who will evaluate your symptoms and decide on how to continue your blood pressure medication.

Other possible side effects with Sevikar:

Common (may affect less than 1 in 10 people):
Dizziness; headache; swelling of ankles, feet, legs, hands, or arms; tiredness.

Uncommon (may affect less than 1 in 100 people):
Dizziness on standing up; lack of energy; tingling or numbness of hands or feet; vertigo; awareness of heart beat; fast heart beat; low blood pressure with symptoms such as dizziness, light-headedness; difficult breathing; cough; nausea; vomiting; indigestion; diarrhoea; constipation; dry mouth, upper abdominal pain; skin rash; cramps; pain in arms and legs; back pain; feeling more of an urge to pass urine; sexual inactivity; inability to get or maintain an erection; weakness.

Some changes in blood test results have also been seen and include the following:
increased as well as decreased blood potassium levels, increased blood creatinine levels, increased uric acid levels, increases in a test of liver function (gamma glutamyl transferase levels).

Rare (may affect less than 1 in 1,000 people):
Drug hypersensitivity; fainting; redness and warm feeling of the face; red itchy bumps (hives); swelling of face.

Side effects reported with use of olmesartan medoxomil or amlodipine alone, but not with Sevikar or in a higher frequency:

Olmesartan medoxomil
Common (may affect less than 1 in 10 people):
Bronchitis; sore throat; runny or stuffy nose; cough; abdominal pain; stomach flu; diarrhoea; indigestion; nausea; pain in the joints or bones; back pain; blood in the urine; infection of the urinary tract; chest pain; flu-like symptoms; pain. Changes in blood test results as increased fat levels (hypertriglyceridaemia), blood urea or uric acid increased and increase in tests of liver and muscle function.

Uncommon (may affect less than 1 in 100 people):
Reduced number of a type of blood cells, known as platelets, which can result in easily bruising or prolonged bleeding time; quick allergic reactions that may affect the whole body and may cause breathing problems as well as a rapid fall of blood pressure that may even lead to fainting (anaphylactic reactions); angina (pain or uncomfortable feeling in the chest, known as angina pectoris); itching; eruption of the skin; allergic skin rash; rash with hives; swelling of the face; muscular pain; feeling unwell.

Rare (may affect less than 1 in 1,000 people):
Swelling of the face, mouth and/or larynx (voice box); acute kidney failure and kidney insufficiency; lethargy.

Amlodipine
Very common (may affect more than 1 in 10 people):
Oedema (fluid retention)

Common (may affect less than 1 in 10 people):
Abdominal pain; nausea; ankle swelling; feeling sleepy; redness and warm feeling of the face, visual disturbance (including double vision and blurred vision), awareness of heartbeat, diarrhoea, constipation, indigestion, cramps, weakness, difficult breathing.

Uncommon (may affect less than 1 in 100 people):
Trouble sleeping; sleep disturbances; mood changes including feeling anxious; depression; irritability; shiver; taste changes; fainting; ringing in the ears (tinnitus); worsening of angina pectoris (pain or uncomfortable feeling in the chest); irregular heartbeat; runny or stuffy nose; loss of hair; purplish spots or patches on the skin due to small haemorrhages (purpura); discoloration of the skin; excessive sweating; eruption of the skin; itching; red itchy bumps (hives); pain of joints or muscles; problems to pass urine; urge to pass urine at night; increased need to urinate (pass urine); breast enlargement in men; chest pain; pain, feeling unwell; increase or decrease in weight.

Rare (may affect less than 1 in 1,000 people):
Confusion

Very rare (may affect less than 1 in 10,000 people):
Reduction in the number of white cells in the blood, which could increase the risk of infections; a reduction in the number of a type of blood cells known as platelets, which can result in easily bruising or prolonged bleeding time; increase in blood glucose; increased tightness of muscles or increased resistance to passive movement (hypertonia); tingling or numbness of hands or feet; heart attack; inflammation of blood vessels; inflammation of the liver or the pancreas; inflammation of stomach lining; thickening of gums; elevated liver enzymes; yellowing of the skin and eyes; increased sensitivity of the skin to light; allergic reactions: itching, rash, swelling of the face, mouth and/or larynx (voice box) together with itching and rash, severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis), sometimes life-threatening.

Not known (frequency cannot be estimated from the available data**):**
Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sevikar

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

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

This medicinal product does not require any special storage condition.

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 contains

The active substances are olmesartan medoxomil and amlodipine (as besilate).
Each tablet contains 20 mg of olmesartan medoxomil and 5 mg amlodipine (as besilate).
Each tablet contains 40 mg of olmesartan medoxomil and 5 mg amlodipine (as besilate).
Each tablet contains 40 mg of olmesartan medoxomil and 10 mg amlodipine (as besilate).

The other ingredients are
Tablet core: Pregelatinised maize starch, silicified microcrystalline cellulose, croscarmellose sodium, magnesium stearate,
Tablet coat: polyvinyl alcohol, macrogol 3350, talc, titanium dioxide (E171) and iron (III) oxide (E172, Sevikar 40 mg/ 5 mg and 40 mg/10 mg film coated tablets only).

What Sevikar looks like and contents of the pack

Sevikar 20 mg/5 mg film-coated tablets are white, round with C73 on one side.
Sevikar 40 mg/5 mg film-coated tablets are cream, round with C75 on one side.
Sevikar 40 mg/10 mg film-coated tablets are brownish-red, round with C77 on one side.

Sevikar film-coated tablets are available in packs of 14, 28, 30, 56, 90, 98 and 10 x 28, 10 x 30 film-coated tablets and in packs with perforated unit dose blisters of 10, 50 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Daiichi Sankyo Ireland Limited
Riverside One
Sir John Rogerson's Quay
Dublin 2
Ireland

Manufacturer
DAIICHI SANKYO EUROPE GmbH
Luitpoldstrasse 1
85276 Pfaffenhofen, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Belgium: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Denmark: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Finland: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
France: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Germany: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Greece: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Iceland: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Ireland: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Italy: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Luxembourg: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
The Netherlands: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Norway: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Portugal: Sevikar 20 mg+5 mg, 40 mg+5 mg, 40 mg+10 mg
Romania: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Spain: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
UK: Sevikar 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg

This leaflet was last revised in July 2022.

Other sources of information
Detailed information on this medicine is available on the web site of: IE/HPRA