

Package leaflet: Information for the patient

## Suvezen 10 mg/10 mg film-coated tablets

## Suvezen 20 mg/10 mg film-coated tablets

## Suvezen 40 mg/10 mg film-coated tablets

rosuvastatin/ezetimibe

SANOFI

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

#### 1. What Suvezen is and what it is used for

Suvezen contains two different active substances in one tablet. One of the active substances is rosuvastatin, belonging to the group of so called statins, the other active substance is ezetimibe. Suvezen is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Suvezen raises levels of "good" cholesterol (HDL cholesterol).

Suvezen works to reduce your cholesterol in two ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

It is used for patients who cannot control their cholesterol levels by diet alone. You should always stay on a cholesterol-lowering diet while taking this medicine.

Suvezen is used in addition to your cholesterol lowering diet if you have a raised cholesterol level in your blood level due to:

- o primary hypercholesterolaemia [heterozygous familial and non-familial]
- o a hereditary illness (homozygous familial hypercholesterolaemia) for which were previously using a statin alone which did not control your cholesterol level or you have used a statin and ezetimibe as separate tablets

You may also receive other treatments.

If you have heart disease, Suvezen reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Suvezen does not help you lose weight.

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. If you correct your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to keep taking Suvezen, even if it has got your cholesterol to the right level, because it prevents your cholesterol levels from creeping up again and causing build up of fatty deposits. However, you should stop if your doctor tells you to do so, or you have become pregnant.

## **2. What you need to know before you take Suvezen**

### **Do not take Suvezen:**

- If you are allergic to rosuvastatin, ezetimibe or any of the other ingredients of this medicine (listed in section 6).
- If you currently have liver problems.
- If you are pregnant or breast-feeding. If you become pregnant while taking Suvezen stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Suvezen by using suitable contraceptive measures.
- If you have severe kidney problems.
- If you have repeated or unexplained muscle aches or pains (myopathy).
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Suvezen or other rosuvastatin containing medicinal products.
- If you take a drug called ciclosporin (used, for example, after organ transplants).

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

### **In addition, do not take Suvezen 40 mg/10 mg (the highest dose):**

- If you have moderate kidney problems (if in doubt, please ask your doctor).
- If your thyroid gland is not working properly (hypothyroidism).
- If you have had any repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- If you regularly drink large amounts of alcohol.
- If you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- If you take other medicines called fibrates to lower your cholesterol (see section "Other medicines and Suvezen").

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Suvezen:

- If you have problems with your kidneys.
- If you drink large amounts of alcohol or have ever had liver disease. Suvezen may not be right for you.
- If you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever. Also tell your doctor or pharmacist if you have a muscle weakness that is constant.
- If your thyroid gland is not working properly.
- If you have severe respiratory failure.
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).
- If you take medicines used to fight the HIV infection e.g. ritonavir with lopinavir and/or atazanavir, please see "Other medicines and Suvezen"
- If you are over 70 (as your doctor needs to choose the right start dose of Suvezen to suit you).
- If you take other medicines called fibrates to lower your cholesterol (Please see "Other medicines and Suvezen").
- If you are due to have an operation. You may need to stop taking Suvezen for a short time.
- If you are of Asian origin - that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of Suvezen to suit you.
- If you are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Suvezen can lead to serious muscle problems (rhabdomyolysis).

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will regularly carry out this blood test (liver function test) during treatment with Suvezen. It is important to go to the doctor for the prescribed laboratory checks.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported in association with Suvezen treatment. Stop using Suvezen and seek medical attention immediately if you notice any of the symptoms described in section 4.

#### **Other medicines and Suvezen**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking medicine(s) with any of the following active ingredients:

- ciclosporin (often used in organ transplant patients). **Do not take Suvezen while taking ciclosporin.**
- blood thinners e.g. warfarin, acenocoumarol, phenprocoumon or fluindione (their blood thinning effect and the risk of bleeding may be increased while taken together with this medicine), ticagrelor or clopidogrel.
- colestyramine (also used to lower cholesterol), because it affects the way Suvezen works.
- fibrates such as gemfibrozil, fenofibrate (also used to lower cholesterol). **Do not take the Suvezen 40 mg/10 mg tablets with concomitant use of a fibrate.**
- indigestion remedies containing aluminium and magnesium (used to neutralise acid in your stomach).
- erythromycin (an antibiotic).
- an oral contraceptive (the pill).
- hormone replacement therapy.
- regorafenib (used to treat cancer).
- any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Warnings and precautions): ritonavir, lopinavir, atazanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
- fusidic acid - if you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Suvezen. Taking Suvezen with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

You should also tell any doctor who is prescribing a new medicine for you that you are taking Suvezen.

#### **Suvezen with alcohol**

Do not take Suvezen 40 mg/10 mg tablets (the highest dose), if you regularly drink large amounts of alcohol.

#### **Pregnancy and breast-feeding**

Do not take Suvezen if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking Suvezen, stop taking it immediately and tell your doctor. Do not take Suvezen if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

#### **Children and adolescents**

Suvezen is not suitable for use in children and adolescents below 18 years of age.

#### **Driving and using machines**

Suvezen is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people may get dizzy after taking Suvezen.

#### **Suvezen contains lactose (a type of sugar) and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

### **3. How to take Suvezen**

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

- Before starting Suvezen, you should be on a diet to lower your cholesterol.
- You should keep on this cholesterol lowering diet whilst taking Suvezen.

The recommended dose is one Suvezen tablet once a day.

Suvezen is not suitable to start a treatment.

If your cholesterol level is not controlled your doctor will determine the appropriate tablet strength for you, depending on your current treatment and your personal risk status.

Treatment initiation or dose adjustment if necessary should only be done by giving the active substances separately as monocomponents and after setting the appropriate doses the switch to

Suvezen of the appropriate strength is possible. The maximum daily dose of rosuvastatin is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

Try to take your tablet at the same time every day to help you to remember it. You can take it with or without food. Swallow each tablet whole with a drink of water.

If your doctor has prescribed Suvezen along with another medicine for lowering cholesterol containing the active ingredient colestyramine or any other medicine containing bile acid sequestrant, you should take Suvezen at least 2 hours before or 4 hours after taking the bile acid sequestrant.

#### **Regular cholesterol checks**

It is important to go back to your doctor for regular cholesterol checks to make sure your cholesterol has reached and is staying at the correct level. Your doctor may decide to increase your dose so that you are taking the amount of the medicine that is right for you.

#### **If you take more Suvezen than you should**

Please contact your doctor or pharmacist.

#### **If you forget to take Suvezen**

Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking Suvezen**

Talk to your doctor or pharmacist because your cholesterol may rise again. 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.

#### **Stop taking Suvezen and seek medical help immediately if you experience any of the following symptoms:**

- any unexplained muscle pain, tenderness, or weakness which go on for longer than expected. This is because muscle problems, including muscle breakdown resulting in kidney damage, can be serious and may become a potentially life-threatening condition (rhabdomyolysis). This is rare (may affect up to 1 in 1,000 people);
- severe allergic reaction (angioedema) – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing and a severe itching of the skin (with raised lumps). This is rare (may affect up to 1 in 1,000 people);
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells);
- muscle rupture.

#### **Other known side effects:**

**Common** (may affect up to 1 in 10 people):

Diarrhoea; flatulence; feeling tired; elevations in some laboratory blood tests of liver function (transaminases); headache; stomach pain; constipation; feeling sick; muscle pain; feeling weak; dizziness; an increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking Suvezen (only rosuvastatin 40 mg); diabetes – this is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

**Uncommon** (may affect up to 1 in 100 people):

Elevations in some laboratory blood tests of muscle (CK) function; cough; indigestion; heartburn; joint pain; muscle spasms; neck pain; decreased appetite; pain; chest pain; hot flush; high blood pressure; tingling sensation; dry mouth; inflammation of the stomach; itching; rash; hives or other skin reactions; back pain; muscle weakness; pain in arms and legs; swelling, especially in the hands and feet; an increase in the amount of protein in the urine - this usually

returns to normal on its own without having to stop taking Suvezen (only rosuvastatin 10 mg and 20 mg).

**Rare** (may affect up to 1 in 1,000 people):

Reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia); a severe stomach pain (inflamed pancreas).

**Very rare** (may affect up to 1 in 10,000 people):

Jaundice (yellowing of the skin and eyes); hepatitis (an inflamed liver); traces of blood in your urine; damage to the nerves of your legs and arms (such as numbness); memory loss; gynecomastia (breast enlargement in men).

**Not known** (frequency cannot be estimated from the available data):

shortness of breath; swelling; sleep disturbances including sleeplessness and nightmares; sexual difficulties; depression; breathing problems including persistent cough and/or shortness of breath or fever; tendon injury; muscle weakness that is constant; raised red rash, sometimes with target shaped lesions (erythema multiforme); muscle tenderness; gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting), myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing); ocular myasthenia (a disease causing eye muscle weakness). Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://www.hpra.ie)

#### **5. How to store Suvezen**

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 and blister after EXP. The expiry date refers to the last day of that month.

Store below 30 °C in the original package in order to protect from moisture and light.

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 Suvezen contains**

- The active substances are rosuvastatin and ezetimibe. Each tablet contains 10 mg, 20 mg or 40 mg of rosuvastatin (as rosuvastatin calcium) and 10 mg of ezetimibe.
- The other ingredients are:
  - o Core: lactose monohydrate, microcrystalline cellulose, sodium laurilsulfate, povidone, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate.
  - o Coating layer: hypromellose (E464), macrogol, titanium dioxide (E171), talc(E553).

Suvezen 20 mg/10 mg also contains iron oxide yellow (E172).

Suvezen 40 mg/10 mg also contains iron oxide red (E172).

##### **What Suvezen looks like and contents of the pack**

Suvezen 10 mg/10 mg are white to off-white, round, biconvex, film-coated tablets (tablets) with a diameter about 9.1 mm. Suvezen 20 mg/10 mg are yellow to light yellow, round, biconvex, film-coated tablets (tablets) with a diameter about 9.9 mm.

Suvezen 40 mg/10 mg are pink, round, biconvex, film-coated tablets (tablets) with a diameter about 11.1 mm.

Film-coated tablets are packed in blister and paper folding box.

Pack sizes: 10, 15, 30, 60, 90, 100 film-coated tablets.

Not all pack sizes may be marketed.

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

##### **Marketing Authorisation Holder**

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**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Zenon Neo in the Czech Republic; SUVEZEN in Belgium and Ireland ; Suvezen in Romania; Zenon in Greece, Norway and Portugal; SUVEZEN NEO in Poland.

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