

Package leaflet: Information for the patient**Simvastatin Rosemont 40mg/5ml Oral Suspension**
Simvastatin

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

1. What Simvastatin Rosemont is and what it is used for

The name of your medicine is Simvastatin Rosemont 40mg/5ml Oral Suspension (called simvastatin in this leaflet). This belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as statins).

This medicine works by lowering the amount of cholesterol and fatty substances called triglycerides in your blood.

Simvastatin can be used along with diet for:

- lowering high cholesterol levels or fat levels in the blood when diet, exercise and weight loss are not enough
- lowering high cholesterol levels that are hereditary (close members of your family also have high cholesterol levels). Simvastatin may be given at the same time as other medicines that lower your cholesterol
- lowering risk of coronary heart disease (CHD) if you have diabetes, have had a stroke or you have other blood vessel diseases.

In most people, there are no immediate symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, keep track of your cholesterol, and discuss your goals with your doctor.

2. What you need to know before you take Simvastatin Rosemont

Do not take Simvastatin if:

- you are allergic to simvastatin or any of the other ingredients of this medicine (listed in section 6). An allergic reaction can include a rash, itching or shortness of breath
- you have liver problems
- you are pregnant or breast-feeding (see section below ‘Pregnancy and breast-feeding’)
- you are taking antifungal drugs such as itraconazole, ketoconazole, posaconazole or voriconazole
- you are taking antibiotics such as erythromycin, clarithromycin or telithromycin
- you are taking medicines to treat HIV infections such as indinavir, nelfinavir, ritonavir or saquinavir
- you are taking boceprevir or telaprevir, used to treat hepatitis C virus
- you are taking a medicine to treat depression called nefazodone
- you are taking cobicistat
- you are taking a medicine to lower cholesterol called gemfibrozil
- you are taking ciclosporin (a medicine often used in transplant patients)
- you are taking danazol (a man-made hormone used to treat endometriosis).

Do not take more than 40 mg simvastatin if you are taking lomitapide (used to treat a serious and rare genetic cholesterol condition).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking simvastatin.

Warnings and precautions

Talk to your doctor or pharmacist before taking simvastatin if:

- you have an existing medical condition including allergies
- you drink large amounts of alcohol
- you have a history of liver disease. Your doctor may give you some blood tests to check your liver before and after starting treatment
- you have kidney problems
- you have severe lung disease (respiratory failure).
- you are due to have an operation, you may need to stop taking simvastatin for a short time
- you are Asian, because a different dose may be applicable to you
- 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 simvastatin can lead to serious muscle problems (rhabdomyolysis).

Your doctor should do a blood test before you start taking simvastatin and if you have any symptoms of liver problems while you take simvastatin. This is to check how well your liver is working.

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking simvastatin.

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.

Tell your doctor if you have severe lung disease.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.

The risk of muscle breakdown is greater at higher doses of simvastatin, particularly the 80 mg dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- you drink large amounts of alcohol
- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are female
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” or fibrates
- you or a close family member have a hereditary muscle disorder.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking simvastatin.

Other medicines and Simvastatin

It is particularly important to tell your doctor if you are taking any of the following medicines. Taking simvastatin with any of these medicines can increase the risk of muscle problems (some of these have already been listed in the above section ‘Do not take Simvastatin’):

- **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 simvastatin. Taking simvastatin with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.**
- ciclosporin, used to dampen the immune system
- danazol, a steroid used to treat endometriosis and breast cysts in women
- medicines to treat fungal infections such as itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole
- medicines to lower cholesterol called fibrates (such as gemfibrozil or bezafibrate)
- antibiotics, such as erythromycin, clarithromycin or telithromycin

- medicines to treat HIV infections such as indinavir, nelfinavir, ritonavir or saquinavir
- boceprevir or telaprevir, used to treat hepatitis C virus infection
- nefazodone, used to treat depression
- medicines with the active ingredient cobicistat
- amiodarone, used to treat irregular heart beats
- verapamil, diltiazem or amlodipine, used to treat heart conditions
- lomitapide (used to treat a serious and rare genetic cholesterol condition)
- colchicines, used to treat gout.

As well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines bought without a prescription, including herbal medicines.

In particular tell your doctor if you are taking any of the following medicines:

- medicines that stop blood clots from forming such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)
- fenofibrate (another medicine for lowering cholesterol)
- niacin (nicotinic acid, another medicine for lowering cholesterol)
- rifampicin (used to treat tuberculosis).

Also tell your doctor if you are taking niacin (nicotinic acid) or a niacin-containing product and are Chinese.

Also tell any doctor who is prescribing a new medicine for you that you are taking simvastatin.

Having operations and tests

If you are going to have an operation, tell the doctor that you are taking simvastatin as it should be stopped a few days before.

Simvastatin with food and drink

Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including simvastatin. Consuming grapefruit juice should be avoided.

Pregnancy and Breast-feeding

Do not use simvastatin if you are pregnant or planning to become pregnant. If you become pregnant while on this medicine, stop taking it and talk to your doctor straight away.

Do not use simvastatin if you are breast-feeding.

Children and adolescents

Safety and effectiveness have been studied in 10 -17 year old boys and in girls who had started their menstrual period at least one year before (see How to take Simvastatin Rosemont). Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Driving and using machines

This medicine should not affect your ability to drive or operate machinery. However, this medicine may cause dizziness. If you feel this, take extra care when driving or using tools or machines.

Simvastatin Rosemont contains methyl parahydroxybenzoates, ethyl parahydroxybenzoate and propyl parahydroxybenzoate:

- Methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214) and propyl parahydroxybenzoate (E216). These may cause an allergic reaction. This allergy may happen some time after starting the medicine.

3. How to take Simvastatin Rosemont

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

You should stay on a cholesterol-lowering diet while taking simvastatin.

Taking this medicine

- This medicine contains 8mg of simvastatin in each 1ml, (40mg of simvastatin in each 5ml).
- Take this medicine by mouth using the double-sided measuring spoon provided. The measuring spoon is graduated to deliver a 1.25ml, 2.5ml or 5ml dose as prescribed by your doctor or pharmacist.
- This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. There is further information in the SmPC, ask your doctor, pharmacist or nurse for this information.
- Do not use with a tube which is made of latex.
- Instructions for use via NG or PEG tube:
 1. Ensure the tube is clear before taking the medicine
 2. Flush the tube with sufficient amount of water to remove any feed left in the tube
 3. Administer the medicine into the tube, with a suitable measuring device
 4. Flush the tube again with 10ml of water.
- Shake the product well before use.
- If you feel that the effect of your medicine is too strong or too weak, do not change the dose yourself, but talk to your doctor or pharmacist.

The usual doses are given below. Your doctor may change these.

Adults including older people

The usual dose range is 5mg to 80mg each day. The 80mg dose is only recommended in patients with very high cholesterol levels and at high risk of heart disease problems. The dose will be decided by your doctor depending upon what you are being treated for.

This product should not be used for doses of 20mg or below. For doses of 20mg or below use the 20mg/5ml strength product.

Treatment of high cholesterol levels:

- The usual starting dose is 10mg (1.25ml) to 20mg (2.5ml) each day. This may be increased gradually by your doctor up to 40mg (5ml) each day
- Take this dose in the evening.

Treatment of high cholesterol levels if there is a family history of this:

- The usual dose is 40mg (5ml) in the evening, or
- 20mg (2.5ml) in the morning, 20mg (2.5ml) at lunch time and 40mg (5ml) in the evening.

Prevention of coronary heart disease (CHD):

- The usual dose is 20mg (2.5ml) to 40mg (5ml) each day.
- Take this dose in the evening.

People with kidney problems

- The doctor will start you on a lower dose and gradually increase it.

Use in children and adolescents (10 – 17 years old)

- The recommended usual starting dose is 10mg (1.25ml) a day in the evening.
- The maximum recommended dose is 40mg (5ml) a day.

If you take more Simvastatin than you should

If you take more of this medicine than you should, talk to your doctor or go to your nearest hospital straight away. Take the medicine pack with you.

If you forget to take Simvastatin

- If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Simvastatin

Do not stop taking simvastatin unless your doctor tells you to. It may make your cholesterol levels 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.

The following terms are used to describe how often side effects have been reported:

- Rare (occurring in 1 or more of 10,000 and less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 10,000 patients treated)
- Frequency not known.

The following rare serious side effects were reported.

If any of these serious side effects happen, stop taking simvastatin and tell your doctor immediately or go to the emergency room at your nearest hospital:

- muscle pain, tenderness, weakness or cramps. On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare, deaths have occurred
- an allergic reaction including:
 - swelling of the face, tongue and throat which may cause difficulty in breathing (angioedema)
 - severe muscle pain usually in the shoulders and hips
 - rash with weakness of limbs and neck muscles
 - pain or inflammation of the joints
 - inflammation of the blood vessels
 - unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, flushing
 - shortness of breath and feeling unwell
 - lupus-like disease picture (including rash, joint disorders and effects on blood cells)
- inflammation of the liver with yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stools, liver failure (very rare)
- inflammation of the pancreas often with severe abdominal pain.

The following very rare serious side effect was reported:

- a serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis)

The following side effects have also been reported rarely:

- low red blood cell count (anaemia)
- numbness or weakness of the arms and legs
- headache, tingling sensation, feeling dizzy
- feeling sick (nausea) or being sick (vomiting)
- stomach upset including constipation, diarrhoea, wind, heartburn and stomach pain
- rash, itching, hair loss
- feeling weak
- trouble sleeping (very rare)
- poor memory (very rare).

The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):

- erectile dysfunction
- depression
- breathing problems including persistent cough and/or shortness of breath or fever
- tendon problems, sometimes complicated by rupture of the tendon
- muscle weakness that is constant.

Additional possible side effects reported with some statins:

- sleep disturbances, including nightmares
- sexual difficulties

- 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
- muscle pain, tenderness, or weakness that is constant that may not go away after stopping simvastatin (frequency not known).

Laboratory Values

Elevations in some laboratory blood tests of liver function and a muscle enzyme (creatine kinase) have been observed.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Simvastatin Rosemont

- Keep out of the sight and reach of children
- Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- After first opening: Use within 1 month.
- 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 to protect the environment.

6. Contents of the pack and other information

What Simvastatin Rosemont 40mg/5ml Oral Suspension contains

- The active ingredient is simvastatin. Each 1ml contains 8mg simvastatin, (each 5ml contains 40mg simvastatin).
- The other ingredients are methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), propylene glycol (E1520), aluminium magnesium silicate, carmellose sodium (E466), simeticone emulsion, citric acid monohydrate (E330), disodium hydrogen phosphate anhydrous (E339), sodium laurilsulfate (E470a), acesulfame potassium (E950), butylhydroxyanisole (BHA), lime flavour and purified water.

What Simvastatin Rosemont 40mg/5ml Oral Suspension looks like and contents of the pack

A white to off-white suspension with a flavour and odour of lime.

It comes in a brown glass bottle 150ml with HDPE, EPE wadded, tamper evident, child resistant closure.

A double-sided dosing spoon is provided to measure 1.25ml, 2.5ml and 5ml doses as prescribed.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd., Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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

Greece	KYMORAL Πόσιμο εναιώρημα 40 mg/5 ml
Ireland	Simvastatin Rosemont 40mg/5ml Oral Suspension
United Kingdom	Simvastatin Rosemont 40mg/5ml Oral Suspension

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