

Patient Information Leaflet

Simvastatin 40mg/5ml Oral Suspension

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 only for you. 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

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1. What Simvastatin 40mg/5ml Oral Suspension is and what it is used for

The name of your medicine is Simvastatin 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 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.

2. What you need to know before you take Simvastatin 40mg/5ml Oral Suspension

Do not take simvastatin and tell your doctor if:

- you are allergic (hypersensitive) to simvastatin or any other ingredients in this liquid (see section 6 'Further information'). 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 gemfibrozil, used to lower cholesterol
- you are taking ciclosporin, used in organ transplant patients
- you are taking danazol, a man-made hormone used to treat endometriosis
- you are taking, or have taken in the last 7 days, a medicine called fusidic acid, used to treat bacterial infections.

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 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).

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 and is 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 or a close family member have a hereditary muscle problem
- you have ever had muscle problems whilst taking other medicines used to lower cholesterol (see Section 2 ‘Other medicines and Simvastatin Oral Suspension’).

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.

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

Children

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 Oral

Suspension). Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Other medicines and Simvastatin Oral Suspension

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'):

- 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, telithromycin or fusidic acid. Do not take fusidic acid while using this medicine
- 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
- amiodarone, used to treat irregular heart beats
- verapamil, diltiazem or amlodipine, used to treat heart conditions
- 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
- fenofibrate (another medicine for lowering cholesterol)
- niacin (nicotinic acid, another medicine for lowering cholesterol)
- medicines to lower cholesterol called bile acid sequestrants such as colestyramine. Take simvastatin at least 2 hours before or 4 hours after taking the bile acid sequestrant
- rifampicin (a medicine used to treat tuberculosis).

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

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 Oral Suspension with food and drink

You must not drink grapefruit juice while taking this medicine as it could increase your risk of muscle damage.

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.

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 40mg/5ml Oral Suspension contains methyl parahydroxybenzoate, ethyl parahydroxybenzoate and propyl parahydroxybenzoate:

- Methyl, ethyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may happen some time after starting the medicine.

3. How to take Simvastatin 40mg/5ml Oral Suspension

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure.

Taking this medicine

- This medicine contains 40mg of simvastatin in each 5ml
- Take this medicine by mouth
- Always shake the bottle before using it
- 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 who have not reached their cholesterol goal on lower doses. The dose will be decided by your doctor depending upon what you are being treated for.

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 you have 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.

Children (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 Oral Suspension 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 Oral Suspension

- 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 Oral Suspension

Do not stop taking Simvastatin Oral Suspension 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, Simvastatin Oral Suspension 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
 - 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 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).

Side effects where the frequency is not known (cannot be estimated from the available data):

- erectile dysfunction
- depression
- inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever
- tendon problems, sometimes complicated by rupture of the tendon.

Additional possible side effects reported with some statins:

- sleep disturbances, including trouble sleeping and nightmares
- memory loss
- 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.

Laboratory Values

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

IMB Pharmacovigilance

Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

5. How to store Simvastatin 40mg/5ml Oral Suspension

- Keep out of the sight and reach of children

- Do not store above 25°C
- Do not use 1 month after you first open it. Take it back to the pharmacy
- Do not use after the expiry date (month, year) stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- If it is out of date or you no longer want it, take it back to the pharmacy
- Do not use Simvastatin Oral Suspension if you notice anything wrong with the medicine. Talk to your pharmacist
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help to protect the environment.

6. Further information

What Simvastatin 40mg/5ml Oral Suspension contains

- The active ingredient is 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 (E467), simeticone emulsion, citric acid (E330), disodium hydrogen phosphate (E339), sodium laurilsulfate (E470a), acesulfame potassium (E950), lime flavour and purified water.

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

A white to off-white suspension with an odour of lime.

It comes in a brown glass bottle holding 150ml of suspension.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised in 06/2014.