

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Simvastatin 40 mg Film-coated Tablets 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 40 mg is and what it is used for
2. What you need to know before you take Simvastatin 40 mg
3. How to take Simvastatin 40 mg
4. Possible side effects
5. How to store Simvastatin 40 mg
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1. What Simvastatin 40 mg is and what it is used for

Simvastatin belongs to the group of medicines known as statins. These medicines block the production of cholesterol in the liver and lower the cholesterol and fat content in the blood.

Simvastatin is used to treat:

- high blood cholesterol levels in the blood (hypercholesterolaemia), with or without high levels of certain fats in the blood (triglycerides), when the combination of a diet, physical exercise and weight loss has not lowered the cholesterol level.
- high blood cholesterol levels in the blood resulting from a hereditary disorder (homozygous familial hypercholesterolaemia), as a supplement to a diet and other fat-lowering treatments or if other treatments to lower the cholesterol level are inappropriate.
- existent heart problems (arteriosclerotic cardiovascular disease) or diabetes (diabetes mellitus), to lower a normal or raised cholesterol level and thereby reduce the risk of complications of cardiovascular disease.

2. What you need to know before you take Simvastatin 40 mg

Do not take Simvastatin 40 mg

- if you are **allergic** to simvastatin 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** (see section 2, Pregnancy and breast-feeding).
- if you are **taking one or more of the following medicines at the same time**: antifungal medicines (ketoconazole, itraconazole, posaconazole or voriconazole), anti-HIV medicines (e.g. nelfinavir), specific types of antibiotics (erythromycin, clarithromycin and telithromycin), anti-hepatitis C medicines (boceprevir or telaprevir), specific types of antidepressants (nefazodone), cobicistat, specific medicine to lower cholesterol (gemfibrozil), ciclosporin and/or danazol (see section 2, Other medicines and Simvastatin 40 mg).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Simvastatin 40 mg.

Check if one of the warnings listed below applies to you or applied to you in the past. **Tell your doctor or pharmacist:**

- if you have once had an **allergic reaction** to this or similar medicines or to any of the ingredients listed.
- if you ever had **liver disease**.
- if you drink **large amounts of alcohol**.
- if you need to have **major surgery**, your doctor will tell you that treatment with simvastatin must be discontinued temporarily, a few days before major surgery.
- if you have **severe lung disease**.
- 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 Simvastatin 40 mg can lead to serious muscle problems (rhabdomyolysis).
- if you are **Asian**, because a different dose may be applicable to you.
- 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).

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.

Your doctor should do a blood test before you start taking 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.

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, and is greater in certain patients. Talk with your doctor if any of the following applies:

- you have previously experienced **problems with your muscles** as a result of the use of statins or fibrates (medicines to reduce fat levels in the blood).
- you are **female**.
- you are **more than 65 years old**.
- your **thyroid does not function well** and you are not being treated for it.
- you or your family members suffer from **hereditary muscle disorders**.
- you drink large amounts of **alcohol**.
- you have an impaired **kidney** function.

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.

Children

Safety and effectiveness have been studied in 10-17 year old boys and in girls who had started their menstrual period (menstruation) at least one year before (see section 3 How to take Simvastatin 40 mg). Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Other medicines and Simvastatin 40 mg

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

Other medicines may be affected by simvastatin. They, in turn, may affect how well simvastatin works.

The chance of a muscle disorder (myopathy) increases with simultaneous use of the following medicines:

- **gemfibrozil** (a medicine to lower the fats (lipids), such as cholesterol, in the blood).
- **ciclosporin** (a medicine used to suppress the immune system).
- **danazol** (a synthetic (man-made) steroid used to treat endometriosis and breast cysts in women).
- **flucanazole, itraconazole, ketoconazole, posaconazole** or **voriconazole** (antifungal medicines).
- **erythromycin, clarithromycin** or **telithromycin** (antibiotics).
- anti-HIV medicines such as **nelfinavir**.
- hepatitis C antiviral agents such as **boceprevir, telaprevir, elbasvir** or **grazoprevir** (used to treat hepatitis C virus infection).
- **nefazodone** (a medicine used to treat depression).
- medicines with the active ingredient **cobicistat**.
- **amiodarone** (a medicine used to treat irregular heartbeat).
- **verapamil** and **diltiazem** (medicines used to treat high blood pressure).
- **amlodipine** (a medicine used to treat high blood pressure and chest pain (angina) caused by the heart muscle receiving less oxygen than required).
- **lomitapide** (used to treat a serious and rare genetic cholesterol condition).
- **colchicine** (a medicine used to treat gout or other diseases).
- **daptomycine** (a drug used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin (e.g. Simvastatin 40 mg). Your doctor may decide that you stop taking Simvastatin 40 mg for a while.
- 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 40 mg. Taking Simvastatin 40 mg with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- ticagrelor (antiplatelet medicine).

Tell your doctor if you are taking any of the following:

- medicines to prevent blood clots, such as **warfarin, phenprocoumon** or **acenocoumarol** (anticoagulants).
- **fenofibrate** (another medicine for lowering cholesterol).
- **niacin** (another medicine for lowering cholesterol).
- **rifampicin** (a medicine used to treat tuberculosis).

Simvastatin 40 mg with drink

Do not drink any grapefruit juice if you are using Simvastatin 40 mg. Grapefruit juice increases the effect of this medicine, which may lead to side effects.

Pregnancy and breast-feeding

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.

Simvastatin must **not be used during pregnancy**. Simvastatin may only be used by women of childbearing age if pregnancy has been excluded. If you wish to become pregnant or suspect that you may be pregnant, you must immediately stop using simvastatin.

It is not known whether simvastatin passes into breast milk. Since many medicines do pass into breast milk and because simvastatin may cause serious side effects in infants, simvastatin **must not be used during breast-feeding**.

Driving and using machines

There are no indications that simvastatin negatively affects the ability to react. Simvastatin 40 mg may cause dizziness in rare cases. If you feel dizzy, then do not drive or operate any machines.

Simvastatin 40 mg contains lactose

Simvastatin tablets contain the milk sugar **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Simvastatin 40 mg

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

Your doctor has prescribed the amount of Simvastatin 40 mg you have to take. You should stay on a cholesterol-lowering diet while taking Simvastatin 40 mg.

The recommended dose is 1 Simvastatin 40 mg tablet by mouth once a day in the evening.

Take the tablet or tablet halves with water, before or after a meal.

The usual **dose** in adult patients is:

High blood cholesterol level (hypercholesterolaemia)

The usual starting dose is 10-40 mg once daily in the evening, in combination with a prescribed diet. If your cholesterol level has to be greatly lowered, then your doctor may prescribe a starting dose of 20-40 mg per day as a single daily dose taken in the evening.

If you have a seriously high blood cholesterol level and a high risk of cardiovascular disease, then your doctor may adjust the dose to 80 mg per day as a single daily dose taken in the evening. This is the maximum dose.

Hereditary high cholesterol (homozygous familial hypercholesterolaemia)

The recommended dose is:

- 40 mg once daily in the evening,
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This dosage is supplementary to other cholesterol-lowering treatments. It is also used if other cholesterol-lowering treatments are not available.

Cardiovascular disease

The usual starting dose is 20-40 mg taken once daily in the evening, possibly in combination with a prescribed diet and physical exercise.

Combination treatment

If you are using bile acid sequestrants such as colestipol and cholestyramine simultaneously, then take simvastatin 2 hours before or at least 4 hours after taking these medicines.

Take a maximum of 10 mg once daily if you have to take simvastatin simultaneously with the following medicines:

- medicines that lower the fat content in the blood (fibrates or fenofibrate)

Take a maximum of 20 mg once daily if you have to take simvastatin simultaneously with the following medicines:

- medicines against irregular heartbeat (arrhythmia) and/or high blood pressure (hypertension) (amiodarone, verapamil or diltiazem).
- medicines to treat hepatitis C virus infection (elbasvir or grazoprevir).
- amlodipine (medicine used to treat high blood pressure and chest pain (angina)).

Patients with severe renal impairment

Take 10 mg of simvastatin in the evening when starting the treatment. Your doctor will determine the subsequent dosage.

Use in children and adolescents aged 10 - 17 years

The recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.

Use in the elderly

It is unnecessary to adjust the dosage.

If you take more Simvastatin 40 mg than you should

Immediately contact your doctor or pharmacist if you have taken too much simvastatin.

If you forget to take Simvastatin 40 mg

Do not take a double dose to make up for a forgotten dose. Just take your normal amount of Simvastatin 40 mg at the usual time the next day.

If you stop taking Simvastatin 40 mg

Continue taking simvastatin, unless your doctor tells you to stop. Your blood cholesterol levels may rise again once you stop taking simvastatin.

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 (may affect up to 1 in 1,000 people)
- Very rare (may affect up to 1 in 10,000 people)
- Not known (frequency cannot be estimated from the available data)

The following rare serious side effects were reported.

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

• muscle pain, tenderness, weakness, muscle rupture, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred. • hypersensitivity (allergic) reactions 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 • rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions) • pain or inflammation of the joints (polymyalgia rheumatica) • inflammation of the blood vessels (vasculitis) • unusual bruising, skin eruptions and swelling (dermatomyositis), hives, skin sensitivity to the sun, fever, flushing • shortness of breath (dyspnoea) and feeling unwell • lupus-like disease picture (including rash, joint disorders, and effects on blood cells) • inflammation of the liver with the following symptoms: yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, feeling tired or weak, loss of appetite, 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) • gynecomastia (breast enlargement in men).

The following rare side effects have also been reported:

low red blood cell count (anaemia) • numbness or weakness of the arms and legs (peripheral neuropathy) • headache, tingling sensation (paresthesia), dizziness • blurred vision, impaired vision • digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting) • rash, itching, hair loss • weakness • memory loss, confusion.

The following very rare side effects have also been reported:
trouble sleeping • poor memory.

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

erectile dysfunction • depression • inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever • tendon injuries • muscle weakness that is constant • 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.

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 may monitor you while you are taking this medicine.

Laboratory Values

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

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Simvastatin 40 mg

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

No special storage temperature is required for Simvastatin 40 mg.

Do not use this medicine after the expiry date which is stated on the blister and carton after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that 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 protect the environment.

6. Contents of the pack and other information

What Simvastatin 40 mg contains

- The active substance is simvastatin; each tablet contains 10 mg simvastatin.
- The other ingredients are: anhydrous lactose, microcrystalline cellulose (E 460), pregelatinised maize starch, butylhydroxyanisole (E 320), magnesium stearate, talc (E 553b), hydroxypropyl cellulose (E 463), hypromellose (E 464), and titanium dioxide (E 171).

What Simvastatin 40 mg looks like and contents of the pack

Simvastatin 40 mg film-coated tablets are white capsule-shaped tablets. The tablets are debossed with SVT on the side without a score line and with 10 on the side with the score line.

Simvastatin 40 mg is available in cartons with 10, 14, 20, 28, 30, 50, 56, 60, 84, 98 or 100 tablets in blister or blister in aluminium pouches. The blister contains 10, 14 or 20 tablets.

Simvastatin 40 mg is also available in cartons with 49, 50, 56 or 100 tablets, per blister 5, 7, 10 or 14 tablets (single unit delivery package for hospital use).

Simvastatin 40 mg is also available in tablet containers with 100, 250 or 300 tablets, sealed with a child-proof cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

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Microweg 22
6545 CM Nijmegen
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Manufacturers:

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