

1 Package leaflet

Package leaflet: Information for the user:

Simvastatin Genthon 5 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 Genthon 5 mg is and what it is used for
2. What you need to know before you take Simvastatin Genthon 5 mg
3. How to take Simvastatin Genthon 5 mg
4. Possible side effects
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1. What Simvastatin Genthon 5 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 Genthon 5 mg

Do not take Simvastatin Genthon 5 mg

- if you are **allergic** to simvastatin or any of the other ingredients of this medicine (listed in section 6), such as lactose.

- if you have a **liver disorder**.
- if you have high levels of certain **liver enzymes** (serum transaminases) in your blood.
- if you are **pregnant** or are **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 or posaconazole), anti-HIV medicines (e.g. nelfinavir, indinavir, zidovudine and zalcitabine) (HIV protease inhibitors are used for HIV infections), specific types of antibiotics (erythromycin, clarithromycin and telithromycin) and/or specific types of antidepressants (nefazodone) (see section 2, Other medicines and Simvastatin Genthon 5 mg).

Warnings and precautions

Talk to your doctor or pharmacist before taking Simvastatin Genthon 5 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 consume **substantial quantities 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**.

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 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 consume considerable amounts of **alcohol**.
- you have an impaired **kidney** function.

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 section 3 How to take Simvastatin Genthon 5 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 Genthon 5 mg

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

Tell your doctor if you are using medicines to prevent **blood clotting** (coumarin derivatives, e.g. warfarin), or if you took these recently.

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

- fibrates like gemfibrozil and bezafibrate (medicines used 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 and posaconazole (antifungal medicines).
- erythromycin, clarithromycin, telithromycin or fusidic acid (antibiotics).
- anti-HIV medicines such as nelfinavir, indinavir, ritonavir and saquinavir (HIV protease inhibitors are used for HIV infections).
- nefazodone (a medicine used to treat depression).
- 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).
- rifampicin (a medicine used to treat tuberculosis).
- colchicine (a medicine used to treat gout or other diseases).

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. In particular, 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).

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

Simvastatin Genthon 5 mg with food and drink

Do not drink any grapefruit juice if you are using Simvastatin Genthon 5 mg. Grapefruit juice increases the effect of this medicine, which may lead to side effects.

Pregnancy and breast-feeding

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**.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There are no indications that simvastatin negatively affects the ability to react. Simvastatin Genthon 5 mg may cause dizziness in rare cases. If you feel dizzy, then do not drive or operate any machines.

Simvastatin Genthon 5 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 Genthon 5 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 Genthon 5 mg you have to take. Before taking Simvastatin Genthon 5 mg your doctor will prescribe a cholesterol-lowering diet. You have to continue this diet while taking Simvastatin Genthon 5 mg.

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

The usual **dose** is:

High blood cholesterol level (hypercholesterolaemia)

The usual starting dose is 10-20 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 and is recommended for those patients who have not achieved their cholesterol goal on lower doses.

Hereditary high cholesterol (homozygous familial hypercholesterolaemia)

The recommended dose is:

- 40 mg once daily in the evening,
- or

- 80 mg daily divided into three separate doses of 20 mg, 20 mg and an evening dose of 10 mg, respectively.

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 against rejection reactions (ciclosporin)
- medicines that lower the fat content in the blood (fibrates such as gemfibrozil, with the exclusion of fenofibrate)
- vitamin B3 (niacin)

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).

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.

The 80 mg dose is only recommended in adult patients with very high cholesterol levels and at high risk of heart disease problems.

Use in the elderly

It is unnecessary to adjust the dosage.

If you take more Simvastatin Genthon 5 mg than you should

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

If you forget to take Simvastatin Genthon 5 mg

Do not take a double dose to make up for the dose you missed. If you forget to take a dose, take it as soon as you remember, unless it is less than 4 hours before your next dose. In that case just continue following the normal dosage pattern.

If you stop taking Simvastatin Genthon 5 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, 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
- 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 stool, 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, dizziness • digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting) • rash, itching, hair loss • weakness • 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 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.

Additional possible side effects reported with some statins:

sleep disturbances, including 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 may monitor you while you are taking this medicine.

Laboratory Values

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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, 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 Genthon 5 mg

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

No special storage temperature is required for Simvastatin Genthon 5 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 Genthon 5 mg contains

- The active ingredient 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 Genthon 5 mg looks like and the contents of the pack

Simvastatin Genthon 5 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 Genthon 5 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 Genthon 5 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 Genthon 5 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.

Market Authorisation Holder and Manufacturer

Marketing authorisation holder:

Genthon BV
Microweg 22
6545 CM Nijmegen
The Netherlands

Manufacturers:

Synthon BV
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PA 740/6/1; Simvastatin Genthon 5 mg Film-coated Tablets

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