Package leaflet: Information for the user

Simvastatin 5 mg/10 mg/20 mg/ 30 mg/40 mg/60 mg/80 mg film-coated tablets

simvastatin

Read all of this leaflet carefully before you start taking this medicine 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.

What is in this leaflet

1 What Simvastatin film-coated tablets is and what it is used for

Simvastatin film-coated tablets is a medicinal product to lower elevated cholesterol levels in blood.

Simvastatin film-coated tablets is used:
- <u>in elevated blood lipid values</u>
  Treatment of elevated blood lipid values which are not attributable to another disease (primary hypercholesterolaemia or mixed hyperlipidaemia), additionally to diet when response to diet and other non-pharmacological measures (e.g. physical exercise, weight reduction) are not sufficient.

  To treat hereditary elevated blood lipid values (homozygous familial hypercholesterolaemia). Simvastatin
  film-coated tablets is used as an adjunct to diet and other lipid-lowering measures or if such measures are not appropriate.

- <u>to prevent cardiovascular events</u>
  Reduction in the frequency of cardiovascular-induced deaths and events in patients with manifest atherosclerotic heart disease or diabetes mellitus whose cholesterol values are normal or elevated. As an adjunct to correct other risk factors and cardioprotective therapy.

2 What you need to know before you take Simvastatin film-coated tablets

Do not take Simvastatin film-coated tablets

- if you are allergic to simvastatin or to any of the other ingredients of this medicine (listed in section 6)
- if you have an active liver disease or suffer from an unexplained, persistent elevation of certain liver enzymes in blood (transaminases)
- if you are pregnant or breast-feeding
- if you concomitantly take medicinal products which inhibit the enzyme cytochrome P 450 3A4 [e.g. itraconazole, ketoconazole, posaconazole (medicinal products against pathogenic fungi), HIV protease inhibitors (medicinal products in HIV infection, e.g. nelfinavir), erythromycin, clarithromycin, telithromycin (antibiotics) and nefazodone (antidepressant)] (see section "Other medicines and simvastatin").

Warnings and precautions

- If you experience muscle pain, weakness or cramps during therapy with Simvastatin film-coated tablets, please inform your doctor immediately. Simvastatin occasionally causes a disease of skeletal muscles (myopathy). In rare cases Simvastatin can cause severe muscle problems that can produce renal impairment (rhabdomyolysis). The risk of a muscle disease/decomposition of muscle cells is higher in patients who take high doses of Simvastatin film-coated tablets or who take Simvastatin film-coated tablets with certain medicines, (see section “Other medicines and simvastatin”).
- Inform your doctor if you are older than 65 years, if you are female, if you experience renal dysfunction, untreated thyroid hypofunction , if you have familial history or have previously suffered from muscular disorders or if you regularly consume alcohol, since these factors can increase the risk of muscle disorders.
- If you have had some liver disease. Moderate increases of transaminase levels are likely to occur and usually return to baseline without discontinuing simvastatin treatment. Persistent increases in serum transaminases usually fall slowly to pre-treatment levels when simvastatin is discontinued or interrupted.
- If you have a scheduled surgery, it is advisable to stop taking Simvastatin film-coated tablets at least a few days prior to surgery.

Talk to your doctor or pharmacist before taking Simvastatin film-coated tablets if you:

- have severe respiratory failure

Your doctor may want to carry out blood/liver function tests to check that liver and muscles are working properly before and during treatment with Simvastatin film-coated tablets.

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.

Other medicines and simvastatin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines can interact with Simvastatin film-coated tablets and can increase the risk of muscle adverse reactions. In these cases dosage adjustment or discontinuation of simvastatin can be necessary:

- **itraconazole, ketoconazole, posaconazole, erythromycin, clarithromycin, telithromycin**, **HIV protease inhibitors** (e.g. nelfinavir) and **nefazodone**. These medicinal products must therefore not be taken concomitantly with Simvastatin film-coated tablets (see "Do not take Simvastatin film-coated tablets")
- Fibrates (other cholesterol-lowering medicines such as gemfibrozil, bezafibrat)
- Niacin or nicotinic acid (cholesterol-lowering medicines) in large doses (> 1 g/day)
- **ciclosporin** (medicine to prevent transplant rejection)
- **verapamil, diltiazem, amlodipine** (medicinal products to treat high blood pressure or chest tightness) and **amiodarone** (medicinal product to treat arrhythmias)
- **fusidic acid** (medicine for bacterial infections)
- **Danazol** (synthetic hormone, gonadotrophin inhibitor)
- **Colchicine** (medicinal product to treat gout)

Tell your doctor if you are taking any of these.

It is also important to tell your doctor if you are taking or have within the last 4 weeks taken:

- **Medicinal products for oral intake which inhibit blood coagulation (oral anticoagulants**), since the anticoagulant effect is increased if they are taken with Simvastatin film-coated tablets
- **Rifampicin** (medicine for bacterial infections), since the cholesterol-lowering effect of simvastatin may be diminished by rifampicin

Simvastatin film-coated tablets with food, drink and alcohol
Grapefruit juice can increase the concentration of simvastatin in blood. Avoid a consumption of grapefruit juice during therapy with Simvastatin film-coated tablets.
Alcohol: Inform your doctor if you consume larger quantities of alcohol.

Elderly patients
No dose adjustment is necessary for elderly patients.

Children and adolescents (10–17 years of age)
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 film-coated tablets"). Simvastatin film-coated tablets has not been studied in children under the age of 10 years.
For more information, talk to your doctor.

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.

Pregnancy
Do not use Simvastatin film-coated tablets if you are pregnant, trying to become pregnant or suspect that you are pregnant, as the safety in pregnant woman has not been established. If you become pregnant while using Simvastatin film-coated tablets, you must stop taking the tablets immediately and contact your doctor (see "Do not take Simvastatin film-coated tablets")

Breast-feeding
No data on the passage of the active substance of Simvastatin film-coated tablets in breast milk are available. On account of the risk of serious adverse reactions in infants, Simvastatin film-coated tablets must not be used in the breast-feeding period. If therapy is indispensable, breastfeeding must be stopped.

Driving and using machines
You are allowed to drive and use machines. Simvastatin film-coated tablets has no or only negligible influence on the ability to drive and to operate machines. However, when driving or operating machines, it should be taken into account that dizziness has rarely been reported in the post-marketing period.

Simvastatin film-coated tablets contains lactose
This medicinal product contains 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 film-coated tablets

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

Take the tablets with sufficient liquid (a glass of water) as single dose in the evening. You may take Simvastatin film-coated tablets irrespective of meals. The tablet can be divided into equal doses.

You should stay on a cholesterol-lowering diet while taking Simvastatin film-coated tablets.

The recommended dose is:
See table below.

<5 mg>
Maximum dose:
80 mg simvastatin once daily (corresponding 16* film-coated tablets).

Your attending doctor will increase the dose – if required – at intervals of at least 4 weeks. The 80 mg dose (corresponding 16* film-coated tablets) is only recommended in adult patients with very high cholesterol levels and at high risk of c heart disease problems.

	Usual initial dose	Patients who require a large starting dose
In case of elevated blood lipid values	2–4 film-coated tablets of Simvastatin 5 mg film-coated tablets once daily (corresponding to 10 mg to 20 mg simvastatin)	4–8* film-coated tablets of Simvastatin 5 mg film-coated tablets once daily (corresponding to 20 mg to 40 mg simvastatin)
In case of hereditary elevated blood lipid values (homozygous familial hypercholesterolaemia)	8* film-coated tablets of Simvastatin 5 mg film-coated tablets once daily (corresponding to 40 mg simvastatin) or 4 film-coated tablets of Simvastatin 5 mg film-coated tablets in the morning, 4 film-coated tablets of Simvastatin 5 mg film-coated tablets at noon and 8* film-coated tablets of Simvastatin 5 mg film-coated tablets in the evening (corres-ponding to 80 mg simvastatin a day)	
To prevent cardiovascular events	4–8* film-coated tablets of Simvastatin 5 mg film-coated tablets once daily (corresponding to 20 mg to 40 mg simvastatin)	

Concomitant administration with other medicinal products
Simvastatin film-coated tablets is effective alone or together with anion exchangers such as colestyramine and colestipol. Simvastatin film-coated tablets should be taken at least 2 hours before or at least 4 hours after intake of anion exchangers.

In patients taking ciclosporin, danazol, gemfibrozil or other fibrates (except fenofibrate) concomitantly with Simvastatin film-coated tablets, a dose of 10 mg simvastatin a day should not be exceeded. In patients taking amiodarone or verapamil concomitantly with Simvastatin film-coated tablets, a dose of 20 mg simvastatin a day should not be exceeded. In patients taking diltiazem or amlodipine concomitantly with Simvastatin film-coated tablets, a dose of 40 mg* simvastatin a day should not be exceeded.

Elderly patients
No dose adjustment is necessary for elderly patients.

Use in children and adolescents (10–17 years of age)

For children (10–17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg* a day.

Use in renal dysfunction
No dose adjustment is usually necessary in patients with moderate renal dysfunction. In patients with severe renal dysfunction (creatinine clearance below 30 ml/min), doses above 10 mg simvastatin a day should be carefully considered and, if necessary, prescribed with caution.

* For this dosage, film-coated tablets with a higher content of active substance are available.

<10 mg>
Maximum dose:
8 film-coated tablets once daily (corresponding 80 mg simvastatin).

Your attending doctor will increase the dose – if required – at intervals of at least 4 weeks. 8 film-coated tablets are only recommended in adult patients with very high cholesterol levels and at high risk of heart disease problems.

	Usual initial dose	Patients who require a large starting dose
In case of elevated blood lipid values	1–2 film-coated tablets of Simvastatin 10 mg film-coated tablets once daily (corresponding to 10 mg to 20 mg simvastatin)	2–4 film-coated tablets of Simvastatin 10 mg film-coated tablets once daily (corresponding to 20 mg to 40 mg simvastatin)
In case of hereditary elevated blood lipid values (homozygous familial hypercholesterolaemia)	4 film-coated tablets of Simvastatin 10 mg film-coated tablets once daily (corresponding to 40 mg simvastatin) or 2 film-coated tablets of Simvastatin 10 mg film-coated tablets in the morning, 2 film-coated tablets of Simvastatin 10 mg film-coated tablets at noon and 4 film-coated tablets of Simvastatin 10 mg film-coated tablets in the evening (corresponding to 80 mg simvastatin a day)	
To prevent cardiovascular events	2–4 film-coated tablets of Simvastatin 10 mg film-coated tablets once daily (corresponding to 20 mg to 40 mg simvastatin)	

Concomitant administration with other medicinal products
Simvastatin film-coated tablets is effective alone or together with anion exchangers such as

colestyramine and colestipol. Simvastatin film-coated tablets should be taken at least 2 hours before or at least 4 hours after intake of anion exchangers.

In patients taking ciclosporin, danazol, gemfibrozil or other fibrates (except fenofibrate) concomitantly with Simvastatin film-coated tablets, a dose of 10 mg simvastatin a day should not be exceeded. In patients taking amiodarone or verapamil concomitantly with Simvastatin film-coated tablets, a dose of 20 mg* simvastatin a day should not be exceeded. In patients taking diltiazem or amlodipine concomitantly with Simvastatin film-coated tablets, a dose of 40 mg* simvastatin a day should not be exceeded.

Elderly patients
No dose adjustment is necessary for elderly patients.

Use in children and adolescents (10–17 years of age)
For children (10–17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg* a day.

Use in renal dysfunction
No dose adjustment is usually necessary in patients with moderate renal dysfunction. In patients with severe renal dysfunction (creatinine clearance below 30 ml/min), doses above 10 mg simvastatin a day should be carefully considered and, if necessary, prescribed with caution.

* For this dosage, film-coated tablets with a higher content of active substance are available.

<20 mg>
Maximum dose: 4 film-coated tablets once daily (corresponding 80 mg simvastatin).

Your attending doctor will increase the dose – if required – at intervals of at least 4 weeks. 4 film-coated tablets are only recommended in adult patients with very high cholesterol levels and at high risk of heart disease problems.

	Usual initial dose	Patients who require a large starting dose
In case of elevated blood lipid values	½–1 film-coated tablet of Simvastatin 20 mg film-coated tablets once daily (corresponding to 10 mg to 20 mg simvastatin)	1–2 film-coated tablets of Simvastatin 20 mg film-coated tablets once daily (corresponding to 20 mg to 40 mg simvastatin)
In case of hereditary elevated blood lipid values (homozygous familial hypercholesterolaemia)	2 film-coated tablets of Simvastatin 20 mg film-coated tablets once daily (corresponding to 40 mg simvastatin) or 1 film-coated tablets of Simvastatin 20 mg film-coated tablets in the	

	morning, 1 film-coated tablets of Simvastatin 20 mg film-coated tablets at noon and 2 film-coated tablets of Simvastatin 20 mg film-coated tablets in the evening (corresponding to 80 mg simvastatin a day)	
To prevent cardiovascular events	1–2 film-coated tablets of Simvastatin 20 mg film-coated tablets once daily (corresponding to 20 mg to 40 mg simvastatin)	

Concomitant administration with other medicinal products
Simvastatin film-coated tablets is effective alone or together with anion exchangers such as colestyramine and colestipol. Simvastatin film-coated tablets should be taken at least 2 hours before or at least 4 hours after intake of anion exchangers.

In patients taking ciclosporin, danazol, gemfibrozil or other fibrates (except fenofibrate) concomitantly with Simvastatin film-coated tablets, a dose of 10 mg simvastatin a day should not be exceeded. In patients taking amiodarone or verapamil concomitantly with Simvastatin film-coated tablets, a dose of 20 mg simvastatin a day should not be exceeded. In patients taking diltiazem or amlodipine concomitantly with Simvastatin film-coated tablets, a dose of 40 mg simvastatin a day should not be exceeded.

Elderly patients
No dose adjustment is necessary for elderly patients.

Use in children and adolescents (10–17 years of age)
For children (10–17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.

Use in renal dysfunction
No dose adjustment is usually necessary in patients with moderate renal dysfunction. In patients with severe renal dysfunction (creatinine clearance below 30 ml/min), doses above 10 mg simvastatin a day should be carefully considered and, if necessary, prescribed with caution.

<30 mg>
Maximum dose: 80 mg simvastatin.

Your attending doctor will increase the dose – if required – at intervals of at least 4 weeks. The 80 mg dose is only recommended in adult patients with very high cholesterol levels and at high risk of heart disease problems.

	Usual initial dose	Patients who require a large

		starting dose
In case of elevated blood lipid values	10 mg* to 20 mg* simvastatin once daily (e.g. to ½ film-coated tablet of Simvastatin 30 mg film-coated tablets)	20 mg* to 40 mg* simvastatin once daily (e.g. to 1 film-coated tablet of Simvastatin 30 mg film-coated tablets)
In case of hereditary elevated blood lipid values (homozygous familial hypercholesterolaemia)	40 mg* simvastatin once daily or 20 mg* simvastatin in the morning, 20 mg* simvastatin at noon and 40 mg* simvastatin in the evening (corresponding to 80 mg simvastatin a day)	
To prevent cardiovascular events	20 mg* to 40 mg* simvastatin once daily (e.g. to 1 film-coated tablet of Simvastatin 30 mg film-coated tablets)	

Concomitant administration with other medicinal products
Simvastatin film-coated tablets is effective alone or together with anion exchangers such as colestyramine and colestipol. Simvastatin film-coated tablets should be taken at least 2 hours before or at least 4 hours after intake of anion exchangers.

In patients taking ciclosporin, danazol, gemfibrozil or other fibrates (except fenofibrate) concomitantly with Simvastatin film-coated tablets, a dose of 10 mg simvastatin a day should not be exceeded. In patients taking amiodarone or verapamil concomitantly with Simvastatin film-coated tablets, a dose of 20 mg simvastatin a day should not be exceeded. In patients taking diltiazem or amlodipine concomitantly with Simvastatin film-coated tablets, a dose of 40 mg* simvastatin a day should not be exceeded.

Elderly patients
No dose adjustment is necessary for elderly patients.

Use in children and adolescents (10–17 years of age)
For children (10–17 years old), the recommended usual starting dose is 10 mg* a day in the evening. The maximum recommended dose is 40 mg* a day.

Use in renal dysfunction
No dose adjustment is usually necessary in patients with moderate renal dysfunction. In patients with severe renal dysfunction (creatinine clearance below 30 ml/min), doses above 10 mg simvastatin a day should be carefully considered and, if necessary, prescribed with caution.

* For this dosage, film-coated tablets with a lower or higher content of active substance are available.

<40 mg>

Maximum dose: 2 film-coated tablets once daily (corresponding 80 mg simvastatin).

Your attending doctor will increase the dose – if required – at intervals of at least 4 weeks. 2 film-coated tablets are only recommended in adult patients with very high cholesterol levels and at high risk of heart disease problems.

	Usual initial dose	**Patients who require a large starting dose**
In case of elevated blood lipid values	10 mg* to 20 mg simvastatin once daily (corresponding ½ film-coated tablet of Simvastatin 40 mg film-coated tablets)	½–1 film-coated tablet of Simvastatin 40 mg film-coated tablets once daily (corresponding to 20 mg to 40 mg simvastatin)
In case of hereditary elevated blood lipid values (homozygous familial hypercholesterolaemia)	1 film-coated tablet of Simvastatin 40 mg film-coated tablets once daily (corresponding to 40 mg simvastatin) or ½ film-coated tablet of Simvastatin 40 mg film-coated tablets in the morning, ½ film-coated tablet of Simvastatin 40 mg film-coated tablets at noon and 1 film-coated tablets of Simvastatin 40 mg film-coated tablets in the evening (corresponding to 80 mg simvastatin a day)	
To prevent cardiovascular events	½–1 film-coated tablet of Simvastatin 40 mg film-coated tablets once daily (corresponding to 20 mg to 40 mg simvastatin)	

Concomitant administration with other medicinal products
Simvastatin film-coated tablets is effective alone or together with anion exchangers such as colestyramine and colestipol. Simvastatin film-coated tablets should be taken at least 2 hours before or at least 4 hours after intake of anion exchangers.

In patients taking ciclosporin, danazol, gemfibrozil or other fibrates (except fenofibrate) concomitantly with Simvastatin film-coated tablets, a dose of 10 mg* simvastatin a day should not be exceeded. In patients taking amiodarone or verapamil concomitantly with Simvastatin film-coated tablets, a dose of 20 mg simvastatin a day should not be exceeded. In patients taking diltiazem or amlodipine concomitantly with Simvastatin film-coated tablets, a dose of 40 mg simvastatin a day should not be exceeded.

Elderly patients
No dose adjustment is necessary for elderly patients.

Use in children and adolescents (10–17 years of age)
For children (10–17 years old), the recommended usual starting dose is 10 mg* a day in the evening. The maximum recommended dose is 40 mg a day.

Use in renal dysfunction
No dose adjustment is usually necessary in patients with moderate renal dysfunction. In patients with severe renal dysfunction (creatinine clearance below 30 ml/min), doses above 10 mg* simvastatin a day should be carefully considered and, if necessary, prescribed with caution.

* For this dosage, film-coated tablet with a lower content of active substance are available.

<60 mg>
Maximum dose: 80 mg simvastatin.

Your attending doctor will increase the dose – if required – at intervals of at least 4 weeks. The 80 mg dose is only recommended in adult patients with very high cholesterol levels and at high risk of heart disease problems. Simvastatin film-coated tablets are available for lower dosages with lower active substance contents.

	Usual initial dose	**Patients who require a large starting dose**
In case of elevated blood lipid values	10 mg* to 20 mg* simvastatin once daily	20 mg* to 40 mg* simvastatin once daily (e.g. to ½ film-coated tablet of Simvastatin 60 mg film-coated tablets)
In case of hereditary elevated blood lipid values (homozygous familial hypercholesterolaemia)	40 mg* of simvastatin once daily or 20 mg* simvastatin in the morning, 20 mg* simvastatin at noon and 40 mg* in the evening (corresponding to 80 mg simvastatin a day)	
To prevent cardiovascular events	20 mg* to 40 mg* simvastatin once daily (e.g. to ½ film-coated tablet of Simvastatin 60 mg film-coated tablets)	

Concomitant administration with other medicinal products
Simvastatin film-coated tablets is effective alone or together with anion exchangers such as colestyramine and colestipol. Simvastatin film-coated tablets should be taken at least 2 hours before or at least 4 hours after intake of anion exchangers.

In patients taking ciclosporin, danazol, gemfibrozil or other fibrates (except fenofibrate)

concomitantly with Simvastatin film-coated tablets, a dose of 10 mg* simvastatin a day should not be exceeded. In patients taking amiodarone or verapamil concomitantly with Simvastatin film-coated tablets, a dose of 20 mg* simvastatin a day should not be exceeded. In patients taking diltiazem or amlodipine concomitantly with Simvastatin film-coated tablets, a dose of 40 mg* simvastatin a day should not be exceeded.

Elderly patients
No dose adjustment is necessary for elderly patients.

Use in children and adolescents (10–17 years of age)
For children (10–17 years old), the recommended usual starting dose is 10 mg* a day in the evening. The maximum recommended dose is 40 mg* a day.

Use in renal dysfunction
No dose adjustment is usually necessary in patients with moderate renal dysfunction. In patients with severe renal dysfunction (creatinine clearance below 30 ml/min), doses above 10 mg* simvastatin a day should be carefully considered and, if necessary, prescribed with caution.

* For this dosage, film-coated tablet with a lower content of active substance are available.

<80 mg>
Maximum dose: 1 film-coated tablet once daily (corresponding 80 mg simvastatin).

Your attending doctor will increase the dose – if required – at intervals of at least 4 weeks. 1 film-coated tablet is only recommended in adult patients with very high cholesterol levels and at high risk of heart disease problems. Simvastatin film-coated tablets are available for lower dosages with lower active substance contents.

	Usual initial dose	**Patients who require a large starting dose**
In case of elevated blood lipid values	10 mg* to 20 mg* simvastatin once daily	20 mg* to 40 mg simvastatin once daily (corresponding to ½ film-coated tablet of Simvastatin 80 mg film-coated tablets)
In case of hereditary elevated blood lipid values (homozygous familial hypercholesterolaemia)	½ film-coated tablet of Simvastatin 80 mg film-coated tablets once daily (corresponding to 40 mg simvastatin) or 20 mg* simvastatin in the morning, 20 mg* simvastatin at noon and 40 mg (corresponding to ½ film-coated tablet of Simvastatin 80 mg film-coated tablets) in the	

	evening (corresponding to 80 mg simvastatin a day)	
To prevent cardiovascular events	20 mg* to 40 mg simvastatin once daily (corresponding to ½ film-coated tablet of Simvastatin 80 mg film-coated tablets)	

Concomitant administration with other medicinal products
Simvastatin film-coated tablets is effective alone or together with anion exchangers such as colestyramine and colestipol. Simvastatin film-coated tablets should be taken at least 2 hours before or at least 4 hours after intake of anion exchangers.

In patients taking ciclosporin, danazol, gemfibrozil or other fibrates (except fenofibrate) concomitantly with Simvastatin film-coated tablets, a dose of 10 mg* simvastatin a day should not be exceeded. In patients taking amiodarone or verapamil concomitantly with Simvastatin film-coated tablets, a dose of 20 mg* simvastatin a day should not be exceeded. In patients taking diltiazem or amlodipine concomitantly with Simvastatin film-coated tablets, a dose of 40 mg simvastatin a day should not be exceeded.

Elderly patients
No dose adjustment is necessary for elderly patients.

Use in children and adolescents (10–17 years of age)
For children (10–17 years old), the recommended usual starting dose is 10 mg* a day in the evening. The maximum recommended dose is 40 mg a day (corresponding to ½ film-coated tablet of Simvastatin film-coated tablets).

Use in renal dysfunction
No dose adjustment is usually necessary in patients with moderate renal dysfunction. In patients with severe renal dysfunction (creatinine clearance below 30 ml/min), doses above 10 mg* simvastatin a day should be carefully considered and, if necessary, prescribed with caution.

* For this dosage, film-coated tablet with a lower content of active substance are available.

Intake of Simvastatin film-coated tablets is long-term therapy. The attending doctor decides on the duration of treatment.
Please talk to your doctor if you have the impression that the effect of Simvastatin film-coated tablets is too strong or too weak.

If you take more Simvastatin film-coated tablets than you should
Please consult your doctor without delay. In case of overdose, your doctor should take symptomatic and

supportive measures.

If you forget to take Simvastatin film-coated tablets
Do not take a double dose to make up for a forgotten dose, but continue treatment with the dose prescribed.

If you stop taking Simvastatin film-coated tablets
The blood lipid values can 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 rare serious side effects are reported (may affect up to 1 in 1,000 people).
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 (may affect up to 1 in 1,000 people):

- 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.

The following side effects have been reported very rarely (may affect up to 1 in 10,000 people):

- 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
- pain in tendon, sometimes complicated by rupture.

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 will 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 side effects not listed in this leaflet.

5 How to store Simvastatin film-coated tablets

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

Use by Date: Do not use this medicine after the expiry date which is stated on the blister and on the carton after "Exp". The expiry date refers to the last day of that month.

Do not store above 30 °C.

Blister:
Keep the blister in the outer carton, in order to protect from light.

Tablet container:

Store in the original container, in order to protect from light.

Disposal: Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. The measures will help protect the environment.

6 Contents of the pack and other information

What Simvastatin film-coated tablet contains

- The active substance is Simvastatin. One film-coated tablet contains 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg or 80 mg simvastatin

- The other ingredients are pregelatinized starch (maize), lactose monohydrate, microcrystalline cellulose, butylhydroxyanisole (E 320), ascorbic acid (E 300), citric acid monohydrate (E330), magnesium stearate, hypromellose, talc, colouring agents: titanium dioxide (E171), ferric oxide, yellow (E172)

What Simvastatin film-coated tablet looks like and contents of the pack

Simvastatin film-coated tablet is a yellow coated, oval, scored, convex tablet coded SIM 5 on one side which is availabel in following packs:

5 mg:
Blister (Aluminium/PVC)
Pack sizes: 7, 10, 14, 20, 21, 28, 30, 35, 40, 42, 49, 50, 50 x 1, 56, 63, 70, 77, 84, 91, 98 and 100 film-coated tablets.

Polyethylene tablet container with screw cap
Pack sizes: 10, 20, 28, 30, 40, 50, 100 and 250 film-coated tablets.

10 mg:
Blister (Aluminium/PVC)
Pack sizes: 7,10,14,20,21,28,30,35,40,42,49,50,50X1,56,63,70,77,84,91,98 and 100 film-coated tablets.

Polyethylene tablet container with screw cap
Pack sizes: 10,20,28,30,40,50,100 and 250 film-coated tabelts.

20 mg:
Blister (Aluminium/PVC)
Pack sizes: 7,10,14,20,21,28,30,35,40,42,49,50,50X1,56,63,70,77,84,91,98 and 100 film-coated tabelts.

Polyethylene tablet container with screw cap
Pack sizes: 10,20,28,30,40,50,100 and 250 film-coated tablets

30 mg:
Blister (Aluminium/PVC)
Pack sizes: 7,10,14,20,21,28,30,35,40,42,49,50,50X1,56,63,70,77,84,91,98 and 100 film-coated tablets

Polyethylene tablet container with screw cap
Pack sizes: 10,20,28,30,40,50,100 and 250 film-coated tablets

40 mg:
Blister (Aluminium/PVC)
Pack sizes: 7,10,14,20,21,28,30,35,40,42,49,50,50X1,56,63,70,77,84,91,98 and 100 film-coated tablets.

Polyethylene tablet container with screw cap
Pack sizes: 10,20,28,30,40,50,100,250

60 mg:
Blister (Aluminium/PVC)
Pack sizes: 7,10,14,20,21,28,30,35,42,49,50,56,63,70,77,84,91,98 and 100 film-coated tablets.

Polyethylene tablet container with screw cap
Pack sizes: 10,20,28,30,49,50,98 and 100 film-coated tablets

80 mg:
Blister (Aluminium/PVC)
Pack sizes: 7,10,14,20,21,28,30,35,40,42,49,50,50X1,56,63,70,77,84,91,98 and 100 film-coated tablets

Polyethylene tablet container with screw cap
Pack sizes: 10, 20, 28,30,40,50, 100 and 250 film-coated tablets

Not all pack sizes or pack types may be marketed.

Marketing Authorisation Holder

Sandoz GmbH,Kundl Biochemiestrasse 106250 Austria.

Manufacturer

Bulk manufacturer

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