

Package leaflet: Information for the patient
Simvastatin Accord 10 mg film-coated tablets
Simvastatin Accord 20 mg film-coated tablets
Simvastatin Accord 40 mg film-coated tablets
Simvastatin Accord 80 mg film-coated tablets
Simvastatin

Read the entire 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.

Do you have any further questions? Please ask your doctor or pharmacist.

Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects not listed in section 4, or do you experience any side effects not mentioned in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

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1. What is Simvastatin Accord and what is it used for?

Simvastatin Accord contains the active substance simvastatin. Simvastatin Accord is a medicine for lowering the concentrations in the blood of total cholesterol, 'bad' cholesterol (LDL cholesterol), and fatty substances called triglycerides. Additionally, Simvastatin Accord increases the concentration of 'good' cholesterol (HDL cholesterol). Simvastatin belongs to the group of medicines called statins.

Cholesterol is one of several fatty substances present in the bloodstream. Your total cholesterol is mainly composed of LDL and HDL cholesterol.

LDL cholesterol is often called 'bad' cholesterol because it can build up in the walls of your blood vessels, forming 'plaque'. Eventually, this 'plaque' can grow and lead to a narrowing of the blood vessels. This narrowing can slow down or block the blood flow to vital organs, such as the heart or the brain. This blockage of blood flow can lead to a heart attack or a stroke.

HDL cholesterol is often called 'good' cholesterol because it helps prevent the buildup of bad cholesterol in the blood vessels and thus protects against cardiovascular diseases.

Triglycerides are another form of fat in your blood vessels that increase the risk of cardiovascular diseases.

When using this medicine, you should continue your cholesterol-lowering diet.

Simvastatin Accord is used alongside your cholesterol-lowering diet if you:

Have elevated cholesterol levels in your blood (primary hypercholesterolemia) or if the fat levels in your blood are elevated (mixed hyperlipidemia).

Suffer from a hereditary condition (homozygous familial hypercholesterolemia) that causes elevated cholesterol levels in your blood. You may also receive other treatments.

Suffer from coronary heart disease (CHD) or have a high risk of CHD (because you have diabetes, a history of stroke, or another vascular disease). Simvastatin Accord can extend your life by reducing the risk of heart disease or heart disease-related problems, regardless of the amount of cholesterol in your blood.

Most people show no immediate symptoms of high cholesterol levels. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, monitor your cholesterol, and discuss your target levels with your doctor.

2. When should you not use Simvastatin Accord or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the substances in this medicine. You can find these substances under section 6: Contents of the package and other information.

If you currently have liver problems.

If you are pregnant or breastfeeding.

If you are taking medicines containing one or more of the following active substances:

itraconazole, ketoconazole, posaconazole or voriconazole (antifungal agents)

erythromycin, clarithromycin or telithromycin (antibiotics)

HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (used in HIV infections)

boceprevir or telaprevir (used against hepatitis C virus infection)

nefazodone (used in the treatment of depression)

cobicistat

gemfibrozil (used to lower cholesterol)

ciclosporin (used in patients who have undergone an organ transplant)

danazol (an artificial hormone for the treatment of endometriosis, a condition where uterine lining occurs outside the uterus)

If you are currently using a medicine, or have used in the last 7 days, called fusidic acid (a medicine against a bacterial infection), orally or by injection. The combined use of fusidic acid and Simvastatin Accord can lead to serious muscle problems (called rhabdomyolysis).

Do not use more than 40 mg Simvastatin Accord if you are using lomitapide (a medicine for the treatment of a severe, rare, hereditary cholesterol disorder).

If you are not sure whether you are using any of the above medicines, ask your doctor.

When should you be extra careful with this medicine?

Contact your doctor, pharmacist, or nurse before using this medicine. Tell your doctor:

about all your medical conditions, including allergies.

if you drink large amounts of alcohol.

if you have ever had a liver disorder. Simvastatin Accord may not be suitable for you.

if you need to undergo surgery. You may need to stop using Simvastatin Accord for a short time.

if you are of Asian descent, as you may need a different dose.

Your doctor will test your blood before you start using Simvastatin Accord, and if you have symptoms of liver problems, also while you are using Simvastatin Accord. This is to check how well your liver is working. Your doctor may also decide to test your blood to check how well your liver is working after you have started using Simvastatin Accord.

If you have diabetes or are at risk of developing diabetes, your doctor will monitor you closely while you are using this medicine. You are likely at risk of 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 a severe lung condition.

if you have myasthenia (a disease that causes general muscle weakness, in some cases also in muscles used for breathing) or ocular myasthenia (a disease that causes eye muscle weakness) or have had it, as statins can sometimes worsen the condition or lead to the occurrence of myasthenia (see section 4).

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. You should do this because in rare cases, serious muscle problems can occur, including muscle breakdown resulting in kidney damage; in very rare cases, there have been fatalities.

The risk of muscle breakdown is greater at higher doses of Simvastatin Accord, especially at the 80 mg dose. The risk of muscle breakdown is also greater in certain patients. Talk to your doctor if the following applies to you:

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

Also contact your doctor or pharmacist if you constantly suffer from muscle weakness. Additional tests and medications may be needed to demonstrate and treat this.

Children and adolescents up to 18 years

The safety and efficacy of simvastatin have been studied in boys aged 10-17 years and girls of the same age whose menstruation began at least a year before (see section 3: How to use Simvastatin Accord?). Simvastatin has not been studied in children under 10 years. Consult your doctor for more information.

Are you taking any other medicines?

Are you taking any other medicines besides Simvastatin Accord, or have you recently done so, or is there a possibility that you will take other medicines in the near future? Then tell your doctor or pharmacist. Taking Simvastatin Accord together with any of the following medicines can increase the risk of muscle problems (some of these are also mentioned in the above section 'When should you not use this medicine?'):

If you are using oral fusidic acid to treat a bacterial infection, you must temporarily stop using this medicine. Your doctor will tell you when it is safe to resume Simvastatin Accord. Concurrent use of Simvastatin Accord with fusidic acid can in rare cases lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See section 4 for more information on rhabdomyolysis.

cyclosporine (often used in patients who have undergone an organ transplant)

danazol (an artificial hormone for the treatment of endometriosis, a condition where uterine lining occurs outside the uterus)

medicines with an active substance such as itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (antifungal agents)

fibrates with an active substance such as gemfibrozil and bezafibrate (used to lower cholesterol in the blood)

erythromycin, clarithromycin, or telithromycin (medicines against bacterial infections).

HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (for the treatment of AIDS)

agents against a hepatitis C virus infection such as boceprevir, telaprevir, elbasvir, or grazoprevir (used against hepatitis C virus infection)

nefazodone (used in the treatment of depression)

medicines with the active substance cobicistat

amiodarone (used for the treatment of an irregular heartbeat)

verapamil, diltiazem, or amlodipine (used against high blood pressure, chest pain in heart disease, or other heart conditions)

lomitapide (used for the treatment of a severe, rare hereditary cholesterol disorder)

daptomycin (a medicine used for the treatment of difficult-to-treat infections of the skin and skin tissues and bacteremia (where bacteria are present in your blood)).

It is possible that side effects affecting the muscles may worsen if this medicine is taken during treatment with simvastatin (e.g., Simvastatin Accord). Your doctor may decide that you stop using simvastatin for a while.

colchicine (used for the treatment of gout)

ticagrelor (used against the clumping of blood platelets)

As with the above medicines, you should tell your doctor or pharmacist if you are using other medicines, have recently used them, or might use them soon. This also applies to medicines you can obtain without a prescription. You should specifically report the use of medicines with the following active substances to your doctor:

medicines with an active substance that prevents blood clots, such as warfarin, phenprocoumon, or acenocoumarol (anticoagulants)

fenofibrate (also used to lower cholesterol in the blood)

niacin (also used to lower cholesterol in the blood)

rifampicin (used for the treatment of tuberculosis)

Tell any doctor who prescribes you a new medicine that you are using Simvastatin Accord.

What should you pay attention to with food and drink?

Grapefruit juice contains one or more components that affect the way the body uses certain medicines, including Simvastatin Accord. Intake of grapefruit juice should be avoided.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. If

you become pregnant while using Simvastatin Accord, stop using it immediately and contact your doctor.

Do not use Simvastatin Accord if you are breastfeeding, as it is not known whether the medicine passes into breast milk.

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

Driving and using machines

It is not likely that Simvastatin Accord will affect your ability to drive or use machines.

However, be aware that some people may feel dizzy after taking Simvastatin Accord.

Simvastatin Accord contains lactose

Simvastatin Accord tablets contain a sugar called lactose. If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3. How to use Simvastatin Accord?

Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and your personal risk.

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

You should continue your cholesterol-lowering diet while using this medicine.

Dosage:

The recommended dosage is one simvastatin 10 mg, 20 mg, 40 mg, or 80 mg tablet per day taken orally.

Adults:

The recommended starting dose is 10, 20, or, in some cases, 40 mg per day. Your doctor may adjust the dose after at least 4 weeks to a maximum of 80 mg per day. Do not take more than 80 mg per day.

Your doctor may prescribe lower doses, especially if you are using one of the aforementioned medicines or if you have kidney problems.

The 80 mg dose is only recommended for adult patients with severely elevated blood cholesterol levels and a high risk of cardiovascular complications who have not reached their cholesterol target levels on lower doses.

Use in children and adolescents up to 18 years:

For children (aged 10-17 years), the usual recommended starting dose is 10 mg per day, to be taken in the evening. The maximum recommended dose is 40 mg per day.

Method of administration:

Take this medicine in the evening. You can take it with or without food. Continue taking this medicine unless your doctor tells you to stop.

If your doctor has prescribed Simvastatin Accord together with another cholesterol-lowering medicine that contains a bile acid-binding resin, you should take Simvastatin Accord at least 2 hours before or four hours after taking the bile acid-binding resin.

Have you taken too much of this medicine?

Contact your doctor or pharmacist.

Have you forgotten to take this medicine?

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

If you stop taking this medicine

Contact your doctor or pharmacist because your cholesterol levels may rise again.

Do you have any other questions about the use of this medicine? Then contact 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).

If any of the serious side effects mentioned below occur, stop taking the medication and inform your doctor immediately or go to the emergency department of the nearest hospital.

The following rare serious side effects have been reported.

Muscle pain, muscle tenderness, muscle weakness, or muscle cramps. In rare cases, these muscle problems can be severe, including muscle tissue breakdown with kidney damage as a result. Very rare cases of death have occurred.

Hypersensitivity reactions (allergic reactions) including:

swelling of the face, tongue, and throat which may cause difficulty in breathing (angioedema)

severe muscle pain, usually in shoulders and hips

skin rash with weakness of the limbs and neck muscles

pain or inflammation of the joints (polymyalgia rheumatica)

inflammation of the blood vessels (vasculitis)

unusual bruising, skin rash, and swelling (dermatomyositis), hives, sensitivity of the skin to sunlight, flushing (redness of the face)

shortness of breath (dyspnea) and feeling unwell

lupus-like syndrome (including rash, joint disorders, and effects on blood cells)

Liver inflammation with the following symptoms: yellowing of the skin and eyes, itching, dark-colored urine or light-colored stools, feeling tired or weak, loss of appetite, liver failure (very rare).

Pancreatitis, often with severe abdominal pain.

The following side effect was very rare:

A severe allergic reaction causing breathing problems or dizziness (anaphylaxis)
rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions)
muscle rupture
breast enlargement in men (gynecomastia)

In rare cases, the following side effects have also been reported:

low red blood cell count (anemia)
numbness or weakness of arms and legs
headache, tingling, dizziness
digestive disorders (abdominal pain, constipation, flatulence, indigestion, diarrhea, nausea, vomiting)
skin rash, itching, hair loss
weakness
difficulty sleeping (very rarely)
poor memory (very rarely), memory loss, confusion
blurred vision and reduced vision

The following side effects have also been reported, which cannot be determined with the available data (frequency unknown):

erectile dysfunction
depression
tendon problems, sometimes complicated by tendon rupture
pneumonia resulting in breathing problems including persistent cough and/or shortness of breath or fever.
Myasthenia gravis (a disease causing general muscle weakness, in some cases in muscles used for breathing);
ocular myasthenia (a disease causing eye muscle weakness).

Contact your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping eyelids, difficulty swallowing, or shortness of breath.

Possible other side effects reported with some statins

sleep problems, including nightmares
sexual problems
Diabetes. You are at a higher risk if you have high sugar and fat levels in your blood, if you are overweight, and if you have high blood pressure. Your doctor will monitor you during the period you are using this medication.
Pain, tenderness, or muscle weakness that is constant and may not go away after stopping treatment with this medicine (frequency not known).

Laboratory values

In certain blood laboratory tests, increases in liver function and a muscle enzyme (creatinine kinase) have been observed.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store Simvastatin Accord?

Keep out of the sight and reach of children.

There are no special storage conditions for this medicine.

Do not use this medicine after the expiry date. It can be found on the bottles and the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is simvastatin (10 mg, 20 mg, 40 mg, and 80 mg).

Each film-coated tablet of Simvastatin Accord 10 mg contains 10 mg of simvastatin.

Each film-coated tablet Simvastatin Accord 20 mg contains 20 mg simvastatin.

Each film-coated tablet Simvastatin Accord 40 mg contains 40 mg simvastatin.

Each film-coated tablet Simvastatin Accord 80 mg contains 80 mg simvastatin.

The other ingredients in this medicine are:

Tablet core:

Butylated hydroxyanisole (E320)

Ascorbic acid (E300)

Citric acid monohydrate (E330)

Microcrystalline cellulose (E460a)

Pregelatinized maize starch

Lactose monohydrate

Magnesium stearate (E470B)

Film coating:

Hypromellose (E464)

Hydroxypropyl cellulose (E463)

Titanium dioxide (E171)

Talc (E553b)

Iron oxide yellow (E172) - for 10 and 20 mg

Iron oxide red (E172) – for 10, 20, 40 and 80 mg

What does Simvastatin Accord look like and how much is in a package?

Simvastatin Accord 10 mg film-coated tablets:

Light pink, round, biconvex, film-coated tablets with the imprint 'CS' on one side and no imprint on the other side.

Simvastatin Accord 20 mg film-coated tablets:

Light pink, round, biconvex, film-coated tablets with the imprint 'CT' on one side and no imprint on the other side.

Simvastatin Accord 40 mg film-coated tablets:

Pink, round, biconvex, film-coated tablets with the imprint 'CU' on one side and no imprint on the other side.

Simvastatin Accord 80 mg film-coated tablets:

Pink, capsule-shaped, biconvex, film-coated tablets with the imprint 'CV' on one side and no imprint on the other side.

Simvastatin Accord film-coated tablets 10 mg, 20 mg, 40 mg, and 80 mg tablets are available in blister packs of 10, 14, 28, 30, 50, 56, 84, 90, 98, and 100 tablets.

Simvastatin Accord film-coated tablets 10 mg, 20 mg, and 40 mg are also available in bottles of 250, 500, and 1000 tablets (for hospital use or dose dispensing only).

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Accord Healthcare B.V.

Winthontlaan 200

3526 KV Utrecht

Netherlands

Manufacturer

Accord Healthcare Polska Sp.z o.o.

ul. Lutomska 50, 95-200 Pabianice, Poland

Accord Healthcare B.V.

Winthontlaan 200

3526 KV Utrecht

Netherlands

Accord Healthcare single member S.A.

64th Km National Road Athens

Lamia, Schimatari, 32009, Greece

Registered under:

Simvastatin Accord 10 mg film-coated tablets	RVG 100363
Simvastatin Accord 20 mg film-coated tablets	RVG 100364
Simvastatin Accord 40 mg film-coated tablets	RVG 100365
Simvastatin Accord 80 mg film-coated tablets	RVG 100366

This medicine is registered in EEA member states under the following names:

Country Name	Proposed Name
United Kingdom	Simvastatin 10 / 20 / 40 / 80 mg Film coated Tablets
France	Simvastatin Accord Healthcare 10 / 20 / 40 mg film-coated tablet
Netherlands	Simvastatin Accord 10 / 20 / 40 / 80 mg Film-coated tablets

This leaflet was last approved in September 2025.

Transtoyou