Package leaflet: information for the user
Atorvastatin Accord 10 mg film-coated tablets
Atorvastatin Accord 20 mg film-coated tablets
Atorvastatin Accord 40 mg film-coated tablets
Atorvastatin Accord 80 mg film-coated tablets
atorvastatin

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 questions? Contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet

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

This medicine belongs to a group of medicines known as statins. These are lipid-regulating medicines (medicines that affect the fat content in the blood).

This medicine is used to lower fats (lipids) such as cholesterol and triglycerides in the blood when a low-fat diet and lifestyle changes alone have not had enough effect. If you are at increased risk of heart disease, this medicine can also be used to reduce such a risk, even if your cholesterol levels are normal. A standard cholesterol-lowering diet should be continued during treatment.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- You have a disease that affects the liver or you have had such a disease.
- Blood tests have shown unexplained, unusual values for liver function.
- You are a woman who can become pregnant and do not use a reliable medicine to prevent pregnancy (contraception).
- You are pregnant or trying to become pregnant.
- You are breastfeeding.

- If you are using the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C.

When should you be extra careful with this medicine?
Contact your doctor, pharmacist, or nurse before using this medicine

- if you have severely reduced lung function
- if you are currently, or in the last 7 days, have used a medicine called fusidic acid (used against bacterial infections), orally (by mouth) or injected. The combination of fusidic acid and this medicine can lead to serious muscle problems (rhabdomyolysis, breakdown of muscle tissue with symptoms such as muscle cramps, fever, and reddish-brown discoloration of the urine)
- if you have previously had a brain hemorrhage or fluid blisters in the brain due to previous strokes
- if you have kidney problems
- if you have reduced thyroid function (hypothyroidism)
- if you have had repeated or unexplained muscle pain, a personal history or family history of muscle problems
- if you have previously had muscle problems during treatment with other fat-lowering (lipid-lowering) medicines (for example, other '-statin' or '-fibrate' medicines)
- if you regularly drink large amounts of alcohol
- if you have a history of liver disease
- if you are older than 70 years
- if you have or have had myasthenia (a disease where general muscle weakness occurs, in some cases also in muscles used for breathing) or ocular myasthenia (a disease that causes eye muscle weakness), as statins can sometimes worsen the condition or lead to the occurrence of myasthenia (see section 4).

If any of these warnings apply to you, your doctor will need to perform a blood test before and possibly during your treatment with this medicine to predict your risk of muscle side effects. It is known that the risk of muscle side effects such as muscle tissue breakdown with symptoms of muscle cramps, fever, and reddish-brown discoloration of the urine (rhabdomyolysis) increases when certain medications are taken simultaneously (see section 2 'Are you taking any other medicines?').

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.
When you use this medicine, your doctor will closely monitor whether you have diabetes or are at increased risk of developing it. You may be at increased risk of developing diabetes if you have high blood sugar and fat levels, are overweight, and have high blood pressure.

Are you taking any other medicines?

Are you taking any other medicines besides Atorvastatin Accord, have you recently done so, or are you planning to do so soon? Then tell your doctor or pharmacist. Some medicines can affect the action of Atorvastatin Accord or be affected by Atorvastatin Accord. Such an interaction can make one or both medicines less effective.

Additionally, this can increase the risk or severity of side effects, including the important muscle-breaking condition known as rhabdomyolysis, as described in section 4:

- medicines used to affect the way your immune system (natural defense) works, for example, ciclosporin
- certain medicines against certain bacterial infections (antibiotics) or antifungal medicines, for example, erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampicin, fusidic acid
- other medicines to affect blood fat levels (lipid levels), for example, gemfibrozil, other fibrates, colestipol
- some calcium channel blockers used for chest pain (angina pectoris) or high blood pressure, for example, amlodipine, diltiazem, medicines to affect your heart rhythm, for example, digoxin, verapamil, amiodarone
- letermovir, a medicine that helps prevent illness from the cytomegalovirus
- medicines used in the treatment of HIV, for example, ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir, etc.
- some medicines used in the treatment of hepatitis C (a certain type of liver inflammation), for example, telaprevir, boceprevir, and the combination of elbasvir/grazoprevir ledipasvir/sofosbuvir
- other medicines known to interact with Atorvastatin Accord include ezetimibe (lowers cholesterol), warfarin (which reduces blood clotting), oral medicines to prevent pregnancy (contraceptives), stiripentol (a medicine against uncontrollable body shakes, often as part of an epileptic seizure (fits) used in epilepsy), cimetidine (used for heartburn and stomach ulcers), phenazone (a painkiller), colchicine (used for the treatment of gout) and antacids that bind stomach acid containing aluminum or magnesium
- medicines available without a prescription: St. John's wort
- If you need to use oral fusidic acid to treat a bacterial infection, you must temporarily stop using Atorvastatin Accord. Your doctor will tell you when it is safe to start taking Atorvastatin Accord again. The simultaneous use of Atorvastatin Accord and fusidic acid can in rare cases lead to muscle weakness, tenderness, or pain (rhabdomyolysis). For more information on rhabdomyolysis, see section 4.

What should you pay attention to with drinking and alcohol?
See section 3 for instructions on how to use this medicine.

Pay attention to the following:
Grapefruit juice
Do not drink more than one or two small glasses of grapefruit juice per day, as large amounts of grapefruit juice can alter the effects of this medicine.

Alcohol
Avoid drinking too much alcohol while using this medicine. See section 2 'When should you be extra careful with this medicine?' for further information.

Pregnancy and breastfeeding
Do not use this medicine if you are pregnant or trying to become pregnant.

Do not use this medicine if you can become pregnant unless you are using reliable contraceptive measures (such as using a condom or the pill).

Do not use this medicine if you are breastfeeding.
The safety of this medicine during pregnancy and breastfeeding has not yet been proven. Ask your doctor or pharmacist for advice before using medicines.

Driving and using machines

Normally, this medicine does not affect your ability to drive or operate machines. However, you should not drive if this medicine affects your driving ability. Do not use tools or machines if your ability to use them is affected by this medicine.

Atorvastatin Accord contains lactose
If your doctor has told you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

Atorvastatin Accord contains sodium
This medicine contains less than 1 mmol (23 mg) of sodium per tablet and is therefore essentially 'sodium-free'.

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Before starting the treatment, your doctor will put you on a cholesterol-lowering diet which you must also continue during the treatment with this medicine.

The recommended starting dose of this medicine is 10 mg once daily for adults and children aged 10 years and older. If necessary, this can be increased by your doctor until you use the amount you need. Your doctor will adjust the dosage at intervals of 4 weeks or more. The maximum dose of this medicine is 80 mg once daily.

The tablets should be swallowed whole with some water and can be taken at any time of the day, with or without food. However, try to take your tablet at the same time each day.

The duration of treatment with this medicine is determined by your doctor.
Contact your doctor if you think the effect of this medicine is too strong or too weak.

Have you used too much of this medicine?
If you accidentally take too much of this medicine (more than your usual daily dose), contact your doctor or the nearest hospital for advice.

Have you forgotten to take this medicine?
If you forget to take a dose, take the next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine Do you have any other questions about the use of this medicine or do you wish to stop the treatment with this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects. Not everyone gets them.

If you experience any of the following serious side effects or symptoms, stop taking your tablets and contact your doctor immediately or go to the emergency department of the nearest hospital.

- Rare: occur in less than 1 in 1,000 users:
- Severe allergic reaction causing swelling of the face, tongue, and throat, which can lead to severe breathing difficulties.
- Severe illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, and genitals, and fever. Rash with pink-red spots, especially on palms or soles, possibly with blistering.
- Muscle weakness, tenderness, pain, or rupture, or reddish-brown discoloration of the urine, especially if you feel unwell or have a fever at the same time. This can be caused by unusual muscle breakdown (rhabdomyolysis). This unusual muscle breakdown does not always go away, even if you have stopped using this medicine, and it can be life-threatening and lead to kidney problems.

Very rare: occur in less than 1 in 10,000 users
- If you experience problems with unexpected or unusual bleeding or bruising, this may indicate a liver disorder. Contact your doctor as soon as possible.
- Lupus-like syndrome (including rash, joint disorders, and effects on blood cells)

Other possible side effects of this medication
Common: occur in less than 1 in 10 users
- inflammation of the nasal cavities, sore throat, nosebleed
- allergic reactions
- increase in blood sugar levels (if you have diabetes, you should closely monitor your blood sugar levels), increase in the concentration of muscle breakdown product (creatine kinase) in the blood
- headache
- nausea, constipation, flatulence, indigestion, diarrhea
- joint pain, muscle pain, and back pain
- blood test results indicating that your liver function may become abnormal

Uncommon: occur in less than 1 in 100 users
- loss of appetite (anorexia), weight gain, decrease in blood sugar levels (if you have diabetes, you should closely monitor your blood sugar levels)
- nightmares, insomnia

- dizziness, numbness or tingling sensation in fingers and toes, reduced sense of pain or touch, taste alteration, memory loss
- blurred vision
- ringing in ears and/or head
- vomiting, belching, pain in lower and upper abdomen, inflammation of the pancreas, with symptoms of severe pain in the upper abdomen radiating to the back, nausea, and vomiting (pancreatitis)
- liver inflammation (hepatitis)
- rash, skin rash and itching, hives, hair loss
- neck pain, tired muscles.
- fatigue, feeling unwell, weakness, chest pain, swelling especially of the ankles (fluid retention in tissue (edema)), fever
- urine tests that are positive for white blood cells

Rare: occur in less than 1 in 1,000 users
- visual disturbances
- unexpected bleeding or bruising
- accumulation of bile in the bile ducts due to obstructed flow of bile to the intestine resulting in yellowing of the skin and whites of the eyes (cholestasis)
- tendon injury

Very rare: occur in less than 1 in 10,000 users
- an allergic reaction – symptoms may include sudden wheezing and chest pain or tightness, swelling of eyelids, face, lips, mouth, tongue or throat, difficulty breathing, sudden collapse
- hearing loss
- enlargement of the breasts in men (gynecomastia)

Not known: frequency cannot be estimated from the available data
- persistent muscle weakness
- 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 side effects reported with some statins (medicines of the same type):
- sexual problems
- depression
- respiratory problems, including a persistent cough and/or shortness of breath or fever
- diabetes. The risk is higher 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 use this medicine.

<u>Reporting side effects</u>

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

5. How do you store this medicine?

Keep out of the sight and reach of children.
Store below 25°C.
Do not use this medicine after the expiry date. You can find this on the box and the blister pack 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. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the pack and other information

What substances are in this medicine?
The active substance in this medicine is atorvastatin.
Each 10 mg film-coated tablet contains 10 mg atorvastatin (as atorvastatin calcium trihydrate).
Each 20 mg film-coated tablet contains 20 mg atorvastatin (as atorvastatin calcium trihydrate).
Each 40 mg film-coated tablet contains 40 mg atorvastatin (as atorvastatin calcium trihydrate).
Each 80 mg film-coated tablet contains 80 mg atorvastatin (as atorvastatin calcium trihydrate).

The other substances in this medicine are:
Tablet core: calcium carbonate, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, polysorbate 80, magnesium stearate

Tablet coating: hypromellose 2910 (E464), macrogol 8000 (E1521), titanium dioxide (E171), and talc (E553b).

What does Atorvastatin Accord look like and what is in a pack?

Atorvastatin Accord 10 mg film-coated tablet: White to off-white, round, biconvex, film-coated tablets with a diameter of approximately 5.6 mm and the imprint 'FUI' on one side and no imprint on the other side.

Atorvastatin Accord 20 mg film-coated tablet: White to off-white, round, biconvex, film-coated tablets with a diameter of approximately 7.1 mm and the imprint 'FU2' on one side and no imprint on the other side.

Atorvastatin Accord 40 mg film-coated tablet: White to off-white, round, biconvex, film-coated tablets with a diameter of approximately 9.6 mm and the imprint 'FU3' on one side and no imprint on the other side.

Atorvastatin Accord 80 mg film-coated tablet: White to off-white, round, biconvex, film-coated tablets with a diameter of approximately 12.1 mm and the imprint 'FU4' on one side and no imprint on the other side.
Atorvastatin Accord is available in OPA/Alu/PVC-Alu blister packs with 4, 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, and 100 film-coated tablets. Hospital packs with 50, 84, 100, 200 (10 x 20), or 500 film-coated tablets.

Not all pack sizes mentioned are 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. Lutomierska 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

Atorvastatin Accord 10 mg film-coated tablets RVG 118716
Atorvastatin Accord 20 mg film-coated tablets RVG 118717
Atorvastatin Accord 40 mg film-coated tablets RVG 118718
Atorvastatin Accord 80 mg film-coated tablets RVG 118719

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the member state	**Name of the medicine**
Austria	Atorvastatin Accord 10 mg Filmtabletten Atorvastatin Accord 20 mg Filmtabletten Atorvastatin Accord 40 mg Filmtabletten Atorvastatin Accord 80 mg Filmtabletten

Cyprus	Atorvastatin Accord 10 mg film-coated tablets Atorvastatin Accord 20 mg film-coated tablets Atorvastatin Accord 40 mg film-coated tablets
Denmark	Atorvastatin Accord 10 mg film-coated tablet Atorvastatin Accord 20 mg film-coated tablet Atorvastatin Accord 40 mg film-coated tablet Atorvastatin Accord 80 mg film-coated tablet
Germany	Atorvastatin Accord 10 mg film-coated tablets Atorvastatin Accord 20 mg film-coated tablets Atorvastatin Accord 40 mg film-coated tablets Atorvastatin Accord 80 mg film-coated tablets
Finland	Atorvastatin Accord 10 mg film-coated tablets Atorvastatin Accord 20 mg film-coated tablets Atorvastatin Accord 40 mg film-coated tablets Atorvastatin Accord 80 mg film-coated tablets
Ireland	Atorvastatin 10 mg film-coated tablets Atorvastatin 20 mg film-coated tablets Atorvastatin 40 mg film-coated tablets Atorvastatin 80 mg film-coated tablets
Italy	Atorvastatin Accord
Netherlands	Atorvastatin Accord 10 mg film-coated tablets Atorvastatin Accord 20 mg film-coated tablets Atorvastatin Accord 40 mg film-coated tablets Atorvastatin Accord 80 mg film-coated tablets
Norway	Atorvastatin Accord
Sweden	Atorvastatin Accord 10 mg film-coated tablets Atorvastatin Accord 20 mg film-coated tablets Atorvastatin Accord 40 mg film-coated tablets Atorvastatin Accord 80 mg film-coated tablets
United Kingdom (Northern Ireland)	Atorvastatin 10 mg film-coated tablets Atorvastatin 20 mg film-coated tablets Atorvastatin 40 mg film-coated tablets Atorvastatin 80 mg film-coated tablets

This leaflet was last approved in August 2025.