



Frequently Asked Questions (FAQs) About **LIPITOR** and **Cholesterol**

Below are some FAQs that you may still have after visiting LIPITOR.com.

Q: What are LIPITOR tablets?

A: LIPITOR is a prescription medicine that lowers the LDL-C (“bad” cholesterol) and triglycerides in your blood. It can raise your HDL-C (“good” cholesterol) as well. LIPITOR is for adults and children over aged 10 years whose cholesterol does not come down enough with exercise and a low-fat diet alone.

LIPITOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease, such as:

▶ Age, smoking, high blood pressure, low HDL-C, heart disease in the family.

LIPITOR can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:

▶ Eye problems, kidney problems, smoking, or high blood pressure.

LIPITOR starts to work in about 2 weeks.

Q: What are the possible side effects of LIPITOR?

A: LIPITOR can cause serious side effects, which only a small number of people have experienced. Your doctor can monitor you for them. These side effects usually go away if your dose is lowered or LIPITOR is stopped. These serious side effects include:

▶ **Muscle problems.** LIPITOR can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with LIPITOR.

▶ **Liver problems.** Your doctor should do blood tests to check your liver before you start taking LIPITOR and if you have symptoms of liver problems while you take LIPITOR. Call your doctor right away if you have the following symptoms of liver problems:

- Feel tired or weak
- Loss of appetite
- Upper belly pain
- Dark, amber-colored urine
- Yellowing of your skin or of the whites of your eyes



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atorvastatin calcium
tablets

Call your doctor right away if:

- ▶ You have muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual.
- ▶ You have muscle problems that do not go away even after your doctor has advised you to stop taking LIPITOR. Your doctor may do further tests to diagnose the cause of your muscle problems.
- ▶ You have allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty breathing or swallowing, which may require treatment right away.
- ▶ You experience nausea and vomiting.
- ▶ You pass brown or dark-colored urine.
- ▶ You feel more tired than usual.
- ▶ Your skin and the whites of your eyes get yellow.
- ▶ You feel stomach pain.
- ▶ You have an allergic skin reaction.

In clinical studies, patients reported the following common side effects while taking LIPITOR: diarrhea, upset stomach, muscle and joint pain, and alterations in some laboratory blood tests.

The following additional side effects have been reported with LIPITOR: tiredness, tendon problems, memory loss, and confusion.

Talk to your doctor or pharmacist if you have any side effects that bother you or that will not go away.

These are not all the side effects of LIPITOR. Ask your doctor or pharmacist for a complete list.

Q: Is LIPITOR right for me?

A: LIPITOR is a prescription medicine. Only your doctor can properly determine if you need a prescription medicine along with a low-fat diet to lower your high cholesterol.

Make an appointment with your doctor and ask if LIPITOR is right for you.

Q: Who should not take LIPITOR?

A: Do not take LIPITOR if you:

- ▶ Are pregnant or think you may be pregnant, or are planning to become pregnant. LIPITOR may harm your unborn baby. If you get pregnant, stop taking LIPITOR and call your doctor right away.
- ▶ Are breast feeding. LIPITOR can pass into your breast milk and may harm your baby.
- ▶ Have liver problems.
- ▶ Are allergic to LIPITOR or any of its ingredients. The active ingredient is atorvastatin.



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Q: When is the best time to take LIPITOR?

A: LIPITOR is taken once a day. The tablets can be taken with or without food, day or night. It's helpful to remember to try and take LIPITOR at about the same time every day.

Q: Do I need to take LIPITOR with food?

A: LIPITOR can be taken with or without food.

Q: What if my daily schedule interferes with taking my medicine?

A: Try to take your medicine at the same time every day. Try connecting your medicine with something you do every day, such as brushing your teeth or eating breakfast. This may help you remember to take it.

Keep a daily calendar and add taking your medicine to your daily to-do list. Check it off once you have taken it. Or set an alarm clock to go off at the time you need to take your medicine.

You can also use a pill box with the days of the week on it. Some pill boxes even come with built-in alarms.

You should also use a calendar to remind yourself to get refills before you run out of medicine.

Q: Can LIPITOR be prescribed to children?

A: LIPITOR is for adults and children aged over 10 years whose cholesterol does not come down enough with exercise and a low-fat diet alone. LIPITOR is not approved for use in patients aged 10 years and younger.

Q: What should I do if I am taking other prescription medicines in addition to LIPITOR?

A: Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and even herbal supplements. LIPITOR and certain other medicines can interact, causing serious side effects.

Q: I have type 2 diabetes. Should I stop taking LIPITOR? Will it make my blood sugar levels worse?

A: The FDA notes it is aware of studies showing that patients being treated with statins may have a small increased risk of increased blood sugar levels and of being diagnosed with diabetes. We encourage patients to work with their physicians to discuss whether the potential risk of diabetes may be outweighed by the cardiovascular benefits of LIPITOR therapy demonstrated in clinical trials and to discuss their treatment options.



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Q: If I keep taking LIPITOR, will I experience memory loss? Are these effects permanent?

A: We encourage patients to work with their doctors to discuss their treatment options. Certain cognitive effects, specifically memory loss and confusion, have been reported. The FDA notes that reports relating to cognitive effects have generally not been serious and that symptoms went away once the drug was no longer being taken.

Questions about the most recent label update

Q: I currently take LIPITOR. Should I stop taking it based on the most recent label update?

A: We encourage patients to work with their doctors to discuss their treatment options.

Q: Is this affecting all statins? Do these most recent label updates apply to generic statins?

A: Yes. The class labeling is based on an FDA evaluation of all statin labels (including generic statins), the entry of new interacting drugs on the market, and a review of clinical data and post-marketing reports.

Q: Do these most recent label updates apply to drug interactions with protease inhibitors?

A: The class labeling update includes clarifications around doses of statins for certain potential drug-drug interactions. For example, the atorvastatin label now cautions to avoid atorvastatin taken together with:

- Cyclosporine
- The use of certain protease inhibitors (tipranavir plus ritonavir for HIV), telaprevir (for hepatitis C)

Information About the Most Recent FDA Update on Statin Labels

On February 28, 2012, the FDA issued an update to the safety labeling of all statins and combination products containing statins. This change was based on a review of all statin labels, the entry of new interacting drugs on the market, and a review of clinical data and post-marketing reports. Patients are encouraged to report any side effects to their doctors, and patients or doctors should contact Pfizer Medical Information at 1-800-438-1985 or visit PfizerMedicalInformation.com regarding any concerns about a Pfizer medicine.



Cholesterol FAQs

Q: What is cholesterol?

A: Cholesterol is a waxy substance found in the body. Having high “bad” cholesterol means you have too much LDL cholesterol in your blood. LDL cholesterol can build up in your arteries and prevent the blood from getting to your heart. HDL cholesterol is the “good” cholesterol. It carries LDL cholesterol away from your artery walls.

Here is some basic information you should know about cholesterol:

- ▶ **Too much cholesterol in the blood, or high cholesterol, can be serious.** People with high cholesterol are at risk of getting heart disease. This can lead to a heart attack or stroke.
- ▶ **Only about 25% of cholesterol comes from the foods you eat.** The other 75% is made by the body. Factors such as age and family history affect how much cholesterol your body makes.
- ▶ **People with high cholesterol usually have no symptoms.** You need a blood test to determine if you have high cholesterol.

Q: Why is high cholesterol a health risk?

A: When you have high cholesterol, a thick, waxy plaque can build up in your artery walls. As plaque builds up, the artery narrows and becomes less flexible. If a blood clot forms and clogs an artery narrowed by plaque, you could have a heart attack or stroke.

Q: How is cholesterol measured?

A: Cholesterol is measured as milligrams of cholesterol per deciliter of blood (mg/dL). When you get your cholesterol tested, your measurements will include:

- ▶ Total cholesterol
- ▶ LDL (“bad”) cholesterol
- ▶ HDL (“good”) cholesterol
- ▶ Triglycerides (another type of fat in the blood)

Q: At what age should I start having my cholesterol checked?

A: Experts recommend that adults aged 20 to 79 years who are free from atherosclerotic cardiovascular disease (ASCVD) should have their cholesterol levels measured at least once every 4 to 6 years.



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Q: How does smoking affect my risk of heart disease?

A: Smoking increases the risk of heart disease. If you smoke, your risk of death from a sudden heart attack is greatly increased.

Q: Is diabetes a risk factor for coronary artery disease?

A: Diabetes is a risk factor for coronary artery disease. If you have diabetes, you should work with your doctor to help control your diabetes as well as any other risk factors you may have for coronary artery disease.

INDICATION

LIPITOR[®] (atorvastatin calcium) is a prescription medicine that lowers cholesterol in the blood. It lowers the LDL-C (“bad” cholesterol) and triglycerides in your blood. It can raise your HDL-C (“good” cholesterol) as well. LIPITOR is for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

LIPITOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as age, smoking, high blood pressure, low HDL-C, or heart disease in the family. LIPITOR can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as eye problems, kidney problems, smoking, or high blood pressure.

IMPORTANT SAFETY INFORMATION

LIPITOR[®] (atorvastatin calcium) tablets are not for everyone, including anyone who has previously had an allergic reaction to LIPITOR. It is not for those with liver problems. And it is not for women who are nursing, pregnant, or may become pregnant.

If you take LIPITOR[®] (atorvastatin calcium) tablets, tell your doctor if you feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects. Tell your doctor about all your medical conditions and all medications you take. This may help avoid serious drug interactions. Your doctor should do blood tests to check your liver function before starting LIPITOR and during your treatment if you have symptoms of liver problems. Tell your doctor if you have diabetes. Elevated blood sugar levels have been reported with statins, including LIPITOR.

Common side effects are diarrhea, upset stomach, muscle and joint pain, and changes in some blood tests.

Patients should always ask their doctors for medical advice about adverse events.

You may report an adverse event related to Pfizer products by calling 1-800-438-1985 (US only). If you prefer, you may contact the US Food and Drug Administration (FDA) directly. The FDA has established a reporting service known as MedWatch where healthcare professionals and consumers can report serious problems they suspect may be associated with the drugs and medical devices they prescribe, dispense, or use. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Patient Information on last pages and full Prescribing Information at LIPITOR.com.



PATIENT INFORMATION

Read the Patient Information that comes with LIPITOR before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

If you have any questions about LIPITOR, ask your doctor or pharmacist.

WHAT IS LIPITOR?

LIPITOR is a prescription medicine that lowers cholesterol in your blood. It lowers the LDL-C (“bad” cholesterol) and triglycerides in your blood. It can raise your HDL-C (“good” cholesterol) as well. LIPITOR is for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

LIPITOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:

- age, smoking, high blood pressure, low HDL-C, heart disease in the family.

LIPITOR can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:

- eye problems, kidney problems, smoking, or high blood pressure.

LIPITOR starts to work in about 2 weeks.

WHAT IS CHOLESTEROL?

Cholesterol and triglycerides are fats that are made in your body. They are also found in foods. You need some cholesterol for good health, but too much is not good for you. Cholesterol and triglycerides can clog your blood vessels. It is especially important to lower your cholesterol if you have heart disease, smoke, have diabetes or high blood pressure, are older, or if heart disease starts early in your family.

WHO SHOULD NOT TAKE LIPITOR?

Do not take LIPITOR if you:

- are pregnant or think you may be pregnant, or are planning to become pregnant. Lipitor may harm your unborn baby. If you get pregnant, stop taking LIPITOR and call your doctor right away.
- are breast feeding. LIPITOR can pass into your breast milk and may harm your baby.
- have liver problems.
- are allergic to LIPITOR or any of its ingredients. The active ingredient is atorvastatin. See the end of this leaflet for a complete list of ingredients in LIPITOR.

LIPITOR has not been studied in children under 10 years of age.

BEFORE YOU START LIPITOR

Tell your doctor if you:

- have muscle aches or weakness
- drink more than 2 glasses of alcohol daily
- have diabetes
- have a thyroid problem
- have kidney problems

Some medicines should not be taken with LIPITOR. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. LIPITOR and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines for:

- your immune system
- cholesterol
- infections
- birth control
- heart failure
- HIV or AIDS

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist.

HOW SHOULD I TAKE LIPITOR?

- Take LIPITOR exactly as prescribed by your doctor. Do not change your dose or stop LIPITOR without talking to your doctor. Your doctor may do blood tests to check your cholesterol levels during your treatment with LIPITOR. Your dose of LIPITOR may be changed based on these blood test results.
- Take LIPITOR each day at anytime of day at about the same time each day. LIPITOR can be taken with or without food
- Don't break LIPITOR tablets before taking.
- Your doctor should start you on a low-fat diet before giving you LIPITOR. Stay on this low-fat diet when you take LIPITOR.
- If you miss a dose of LIPITOR, take it as soon as you remember. Do not take LIPITOR if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of LIPITOR at the same time.
- If you take too much LIPITOR or overdose, call your doctor or Poison Control Center right away. Or go to the nearest emergency room.

WHAT SHOULD I AVOID WHILE TAKING LIPITOR?

- Talk to your doctor before you start any new medicines. This includes prescription and nonprescription medicines, vitamins, and herbal supplements. LIPITOR and certain other medicines can interact causing serious side effects.
- Do not get pregnant. If you get pregnant, stop taking LIPITOR right away and call your doctor.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF LIPITOR?

LIPITOR can cause serious side effects. These side effects have happened only to a small number of people. Your doctor can monitor you for them. These side effects usually go away if your dose is lowered or LIPITOR is stopped.

These serious side effects include:

- **Muscle problems.** LIPITOR can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with LIPITOR.
- **Liver problems.** Your doctor should do blood tests to check your liver before you start taking LIPITOR and if you have symptoms of liver problems while you take LIPITOR. Call your doctor right away if you have the following symptoms of liver problems:
 - feel tired or weak
 - loss of appetite
 - upper belly pain
 - dark amber colored urine
 - yellowing of your skin or the whites of your eyes

Call your doctor right away if you have:

- muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual. This may be an early sign of a rare muscle problem.
- muscle problems that do not go away even after your doctor has advised you to stop taking LIPITOR. Your doctor may do further tests to diagnose the cause of your muscle problems.
- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away.
- nausea and vomiting.
- passing brown or dark colored urine.
- you feel more tired than usual.
- your skin and whites of your eyes get yellow.
- stomach pain.
- allergic skin reactions.

In clinical studies, patients reported the following common side effects while taking LIPITOR: diarrhea, upset stomach, muscle and joint pain, and alterations in some laboratory blood tests.

The following additional side effects have been reported with LIPITOR: tiredness, tendon problems, memory loss, and confusion.

Talk to your doctor or pharmacist if you have side effects that bother you or that will not go away.

These are not all the side effects of LIPITOR. Ask your doctor or pharmacist for a complete list.

HOW DO I STORE LIPITOR

- Store LIPITOR at room temperature, 68 to 77°F (20 to 25°C).
- Do not keep medicine that is out of date or that you no longer need.
- **Keep LIPITOR and all medicines out of the reach of children.** Be sure that if you throw medicine away, it is out of the reach of children.

GENERAL INFORMATION ABOUT LIPITOR

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use LIPITOR for a condition for which it was not prescribed. Do not give LIPITOR to other people, even if they have the same problem you have. It may harm them.

This leaflet summarizes the most important information about LIPITOR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about LIPITOR that is written for health professionals. Or you can go to the LIPITOR website at www.LIPITOR.com.

WHAT ARE THE INGREDIENTS IN LIPITOR?

Active Ingredient: atorvastatin calcium

Inactive Ingredients: calcium carbonate, USP; candelilla wax, FCC; croscarmellose sodium, NF; hydroxypropyl cellulose, NF; lactose monohydrate, NF; magnesium stearate, NF; microcrystalline cellulose, NF; Opadry White YS-1-7040 (hypromellose, polyethylene glycol, talc, titanium dioxide); polysorbate 80, NF; simethicone emulsion.

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