

FDA-Approved Patient Labeling

LESCOL[®] XL (fluvastatin sodium) Extended-Release Tablets

80 mg

Rx Only

You must read and follow all instructions before using LESCOL XL.

Read the Patient Information every time you or a family member gets LESCOL XL. There may be new information. This Patient Information does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about LESCOL XL, ask your doctor or pharmacist.

What is LESCOL XL?

LESCOL XL tablets are prescription medicines called "statins" that lower cholesterol in your blood. They lower the "bad" cholesterol and triglycerides in your blood. They can raise your "good" cholesterol as well.

LESCOL XL is for people whose cholesterol does not come down enough with exercise and a low-fat diet alone.

LESCOL XL may be used in patients with heart disease (coronary artery disease) to:

- lower the chances of heart problems which would require procedures to help restore blood flow to the heart.
- slow the buildup of too much cholesterol in the arteries of the heart.

Treatment with LESCOL XL has not been shown to prevent heart attacks or stroke.

LESCOL XL is an extended-release tablet that is only taken one time a day.

Who should not take LESCOL XL?

Do not take LESCOL XL if you:

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

LESCOL XL has not been studied in children under 9 years of age.

Before taking LESCOL XL, 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 LESCOL XL. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. LESCOL XL and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines for:

- your immune system
- cholesterol
- infections
- heart failure
- seizures
- diabetes
- heartburn or stomach ulcers

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

How should I take LESCOL XL?

- Your doctor will prescribe the medicine that is right for you. Take LESCOL XL exactly as prescribed. Do not change your dose or stop LESCOL XL without talking to your doctor. Your doctor may do blood tests to check your cholesterol levels during treatment with LESCOL XL. Your dose of fluvastatin may be changed based on these blood test results.
- LESCOL XL tablets may be taken at any time of the day. LESCOL XL can be taken with or without food.
- LESCOL XL tablets must be swallowed whole with a liquid. Do not break, crush or chew LESCOL XL tablets. Tell your doctor if you cannot swallow tablets whole. You may need fluvastatin capsules or a different medicine instead of LESCOL XL tablets.
- Your doctor should start you on a low-fat and low-cholesterol diet before giving you LESCOL XL. Stay on this low-fat and low-cholesterol diet while taking LESCOL XL.
- If you miss a dose of LESCOL XL, take it as soon as you remember. Do not take LESCOL XL if it has been more than 12 hours since your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of LESCOL XL at the same time.
- If you take too much LESCOL XL or overdose, call your doctor or Poison Control Center right away. Or, go to the nearest emergency room.

What should I avoid while taking LESCOL XL?

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

What are the possible side effects of LESCOL XL?

When taking LESCOL XL, some patients may develop serious side effects, including:

muscle problems. Call your health care professional right away if you experience unexplained muscle pain, tenderness, or weakness especially with fever. This may be an early sign of a rare muscle problem that could lead to serious kidney problems.

The risk of muscle problems is greater in people who are 65 years of age or older, or who already have thyroid or kidney problems. The chance of muscle problems may be increased if you are taking certain other medicines with LESCOL XL.

If you have muscle problems that do not go away even after your health care professional has advised you to stop taking LESCOL XL, notify your health care professional. Your health care professional may do further tests to diagnose the cause of your muscle problems.

liver problems. Your doctor should do blood tests to check your liver before you start taking LESCOL XL, and if you have symptoms of liver problems while you take LESCOL XL. 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

The most common side effects of LESCOL XL are headache, upset stomach and stomach pain, diarrhea, flu-like symptoms, muscle pain, sinus infection, tiredness, or trouble sleeping. These side effects are usually mild and may go away. The following additional side effects have been reported with LESCOL XL: 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 LESCOL XL. Ask your doctor or pharmacist for a complete list.

How should I store LESCOL XL?

- Store LESCOL XL at room temperature, 59°F to 86°F (15°C to 30°C). Protect from light.
- Do not keep medicine that is out of date or that you no longer need.
- Keep LESCOL XL out of the reach of children. Be sure that if you throw medicines away, it is out of the reach of children.

General information about LESCOL XL

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

For more information, you can also visit the Novartis Internet site at www.LESCOLXL.com or call the Novartis help line at 1-888-669-6682.

What are the ingredients in LESCOL XL?

Active Ingredient: fluvastatin sodium

Inactive Ingredients:

LESCOL XL Tablets: hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 8000, potassium bicarbonate, povidone, titanium dioxide, and yellow iron oxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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