

FDA-Approved Patient Labeling

LESCOL[®] (fluvastatin sodium) Capsules

20 mg, 40 mg

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

80 mg

Rx Only

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

Read the Patient Information every time you or a family member gets LESCOL or 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, ask your doctor or pharmacist.

What are LESCOL and LESCOL XL?

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

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

LESCOL and LESCOL XL have the same active ingredient, fluvastatin. However, LESCOL is a capsule that is taken one or two times a day and LESCOL XL is an extended-release tablet that is only taken one time a day.

Who should not take LESCOL or LESCOL XL?

Do not take LESCOL or LESCOL XL if you:

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

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

Before taking LESCOL or 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 or LESCOL XL. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. LESCOL and 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 or LESCOL XL?

- Your doctor will prescribe the medicine that is right for you. Take LESCOL or LESCOL XL exactly as prescribed. Do not change your dose or stop LESCOL or LESCOL XL without talking to your doctor. Your doctor may do blood tests to check your cholesterol levels during treatment with LESCOL and LESCOL XL. Your dose of LESCOL or LESCOL XL may be changed based on these blood test results.
- LESCOL XL tablets may be taken at any time of the day. Take LESCOL capsules at the same time every evening. When LESCOL capsules are taken twice daily, the capsules may be taken once in the morning and once in the evening. LESCOL and 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 or open Lescol capsules. Tell your doctor if you cannot swallow tablets whole. You may need LESCOL 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 or LESCOL XL. Stay on this low-fat and low-cholesterol diet while taking LESCOL or LESCOL XL.
- If you miss a dose of LESCOL or LESCOL XL, take it as soon as you remember. Do not take Lescol or 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 or Lescol XL at the same time.
- If you take too much LESCOL or 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 or LESCOL XL?

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

What are the possible side effects of LESCOL and LESCOL XL?

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

- **muscle problems.** These serious muscle problems can sometimes lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with LESCOL or LESCOL XL.
- **liver problems.** Your doctor may do blood tests to check your liver before you start taking LESCOL or LESCOL XL, and while you are taking one of them.

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
- 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

The most common side effects of LESCOL or 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.

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 and LESCOL XL. Ask your doctor or pharmacist for a complete list.

How should I store LESCOL and LESCOL XL?

- Store LESCOL and LESCOL XL at room temperature, 59° to 86° F (15° to 30° C). Protect from light.
- Do not keep medicine that is out of date or that you no longer need.
- Keep LESCOL and 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 and LESCOL XL

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use LESCOL or LESCOL XL for a condition for which it was not prescribed. Do not give LESCOL or 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 and LESCOL XL?

Active Ingredient: fluvastatin sodium

Inactive Ingredients:

LESCOL Capsules: calcium carbonate, gelatin, magnesium stearate, microcrystalline cellulose, pregelatinized starch (corn), red iron oxide, sodium bicarbonate, talc, titanium dioxide, yellow iron oxide, and other ingredients. The capsules may also contain benzyl alcohol, black iron oxide, butylparaben, carboxymethylcellulose sodium, edetate calcium disodium, methylparaben, propylparaben, silicon dioxide, sodium lauryl sulfate, and sodium propionate.

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

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