

LESCOL[®] CAPSULE

Fluvastatin Sodium (20 mg and 40 mg)

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What Lescol is used for

Cholesterol and triglycerides are the major lipid components that can be found in the blood. Cholesterol is mainly produced by the liver whereas most of the triglycerides in the blood are introduced with food. High levels of low-density lipoprotein cholesterol (LDL-C, the 'bad' cholesterol) have been associated with an increased risk of heart disease and stroke. In some cases, elevated levels of 'bad' cholesterol in blood are accompanied by moderate increases in triglycerides and low levels of high-density lipoprotein cholesterol (HDL-C, the 'good' cholesterol). However, it is important that both the 'bad' cholesterol and triglycerides in blood are reduced when elevated. Also it may be important that the levels of the 'good' cholesterol in blood are raised. Your doctor would have already suggested changes to your diet or life style in order to lower your 'bad' cholesterol and triglycerides, if elevated, and to raise the 'good' cholesterol. Sometimes diet and life style changes alone will not be completely successful in achieving these targets. Your doctor will therefore prescribe additional treatment such as Lescol.

How Lescol works

Adults

Lescol also slows the progression of coronary atherosclerosis which causes a thickening and hardening of blood vessel walls at the heart and eventually obstruction.

Your doctor can also prescribe Lescol for the prevention of further serious cardiac events (e.g. heart attack) in patients who still suffer from heart

disease after they already went through a heart catheterisation.

Before you use Lescol

Before taking Lescol, you should be started on a standard cholesterol-lowering diet. You should continue with this diet while taking Lescol. Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Read the following explanations before you take Lescol.

When you must not use it

- If you are allergic (hypersensitive) to Lescol or any of the other ingredients of Lescol listed at the end of this leaflet.
- If you have an active liver disease or unexplained, persistent elevations in liver function values (transaminases).
- If you are pregnant or breast-feeding.

If any of these apply to you, tell your doctor without taking Lescol. If you think you may be allergic, ask your doctor for advice.

Pregnancy and lactation

If you are pregnant, consult your doctor or pharmacist before taking Lescol. Lescol must not be used during pregnancy.

If you are breast-feeding, consult your doctor or pharmacist before taking Lescol. Lescol must not be used when you are breast-feeding.

Before you start to use it

- If you have a liver disease. Liver function tests will normally be done before starting Lescol, at dose increase and at various intervals during treatment to check for undesirable effects.
- If you suffer from kidney disease.
- If you suffer from thyroid disease.
- If you have a medical history of muscle diseases yourself or in your family.

- If you experienced muscular problems with another lipid lowering agent.
- If you regularly consume large amounts of alcohol.
- If you have a serious infection.
- If you have very low blood pressure (signs may include dizziness, light-headedness).
- If you have recently had an injury.
- If you are about to have an operation.
- If you have severe metabolic, endocrine or electrolyte disorders such as decompensated diabetes and low blood potassium.
- If you have uncontrolled epilepsy.

Under such circumstances, your doctor will take blood from you for an analysis before prescribing Lescol.

If any of these apply to you, tell your doctor before taking Lescol.

Taking Lescol with food and drink

You can take Lescol with or without food.

Older people

If you are older than 70 years your doctor may want to clarify whether you have risk factors for muscular diseases. This may require specific blood tests.

Children and adolescents

The efficacy and safety of Lescol have not been established in paediatric patients.

Women of child-bearing potential

Take adequate precautions against pregnancy while taking Lescol. If you become pregnant while taking this medicine, stop taking Lescol and see your doctor. Your doctor will discuss with you the potential risk of taking Lescol during pregnancy.

Taking other medicines

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

Lescol can be taken on its own or with other cholesterol-lowering medicines prescribed by your doctor. After intake of a resin (e.g. cholestyramine) wait at least 4 hours before taking Lescol.

Tell your doctor and pharmacist if you are taking any of the following:

- Ciclosporin (a medicine used to suppress the immune system).
- Fibrates (e.g. gemfibrozil), nicotinic acid or bile acid sequestrants (medicines used to lower bad cholesterol levels).
- Fluconazole (a medicine used to treat fungal infections).
- Rifampicin (an antibiotic).
- Phenytoin (a medicine used to treat epilepsy).
- Oral anticoagulants like warfarin (medicines used to reduce blood clotting).
- Glibenclamide (a medicine used to treat diabetes).
- Colchicines.

Consult your doctor or pharmacist as they will have a more complete and detailed list of medicines that may interact with Lescol.

How to use Lescol

Follow your doctor's instructions carefully. Do not exceed the recommended dosage.

Your doctor will recommend you to follow a low-cholesterol diet. Stay on this diet while taking Lescol.

How much to use

The usual dose range for adults is 40 to 80 mg per day.

In mild cases, Lescol 20 mg once daily may be prescribed.

Your doctor will tell you exactly how many capsules of Lescol to take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

When to use Lescol

Take Lescol in the evening or at bedtime without regard to meals, and swallow whole with a glass of water.

How long to use Lescol

Continue taking Lescol for as long as your doctor recommends.

If you forget to use Lescol

Take one dose as soon as you remember.

In this case take your next dose at the usual time.

Do not take a double dose to make up for the one that you missed.

If you use too much (overdose)

If you have accidentally taken too much Lescol, talk to your doctor straight away. You may require medical attention.

While you are using Lescol

Things you must do

Medicines used to lower cholesterol levels belonging to this class ("statins") have an effect on sugar metabolism. Therefore, during treatment with Lescol:

- If you know you have a medical history of diabetes yourself and/or in your family
- If you get signs or symptoms such as excessive thirst, high urine output, increased appetite with weight loss, tiredness, these may be signs of high levels of sugar in the blood.

In such cases, tell your doctor.

If during treatment with Lescol, you develop symptoms or signs such as nausea, vomiting, loss of appetite, yellow eye or skin, confusion, euphoria or depression, mental slowing, slurred speech, sleep disturbance, tremors or easy bruising or bleeding, these may be signs of liver failure. In such case contact a doctor immediately.

Things you must not do

Remember that Lescol will not cure your condition but it does help control it. Therefore, you must continue to take Lescol as directed to keep the levels of your 'bad' cholesterol down. Your cholesterol levels should be checked regularly to monitor your progress. To maintain the benefits of your treatment, you should not stop taking Lescol unless your doctor tells you to.

Things to be careful of

Driving and using machines

There is no information on the effects of Lescol on your ability to drive and use machines.

Side effects

As with all medicines, patients treated with Lescol may experience side effects, although not everybody gets them.

Some rare or very rare side effects could be serious

- If you have unexplained muscle pain, tenderness or weakness. These might be early signs of a potentially severe muscle degradation which can be avoided if your doctor stops your treatment with fluvastatin as quickly as possible. These side effects have also been found with similar drugs of this class (statins).
- If you have unusual tiredness or fever, yellowing of the skin and eyes, dark colored urine (signs of hepatitis).
- If you have signs of skin reactions such as skin rash, hives, redness, itching, swelling of the face, eyelids, and lips.
- If you have skin swelling, difficulty in breathing, dizziness (signs of severe allergic reaction)
- If you bleed or bruise more easily than normal (signs of decreased number of platelets).
- If you have red or purple skin lesions (signs of blood vessel inflammation).
- If you have red blotchy rash mainly on the face which may be accompanied by fatigue, fever, nausea, loss of appetite (signs of lupus erythematous-like reaction).
- If you have severe upper stomach pain (signs of inflamed pancreas).

If you experience any of these, tell your doctor straight away.

Some side effects are common

These side effects may affect between 1 and 10 in every 100 patients

- Difficulty in sleeping
- Headache
- Stomach discomfort
- Abdominal pain
- Nausea
- Abnormal blood test values for muscle and liver

If any of these affects you severely, tell your doctor

Some side effects are very rare

These side effects may affect less than 1 in every 10,000 patients.

- Tingling or numbness of the hands or feet
- Disturbed or decreased sensibility

If these affect you severely, tell your doctor.

There has been rare post-marketing reports of cognitive impairment (e.g. memory loss, forgetfulness and confusion) associated with statin use. The reports are generally non-serious and reversible upon statin discontinuation.

Other side effects

Other side effects have occurred in a small number of people, but their exact frequency is unknown.

- Impotence

If this affects you severely, tell your doctor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Lescol

Storage

- Do not use after the expiry date shown on the box.
- Do not store Lescol capsules above 25°C, in order to protect from heat.
- Leave your Lescol capsule in the blister pack until required for use, in order to protect from moisture.
- Store in the original package.
- Keep out of the reach and sight of children.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Lescol 20mg Capsules: Hard gelatin capsule, cap is strong reddish brown opaque in colour and the body is pale yellow opaque with 'XU 20mg' imprint in red.

Lescol 40mg Capsules: Hard gelatin capsule, cap is strong reddish brown opaque in colour and the body is orange yellow opaque with 'XU 40mg' imprint in red.

Ingredients

Active ingredient

- The active substance of Lescol capsules is fluvastatin sodium.

Inactive ingredients

- The other ingredients of Lescol capsules are: magnesium stearate, sodium hydrogen carbonate, talc, cellulose microcrystalline, starch pregelatinized, calcium carbonate, gelatin, iron oxide red and yellow, titanium dioxide, shellac.

MAL Number

Lescol 20mg Capsules: MAL19992682ACR

Lescol 40mg Capsules : MAL19992683ACR

Manufacturer

Novartis Farmaceutica S.A., Ronda Santa Maria, 158-08210 Barbera Del Valles, Barcelona, Spain.

Product Registration Holder

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Date of revision

15/07/2015

Serial Number

BPFK(R4/1)080715/00180