Package leaflet: Information for the user

Lescol XL 80 mg prolonged-release tablets
fluvastatin

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lescol XL is and what it is used for
2. What you need to know before you take Lescol XL
3. How to take Lescol XL
4. Possible side effects
5. How to store Lescol XL
6. Contents of the pack and other information

1. What Lescol XL is and what it is used for

Lescol XL contains the active substance fluvastatin sodium which belongs to a group of medicines known as statins, which are lipid-lowering medicines: they lower the fat (lipids) in your blood. They are used in patients whose conditions cannot be controlled by diet and exercise alone.

- Lescol XL is a medicine used to **treat raised levels of fats in the blood in adults,** in particular total cholesterol and so called "bad" or LDL cholesterol, which is associated with an increased risk of heart disease and stroke.
  - in adult patients with high blood levels of cholesterol
  - in adult patients with high blood levels of both cholesterol and triglycerides (another sort of blood lipid)
- Your doctor can also prescribe Lescol XL to prevent further serious cardiac events (e.g. heart attack) in patients who have already had a heart catheterisation, with an intervention in the heart vessel.

If you have any questions about how Lescol XL works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Lescol XL

Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

Read the following explanations before you take Lescol XL.

Do not take Lescol XL
- if you are allergic (hypersensitive) to fluvastatin or any of the other ingredients of this medicine (listed in section 6).
- if you currently have liver problems, or if you have unexplained, persistently high level of certain liver enzymes (transaminases).
- if you are pregnant or breast-feeding (see "pregnancy and breast-feeding").

If any of these apply to you, do not take Lescol XL and tell your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking Lescol XL.
- If you are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Lescol XL can lead to serious muscle problems (rhabdomyolysis).
- if you previously had a liver disease. Liver function tests will normally be done before you start Lescol XL, when your dose is increased and at various intervals during treatment to check for side effects.
- if you have a kidney disease.
- if you have a thyroid disease (hypothyroidism).
- if you have a medical history of muscle diseases yourself or in your family.
- if you had muscle problems with another lipid-lowering medicine.
- if you regularly drink 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 controlled or uncontrolled excessive muscle exercise.
- 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 or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometime aggravate the condition or lead to the occurrence of myasthenia (see section 4).

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Check with your doctor or pharmacist before taking Lescol XL:
- if you have severe respiratory failure

If any of these apply to you, **tell your doctor before taking** Lescol XL. Your doctor will take a blood test before prescribing Lescol XL.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

If during treatment with Lescol XL, 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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free."

Lescol XL and people over 70 years
If you are over 70 years your doctor may want to check if you have risk factors for muscular diseases. You may need specific blood tests.

Children and adolescents
Lescol XL has not been investigated and is not intended for the use in children below 9 years. For dose information in children and adolescents over 9 years, see section 3.

There is no experience with the use of fluvastatin in combination with nicotinic acid, cholestyramine or fibrates in children and adolescents.

Other medicines and Lescol XL
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using Lescol XL. Your doctor will tell you when it is safe to restart Lescol XL. Taking Lescol XL with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Lescol XL can be taken on its own or with other cholesterol-lowering medicines prescribed by your doctor.

After intake of a resin, e.g. cholestyramine (primarily used to treat high cholesterol) wait at least 4 hours before taking Lescol XL.

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 (used to treat gout).

Pregnancy and breast-feeding
Do not take Lescol XL if you are pregnant or breast-feeding as the active ingredient may lead to harm to your unborn child, and it is not known whether the active ingredient is excreted in human breast milk.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

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

3. How to take Lescol XL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not exceed the recommended dose.

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

How much Lescol XL to take

Recommended doses in adults
The dose range of fluvastatin for adults is 20 to 80 mg per day and depends on the extent of cholesterol lowering which needs to be achieved. Dose adjustments may be made by your doctor at 4-week or longer intervals.

Use in children and adolescents
For children (aged 9 years and older) the usual starting dose is 20 mg of fluvastatin per day. The maximum daily dose is 80 mg. Dose adjustments may be made by your doctor at 6-week intervals.

Your doctor will tell you exactly how much fluvastatin to take.
Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

When to take Lescol XL
If you are taking Lescol XL tablets you can take your dose at any time of the day. Lescol XL can be taken with or without meals. Swallow whole with a glass of water.

If you take more Lescol XL than you should
If you have accidentally taken too many tablets of Lescol XL, talk to your doctor straight away. You may need medical attention.

If you forget to take Lescol XL
Take one dose as soon as you remember. However, do not take it if there is less than 4 hours before your next dose. In this case take your next dose at the usual time.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Lescol XL
To maintain the benefits of your treatment, do not stop taking Lescol XL unless your doctor tells you to. You must continue to take Lescol XL as directed to keep the levels of your 'bad' cholesterol down. Lescol XL will not cure your condition but it does help control it. Your cholesterol levels need to be checked regularly to monitor your progress.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Some rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people) side effects could be serious: get medical help immediately.
- if you have unexplained muscle pain, tenderness or weakness. These might be early signs of a potentially severe muscle degradation. This can be avoided if your doctor stops your treatment with fluvastatin as quickly as possible. These side effects have also been found with similar medicines of this class (statins).
- if you have unusual tiredness or fever, yellowing of the skin and eyes, dark coloured 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 blood 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.

Other side effects: tell your doctor if they worry you.
Common (may affect up to 1 in 10 people):
Difficulty in sleeping, headache, stomach discomfort, abdominal pain, nausea, abnormal blood test values for muscle and liver.
Very rare (may affect up to 1 in 10,000 people):
Tingling or numbness of the hands or feet, disturbed or decreased sensitivity.

Not known (*frequency cannot be estimated from the available data)*:
- Impotence, muscle weakness that is constant, breathing problems including persistent cough and/or shortness of breath or fever.
- Diarrhoea
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Other possible side effects
- Sleep disturbances, including insomnia and nightmares
- Memory loss
- Sexual difficulties
- Depression
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor may monitor you while you are taking this medicine.
- Inflammation, swelling and irritation of a tendon

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lescol XL

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Do not store above 30 °C. Store in the original package in order to protect from moisture
- Do not use this medicine if you notice that the pack is damaged or shows signs of tempering.
- Leave your Lescol XL tablet in the blister pack until required for use, in order to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lescol XL contains
- The active substance is fluvastatin.
  Each prolonged-release tablet contains 84.24 mg fluvastatin sodium equivalent to 80 mg fluvastatin free acid.
- The other ingredients of Lescol XL 80 mg tablets are: cellulose microcrystalline, hypromellose, hydroxypropyl cellulose, potassium hydrogen carbonate, povidone, magnesium stearate, macrogol 8000, iron oxide yellow (E172), titanium dioxide (E 171)

What Lescol XL looks like and contents of the pack
- Lescol XL 80 mg prolonged-release tablets are yellow, round, slightly biconvex with bevelled edges. They have the letters "LE" on one side and "NVR" on the other. They are available in blisters 28 prolonged-release tablets.

Days of the week are printed as follows on the blister:

Sobota	Saturday
Neděle	Sunday
Pondělí	Monday
Úterý	Tuesday
Středa	Wednesday
Ctvrtek	Thursday
Pátek	Friday

Parallel Product Authorisation Holder
IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufacturer
Novartis s.r.o. Na Pankráci 1724/129, 140 00 Prague 4, Czech Republic or Novartis Pharma GmbH, Roonstrasse 25, 90429 Nürnberg, Germany or Siegfried Barbera S.L., Ronda Santa Maria 158, 08210 Barbera Del Valles, Spain.

Repackaged by
Cast Healthcare Ltd, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK(NI) or IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

This medicine is authorised in the 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 Medicinal Product
Croatia, Estonia, Bulgaria, Cyprus, Czech Republic, Greece, Hungary, Ireland, Latvia, Lithuania, Malta, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, United Kingdom (Northern Ireland)	Lescol XL
Denmark, Finland, Iceland, Norway, Sweden	Lescol Depot
Germany	Fluvastatin Novartis
Austria	Lescol MR
Belgium, Luxembourg	Lescol Exel
France	Lescol LP
Germany	Locol
Italy	Lescol, Lipaxan
Portugal	Canef
Spain	Lescol Prolib, Liposit Prolib, Vaditon Prolib, Digaril Prolib

This leaflet was last revised in July 2025.