

Package leaflet: Information for the user

Lescol 20 and 40 mg hard capsules

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.

What is in this leaflet:

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

1. What Lescol is and what it is used for

Lescol contains the active 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 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 to prevent further serious cardiac events (e.g. heart attack) in patients after they already went through a heart catheterisation, with an intervention in the heart vessel.

2. What you need to know before you take 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.

Do not take Lescol

- if you are allergic (hypersensitive) to fluvastatin or any of the other ingredients of Lescol listed in section 6 of this leaflet.

- 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 and tell your doctor.

Warnings and precautions

Talk to you doctor or pharmacist before taking Lescol.

- if you previously had a liver disease. Liver function tests will normally be done before you start Lescol, 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.

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:

- if you have severe respiratory failure

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

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.

Lescol 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.

Lescol and children/adolescents

Lescol 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 Lescol in combination with nicotinic acid, cholestyramine or fibrates in children and adolescents.

Other medicines and Lescol

Please tell your doctor or 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 (primarily used to treat high cholesterol) 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 (used to treat gout).

Lescol with food and drink

You can take Lescol with or without food.

Pregnancy and breast-feeding

Do not take Lescol 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, consult your doctor or pharmacist before taking Lescol.

Take adequate precaution 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.

Driving and using machines

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

3. How to take Lescol

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

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

How much Lescol to take

- The dose range 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.
- For children (aged 9 years and older) the usual starting dose is 20 mg 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 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 take Lescol

Take your Lescol dose in the evening or at bedtime.

If you are taking Lescol twice per day, take one capsule in the morning and one in the evening or at bedtime.

Lescol can be taken with or without meals. Swallow whole with a glass of water.

If you take more Lescol than you should

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

If you forget to take Lescol

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 the one that you missed.

If you stop taking Lescol

To maintain the benefits of your treatment, do not stop taking Lescol unless your doctor tells you to. You must continue to take Lescol as directed to keep the levels of your 'bad' cholesterol down. Lescol 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Lescol can cause side effects, although not everybody gets them.

Very common: affects more than 1 user in 10

Common: affects 1 to 10 users in 100

Uncommon: affects 1 to 10 users in 1,000

Rare: affects 1 to 10 users in 10,000

Very rare: affects less than 1 user in 10,000

Not known: frequency cannot be estimated from the available data.

Some rare or very rare 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 erythematosus-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:

Difficulty in sleeping, headache, stomach discomfort, abdominal pain, nausea, abnormal blood test values for muscle and liver.

Very rare:

Tingling or numbness of the hands or feet, disturbed or decreased sensitivity.

Not known:

Impotence

Other possible side effects

- Sleep disturbances, including insomnia and nightmares
- Memory loss
- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever
- 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

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

5. How to store Lescol

- 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 pack. The expiry date refers to the last day of that month.
- Do not store Lescol capsules above 25°C. Store in the original package in order to protect from light and moisture.
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.
- Leave your Lescol capsule in the blister pack until required for use, in order to protect from moisture.
- 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.

6. Contents of the pack and other information

What Lescol contains

- The active substance is fluvastatin sodium
Each Lescol 20 mg capsule contains 21.06 mg fluvastatin sodium equivalent to 20 mg fluvastatin free acid.
Each Lescol 40 mg capsule contains 42.12 mg fluvastatin sodium equivalent to 40 mg fluvastatin free acid.

The other ingredients of Lescol 20 mg and 40mg capsules are: magnesium stearate, sodium hydrogen carbonate, talc, cellulose microcrystalline, pregelatinised starch, calcium carbonate, titanium dioxide (E 171), iron oxide red (E 172), gelatin, iron oxide yellow (E 172), shellac, propylene glycol, potassium hydroxide.

What Lescol looks like and contents of the pack

- Lescol 20 mg capsules have a strong reddish brown opaque cap and a pale yellow opaque body with the red inprint “XU 20 mg”.
Lescol 40 mg capsules have a strong reddish brown opaque cap and a moderate orange yellow opaque body with the red inprint “XU 40 mg”.
- *Bottles:* The capsules are supplied in packs of 20 (samples not for sale or parts of hospital packs), 30, 50 or 100 (2 x 50 or 1 x 100) capsules and in hospital packs of 300 (15 x 20) or 600 (30 x 20) capsules.
- *Blisters:* The capsules are supplied in packs of 14, 28, 30, 56, 84, 90 or 98 capsules and in hospital packs of 28, 56, 98 or 490 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

The Marketing Authorisation Holder is:

Novartis Pharmaceuticals UK Limited

Trading as:

Sandoz Pharmaceuticals,

Frimley Business Park, Frimley, Camberley, Surrey,

GU16 7SR, United Kingdom.

Lescol capsules are released onto the market by:

Novartis Pharmaceuticals UK Limited,

Wimblehurst Road,

Horsham, West Sussex,

RH12 5AB, United Kingdom.

or

Novartis Pharmaceuticals UK Limited,

Frimley Business Park,

Frimley, Camberley, Surrey, GU16 7SR, United Kingdom.

If you would like any more information, or would like this leaflet in a different format, please contact Medical Information at Novartis Pharmaceuticals UK Ltd, telephone number 01276 698370.

This medicinal product is authorised in the Member States of the EEA under the following names:

20 mg and 40 mg capsules

<u>Member State</u>	<u>Medicinal Product</u>
Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Malta, Norway, Netherlands, Poland, Portugal, Romania, Slovak Republic, Spain, Sweden, United Kingdom	Lescol
Germany, Luxembourg	Locol
Germany	Cranoc
Italy	Lipaxan, Primesin

Portugal	Canef
Spain	Liposit, Vaditon, Digardil

40 mg capsules

<u>Member State</u>	<u>Medicinal Product</u>
Bulgaria, Estonia, Hungary, Slovenia	Lescol

This leaflet was last revised in May 2013.