

Read all of this leaflet carefully before you start taking LESCOL/LESCOL XL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- LESCOL/LESCOL XL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

Scheduling status

S4

Proprietary name and dosage form:

LESCOL® 20 mg capsule

LESCOL® 40 mg capsule

LESCOL XL® film-coated tablet

Fluvastatin sodium

1. WHAT LESCOL/LESCOL XL CONTAINS

- The **active substance** of Lescol capsules and Lescol XL tablets is fluvastatin sodium.
- The **other ingredients** of Lescol capsules are: magnesium stearate, sodium hydrogen carbonate, talc, cellulose microcrystalline, maize starch, calcium carbonate, gelatin, iron oxide red and yellow, titanium dioxide, shellac.

The **other** ingredients of Lescol XL tablets are: cellulose microcrystalline, hypromellose, hydroxypropyl cellulose, potassium hydrogen carbonate, povidone, magnesium stearate, iron oxide yellow, titanium dioxide, macrogol 8000.

2. WHAT LESCOL/LESCOL XL IS USED FOR

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.

Each Lescol XL 80 mg tablet contains 84,24 mg fluvastatin sodium equivalent to 80 mg fluvastatin free acid. Adults and children/adolescents (aged 9 years and older).

Adults:

LESCOL/LESCOL XL is indicated as an add-on to diet for the reduction of elevated “bad” cholesterol and for the increase of “good” cholesterol.

Lescol/Lescol XL also slows the progression of coronary atherosclerosis.

Paediatric population:

LESCOL/LESCOL XL is indicated as an add-on to diet for the reduction of elevated “bad” cholesterol in children and adolescents aged 9 years and older with heterozygous familial hypercholesterolaemia.

3. BEFORE YOU TAKE LESCOL/LESCOL XL

Before taking Lescol/Lescol XL, you should be started on a standard cholesterol-lowering diet. You should continue with this diet while taking Lescol/Lescol XL.

Follow all instructions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Read the following explanations before you take Lescol/Lescol XL.

Do not take Lescol/Lescol XL:

- **If you are allergic** (hypersensitive) to fluvastatin or any of the other ingredients of Lescol/Lescol XL listed at the beginning 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 you think you may be allergic, ask your doctor for advice.

Take special care with Lescol/Lescol XL:

- If you have a liver disease. Liver function tests will normally be done before starting Lescol/Lescol XL, 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.

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

If any of these apply to you, **tell your doctor before you take** Lescol/Lescol XL.

Taking Lescol/Lescol XL with food and drink:

You can take Lescol/Lescol XL with or without food.

Lescol/Lescol XL and 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.

Lescol/Lescol XL and children/adolescents:

Lescol/Lescol XL is intended for children aged 9 years and older.

Your doctor will advise you about the appropriate diet for your child.

Pregnancy and breast-feeding:

Lescol/Lescol XL must not be used during pregnancy.

Take adequate precautions against pregnancy while taking Lescol/Lescol XL.

If you become pregnant while taking Lescol/Lescol XL, stop taking Lescol/Lescol XL and see your doctor.

Your doctor will discuss with you the potential risk of taking Lescol/Lescol XL during pregnancy.

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

Driving and using machinery:

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

Taking other medicines with Lescol/Lescol XL:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Lescol/Lescol XL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Remember also those not prescribed by a doctor.

Lescol/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) wait at least 4 hours before taking Lescol/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.

4. HOW TO TAKE LESCOL/LESCOL XL

Always take Lescol/Lescol XL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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/Lescol XL.

If you have the impression that the effect of Lescol/Lescol XL is too strong or too weak, talk to your doctor or pharmacist.

How much Lescol/Lescol XL to take:

The usual dose is 40 to 80 mg per day regardless of age. In mild cases, Lescol 20 mg once daily may be prescribed.

Your doctor will tell you exactly how many capsules or tablets of Lescol/Lescol XL to take.

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

When and how to take Lescol/Lescol XL:

Take Lescol in the evening or at bedtime or Lescol XL at any time of the day with or after meals, and swallow whole with a glass of water.

If you take more Lescol/Lescol XL than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison center.

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

If you forget to take Lescol/Lescol XL:

Take one dose as soon as you remember.

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.

Effects when treatment with Lescol/LescolXL is stopped:

Remember that Lescol/Lescol XL will not cure your condition but it does help control it. Therefore, you must continue to take Lescol/Lescol XL 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/Lescol XL unless your doctor tells you to.

5. POSSIBLE SIDE EFFECTS

Not all side effects reported for Lescol/Lescol XL are included in this leaflet. Should your general health worsen while taking Lescol/Lescol XL., please consult your doctor, pharmacist or other health care professional for advice.

Lescol/Lescol XL can have side effects

Some rare or very rare 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.
- 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 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:

Common (*likely to affect 1 to 10 of every 100 patients*):

Difficulty in sleeping, headache, stomach discomfort, abdominal pain, nausea.

Very rare (*likely to affect less than 1 in every 10000 patients*):

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

If any of these affects you severely, **tell your doctor**.

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

6. STORING AND DISPOSING OF LESCOL/LESCOL XL

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.

Do not store Lescol XL tablet above 30 °C, in order to protect from heat.

Leave your Lescol capsule/Lescol XL tablet in the blister pack until required for use, in order to protect from moisture.

Store in the original package.

Keep all medicines out of the reach and sight of children.

7. PRESENTATION OF LESCOL/LESCOL XL

LESCOL[®] capsules: Alu/alu blister packs –28 capsules per pack.

LESCOL XL[®] film-coated tablets: PA/Al/PVC aluminium foil blister packs of 28.

The blister strips are packed in a printed cardboard box.

8. IDENTIFICATION OF LESCOL/LESCOL XL

LESCOL[®] 20 mg capsule: A No. 3 hard gelatin capsule with a strong reddish brown opaque cap and pale yellow opaque body with XU 20 mg imprinted in red.

LESCOL[®] 40 mg capsule: A No. 1 hard gelatin capsule with a strong reddish brown opaque cap and a moderate orange yellow opaque body with XU 40 mg imprinted in red.

LESCOL XL[®] film-coated tablet: Yellow, round, slightly biconvex, bevelled edged film-coated tablet, with “LE” imprinted on the one side and “NVR” on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

LESCOL[®] 20 mg capsule 28/7.5/0159

LESCOL[®] 40 mg capsule 28/7.5/0160

LESCOL XL[®] film-coated tablet 35/7.5/0327

10. NAME AND ADDRESS OF REGISTRATION HOLDER

NOVARTIS SOUTH AFRICA (PTY) LTD

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg 2090

South Africa

11. DATE OF PUBLICATION

15 April 2011