

Package leaflet: Information for the user

Lochol 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 Lochol XL is and what it is used for
2. What you need to know before you take Lochol XL
3. How to take Lochol XL
4. Possible side effects
5. How to store Lochol XL
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1. What Lochol XL is and what it is used for

Lochol 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.

- Lochol 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 Lochol XL 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 Lochol XL

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 Lochol XL.

DO NOT take Lochol XL:

- if you are allergic 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 Lochol XL and tell your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lochol XL.

- If you previously had a liver disease. Liver function tests will normally be done before you start Lochol 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.

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 LOCHOL XL:

- if you have severe respiratory failure

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

If during treatment with Lochol 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.

LOCHOL 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.

LOCHOL XL and children/adolescents

Fluvastatin 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 Lochol XL

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Lochol 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 **Lochol 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).

Lochol XL with food and drink

You can take **Lochol XL** with or without food.

Pregnancy and breast feeding

Do not take Lochol 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, consult your doctor or pharmacist before taking **Lochol XL**.

Take adequate precaution against pregnancy while taking **Lochol XL**.

If you become pregnant while taking this medicine, stop taking **Lochol XL** and see your doctor.

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

Driving and using machines

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

3. How to take Lochol XL

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 **Lochol XL**.

How much Lochol XL 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 tablets of **Lochol XL** to take.

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

Please note that you cannot use Lochol XL 80 mg prolonged-release tablets for all the above dosages. Lochol XL 80 mg prolonged-release tablets must not be divided.. For lower doses (20 mg and 40 mg), your doctor will prescribe other fluvastatin medicines.

When to take LOCHOL XL

You can take your Lochol XL dose at any time of the day.

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

If you take more Lochol XL than you should

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

If you forget to take LOCHOL 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 the one that you missed.

If you stop taking LOCHOL XL

To maintain the benefits of your treatment, do not stop taking **Lochol XL** unless your doctor tells you to. You must continue to take **Lochol XL** as directed to keep the levels of your 'bad' cholesterol

down. **Lochol 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 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 (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

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 will monitor you while you are taking this medicine.

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 {to be completed nationally: the national reporting system listed in Appendix V}. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lochol 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 blister and carton, respectively, after EXP. The expiry date refers to the last day of a month.
- Keep the blisters in the outer carton in order to protect from light.
- 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 protect the environment.

6. Contents of the pack and other information

What Lochol XL contains:

- The active substance is fluvastatin.
Each prolonged release tablet contains 80 mg fluvastatin (as fluvastatin sodium).
- The other ingredients are:
 - Tablet core: Povidone, microcrystalline cellulose, hydroxyethyl cellulose, mannitol, magnesium stearate
 - Film-coating: Hypromellose 50, macrogol 6000, iron oxide yellow (E172), titanium dioxide (E171).

What Lochol XL looks like and contents of the pack

Lochol XL are yellow, round, biconvex prolonged release tablets.

Pack sizes:

Blister (OPA/Alu/PVC-Alu) : 7, 20, 28, 30, 50, 56, 98, 100 and 120 prolonged release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Actavis hf., Reykjavikurvegi 78, IS-222 Hafnarfjordur, Iceland

Actavis Ltd, BLB016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta

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

Denmark (RMS): Fluvistad 80 mg

Ireland: Lochol XL 80 mg prolonged-release tablets

The Netherlands: Fluvastatine retard CF 80 mg, tabletten met verlengde afgifte

This leaflet was last revised in May 2013.