

Package leaflet: information for the user

Flavustenol XL 80mg 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

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1. What Flavustenol XL 80 mg is and what it is used for

- Flavustenol XL 80mg contains the active substance fluvastatin sodium which belongs to a group of medicines known as statins, which are lipid-lowering medicines: they reduce the fat (lipids) level in your blood. They are used in patients whose conditions cannot be controlled by diet and exercise alone.
- Flavustenol XL 80mg is a medicine used to **treat raised levels of fat 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 Flavustenol XL 80mg 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 Flavustenol XL 80 mg

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 Flavustenol XL 80 mg .

Do not take Flavustenol XL 80 mg

- if you are allergic to Fluvastatin or to any of the other ingredients of this medicine (listed in section 6)
- if you have liver problems currently, or if you have unexplained, persistently high levels 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 Flavustenol XL 80 mg and tell your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flavustenol XL 80 mg

- If you previously had a liver disease. Liver function tests will normally be done before you start Flavustenol XL 80 mg, when your dose is increased and at various intervals during treatment to check for side effects.
- 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 Flavustenol XL 80 mg can lead to serious muscle problems (rhabdomyolysis).
- 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.
- 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.

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 Flavustenol XL 80 mg :

- If you have severe respiratory failure.

If any of these apply to you, **tell your doctor before you take** Flavustenol XL 80 mg . Your doctor will take a blood test before prescribing Flavustenol XL 80 mg .

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.

Flavustenol XL 80 mg 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.

Flavustenol XL 80 mg and children/adolescents

Flavustenol XL 80 mg has not been investigated and is not intended for 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 Flavustenol XL 80 mg in combination with nicotinic acid, cholestyramine or fibrates in children and adolescents.

Other medicines and Flavustenol XL 80 mg

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

Flavustenol XL 80 mg 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 Flavustenol XL 80 mg .

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

- If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Flavustenol XL 80 mg. Taking Flavustenol XL 80 mg with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- 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)

Flavustenol XL 80 mg with food and drink

You can take Flavustenol XL 80mg with or without food.

Pregnancy, breast-feeding and fertility

Do not take Flavustenol XL 80 mg 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. Use reliable contraception for the whole time that you are taking Flavustenol XL 80 mg .

In animal studies no effects on male and female fertility were observed.

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.

Driving and using machines

There is no information on the effects of Flavustenol XL 80 mg on your ability to drive and use machines.

3. How to take Flavustenol XL 80 mg

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

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

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

How much to take

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

When to take Flavustenol XL 80 mg

- If you are taking Flavustenol XL 80mg , you can take your dose at any time of the day.
- Flavustenol XL 80mg can be taken with or without meals. Swallow whole with a glass of water.

If you take more Flavustenol XL 80 mg than you should

If you have accidentally taken too much Flavustenol XL 80 mg , talk to your doctor straight away. You may need medical attention.

If you forget to take Flavustenol XL 80 mg

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 Flavustenol XL 80 mg

To maintain the benefits of your treatment, do not stop taking Flavustenol XL 80 mg unless your doctor tells you to. You must continue to take Flavustenol XL 80 mg as directed to keep the levels of your 'bad' cholesterol down. Flavustenol XL 80 mg 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.

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

Some rare or very rare effects could be serious: get medical help immediately.

- If you have unexplained muscle pain, tenderness or weakness. These might be early signs of 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 a 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 (sign of an 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 sensibility.

Not known:

Impotence.

Muscle weakness that is constant.

Diarrhoea.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

- 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 label and carton after 'EXP'. The expiry date refers to the last day of that month.
- Store below 30°C in the original container in order to protect from light and 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 protect the environment.

6. Contents of the pack and other information

What Flavustenol XL 80 mg contains

The active substance is fluvastatin sodium.

Each prolonged release tablet contains 84.280 mg of Fluvastatin sodium equivalent to 80 mg Fluvastatin.

The other ingredients are:

Tablet core:

Cellulose microcrystalline, Potassium hydrogen carbonate, Povidone K-30, Hydroxy propyl cellulose, Hypromellose K 100, Hypromellose K 4M, Magnesium stearate

Film coat:

Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc, Iron oxide yellow (E172)

What Flavustenol XL 80 mg looks like and contents of the pack

Yellow colored, round, biconvex, beveled edged film coated tablets, debossed with "F80" on one side and plain on other side.

Flavustenol XL 80 mg is available in OPA-Al-PVC/Al blisters packs containing 7, 14,28,30,56,70,84,90 and 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

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

Name of the Member State	Name of the medicinal product
Austria	Fluvastatin Accord 80mg Retardtabletten
Bulgaria	Fluvastatin Accord 80mg Prolonged-release Tablets
Cyprus	Fluvastatin Accord 80mg Prolonged-release Tablets
Estonia	Fluvastatin Accord
France	Fluvastatin Accord 80 mg, comprimé pelliculé à libération prolongée
Ireland	Flavustenol XL 80mg Prolonged release Tablets
Malta	Flavustenol XL 80mg Prolonged-release tablets
Netherlands	Fluvastatine Accord 80 mg tabletten met verlengde afgifte
Norway	Fluvastatin Accord
United kingdom	Sinfatix 80mg XL Prolonged release Tablets

This leaflet was last revised in 08/2022