

PACKAGE LEAFLET

Package leaflet: Information for the patient

Fluvastatin 20 mg and 40 mg Capsules, hard 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 Fluvastatin is and what it is used for
2. What you need to know before you take Fluvastatin
3. How to take Fluvastatin
4. Possible side effects
5. How to store Fluvastatin
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1. What Fluvastatin is and what it is used for

Fluvastatin 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.

Fluvastatin 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 Fluvastatin to prevent further serious cardiac events (e.g. heart attack) in patients who have already gone through a heart catheterisation, with an intervention in the heart vessel.

2. What you need to know before you take Fluvastatin

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

Do not take Fluvastatin:

- 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 levels of certain liver enzymes (transaminases)
- if you are pregnant or breast-feeding (see ‘Pregnancy and breast-feeding’).

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluvastatin:

- if you previously had liver disease. Liver function tests will normally be done before you start Fluvastatin, 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 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 Fluvastatin can lead to serious muscle problems (rhabdomyolysis).

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.

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

If during treatment with Fluvastatin, you develop symptoms or signs such as nausea, vomiting, loss of appetite, yellow eyes 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.

If you develop breathing problems including persistent cough and/or shortness of breath or fever, contact your doctor.

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.

Older people

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

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 Fluvastatin

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

Fluvastatin 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 Fluvastatin.

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

- ciclosporin (a medicine used to suppress the immune system)
- fibrates (e.g. gemfibrozil), nicotinic acid (niacin) 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 such as warfarin (medicines used to reduce blood clotting)
- glibenclamide (a medicine used to treat diabetes)
- colchicines (used to treat gout).

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 Fluvastatin.

Taking Fluvastatin with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Pregnancy and breast-feeding

Do not take Fluvastatin 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.

Use reliable contraception for the whole time that you are taking Fluvastatin.

If you become pregnant while taking this medicine, stop taking Fluvastatin and see your doctor. Your doctor will discuss with you the potential risk of taking fluvastatin during pregnancy.

Driving and using machines

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

3. How to take Fluvastatin

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

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

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.

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

Take your dose in the evening or at bedtime.

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

Method of administration

Swallow the capsule whole with a glass of water. You can take Fluvastatin with or without food.

Use in children and adolescents

For children (aged 9 years and older) the recommended 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.

If you take more Fluvastatin than you should

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

If you forget to take Fluvastatin

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 Fluvastatin

To maintain the benefits of your treatment, do not stop taking Fluvastatin unless your doctor tells you to. You must continue to take Fluvastatin as directed to keep the levels of your 'bad' cholesterol down. Fluvastatin 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 side effects could be serious. If you think you have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency department immediately.

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

- if you have unexplained muscle pain, tenderness or weakness, especially if this is constant. 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 bleed or bruise more easily than normal (signs of decreased number of blood platelets, which help the blood to clot)
- 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 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 (signs of inflamed pancreas)

Not known (frequency cannot be estimated from the available data):

- if you have signs of inflammation, swelling and irritation of a tendon. In some cases this can lead to tendon rupture
- breathing problems including persistent cough and/or shortness of breath or fever
- diabetes– you may feel hungry, very thirsty and pass large volumes of urine. 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.

If you experience any of these, tell your doctor straight away.

Other possible side effects:

Common (may affect up to 1 in 10 people):

- difficulty in sleeping
- headache
- stomach discomfort e.g. indigestion
- abdominal pain
- nausea (feeling sick)
- 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
- sleep disturbances, including insomnia and nightmares
- memory loss
- sexual difficulties
- depression

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

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

5. How to store Fluvastatin

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 the blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package 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 protect the environment.

6. Contents of the pack and other information

What Fluvastatin contains

Fluvastatin comes as capsules in two strengths containing either 20 mg or 40 mg of the active ingredient fluvastatin sodium in each capsule. Each capsule also contains maize starch, crospovidone, talc, magnesium stearate. The capsule shells contain iron oxide, titanium dioxide, water and gelatine and the printing ink contains iron oxide and shellac.

What Fluvastatin looks like and contents of the pack

Fluvastatin 20 mg capsules are pale yellow capsules, marked 'FL 20' on the body and 'G' on the cap.

Fluvastatin 40 mg capsules are red capsules, marked 'FL 40' on the body and 'G' on the cap.

Fluvastatin Capsules comes in blisters of 10, 14, 15, 28, 30, 50, 56, 98, 100, 500 and in a multipack of 98 comprising 2 cartons, each containing 49 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

McDermott Laboratories (trading as Gerard Laboratories), 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft. H-2900, Komarom, Mylan street 1, Hungary.

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