

Fluvastatin 20 mg and 40 mg Capsules fluvastatin

Package leaflet: Information for the user

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 effect not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fluvastatin Capsules are and what they are used for
2. What you need to know before you take Fluvastatin Capsules
3. How to take Fluvastatin Capsules
4. Possible side effects
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1 What Fluvastatin Capsules are and what they are used for

Fluvastatin Capsules contain 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 Capsules 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 Capsules 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 Fluvastatin Capsules

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 Fluvastatin Capsules.

Do not take Fluvastatin Capsules:

- if you are allergic to fluvastatin or to 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").

If any of these apply to you, do not take Fluvastatin Capsules and tell your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluvastatin Capsules:

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

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.

Children and adolescents

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

Other medicines and Fluvastatin Capsules

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

Fluvastatin Capsules 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 Capsules. 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).

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

Fluvastatin Capsules with food and drink

You can take Fluvastatin Capsules with or without food.

Pregnancy and breast-feeding

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

Do not take Fluvastatin Capsules 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 Fluvastatin Capsules.

If you become pregnant while taking this medicine, stop taking Fluvastatin Capsules and see your doctor.

Driving and using machines

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

Fluvastatin Capsules contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Fluvastatin Capsules contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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How to take Fluvastatin Capsules

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

Adults

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 Fluvastatin Capsules.

The recommended dose is

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 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.

Your doctor will tell you exactly how many capsules to take.

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

When to take Fluvastatin Capsules

If you are taking Fluvastatin Capsules once per day, take your dose in the evening or at bedtime.

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

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

If you take more Fluvastatin Capsules than you should

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

If you forget to take Fluvastatin Capsules

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 Capsules

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

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Possible side effects

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

If you get any of the following serious side effects, stop taking Fluvastatin Capsules and go to your doctor or to the nearest hospital straight away:

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

- if you have unexplained muscle pain, tenderness or weakness. These might be early signs of a potentially severe muscle degradation called rhabdomyolysis. This can be avoided if your doctor stops your treatment with Fluvastatin Capsules as quickly as possible. These side effects have also been found with similar medicines of this class (statins).

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

- if you have a potentially severe muscle degradation called rhabdomyolysis
- if you have unusual tiredness or fever, yellowing of the skin and eyes, dark coloured urine (signs of hepatitis).
- if you have skin swelling, difficulty in breathing, dizziness (signs of severe allergic reaction called anaphylactic reaction).
- if you bleed or bruise more easily than normal (signs of decreased number of blood platelets thrombocytopenia).
- if you have red or purple skin lesions (signs of blood vessel inflammation-vasculitis).
- 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-pancreatitis).
- if you have signs of skin reactions such as redness, itching, swelling of the face, eyelids, and lips.

Other possible side effects with Fluvastatin Capsules

Common: may affect up to 1 in 10 people

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

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

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 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5 How to store Fluvastatin Capsules

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 or label and carton after EXP. The expiry date refers to the last day of the month.

Do not store above 30°C.

Do not throw away any medicines via wastewater. 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 Capsules contain:

The active substance is fluvastatin sodium. Each 20 mg capsule contains 20 mg fluvastatin (as fluvastatin sodium). Each 40 mg capsule contains 40 mg fluvastatin (as fluvastatin sodium).

The other ingredients are lactose monohydrate, colloidal anhydrous silica, crospovidone, magnesium stearate, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172), titanium dioxide (E171), gelatin, shellac and propylene glycol

What Fluvastatin Capsules look like and contents of the pack

Fluvastatin 20 mg Capsules have an ivory opaque body and pink opaque cap marked 93/7442.

Fluvastatin 40 mg Capsules have a yellow opaque body and pink opaque cap marked 93/7443.

Pack sizes:

Blisters: 1, 14, 15, 20, 28, 30, 50, 50 x2, 56, 60, 84, 90, 98 and 100 capsules.

Hospital packs in blisters: 1, 50 and 100 capsules.

Bottles: 100, 250 and 500 capsules.

Not all pack sizes may be marketed.

The capsule should be pushed out carefully from the blister as shown by the picture, in order to avoid damaging the capsule.



Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is TEVA UK Limited, Eastbourne, BN22 9AG and the company responsible for manufacture is TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary

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