

Fluvastatin 20mg and 40mg capsules

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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1 What Fluvastatin is and what it is used for

Fluvastatin contains the active fluvastatin (as 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 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

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.

Do not take Fluvastatin

- if you are **allergic** to fluvastatin or any of the other ingredients of this medicine (listed in section 6 of this leaflet).
- if you are allergic to **soya** or **peanut**.
- 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 Fluvastatin and tell your doctor.

Warnings and precautions Talk to your doctor, pharmacist or nurse before taking Fluvastatin

- if you previously had a **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 severe respiratory failure.

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

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.

Fluvastatin 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.

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 and pharmacist if you are taking any of the following:

- Cyclosporin (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).

Fluvastatin with food and drink

You can take Fluvastatin with or without food.

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, consult your doctor or pharmacist before taking Fluvastatin. 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.

Driving and using machines

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

Fluvastatin contains soya lecithin.

If you are allergic to peanut or soya, do not use this medicine.

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. Do not exceed the recommended dose.

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

How much Fluvastatin to take

- The dose range for adults is 20 to 80mg 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 80mg. Dose adjustments may be made by your doctor at 6-week 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.

When to take Fluvastatin

If you are taking Fluvastatin once a day, 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.

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

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 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 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, pharmacist or nurse.

4 Possible side effects

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

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
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 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:
Difficulty in sleeping, headache, stomach discomfort, abdominal pain, nausea.
Very rare:
Tingling or numbness of the hands or feet, disturbed or decreased sensibility.

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. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

5 How to store

Keep this medicine out of the reach and sight of children. Do not store above 25°C. Store in original container in order to protect from moisture and light.

Do not use this medicine after the expiry date, which is stated on the blister, bottle and carton (after EXP). The expiry date refers to the last day of that month.

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

Fluvastatin capsules contain:

The active substance is fluvastatin sodium. Each capsule contains 20mg or 40mg fluvastatin (as fluvastatin sodium). The other ingredients are mannitol, talc, magnesium stearate.

20mg:

Capsule body: Gelatin, titanium dioxide (E171), yellow iron oxide (E 172), red iron oxide (E 172).

Capsule cap: Gelatin, titanium dioxide (E 171), red iron oxide (E 172).

Ink:

White ink on capsule cap: Titanium dioxide (E171), Shellac, Soya lecithin, Antifoam DC 1510

Brown ink on capsule body: Shellac, Iron oxide, red (E172), Iron oxide, black (E172), Titanium dioxide (E171), Propylene glycol

40mg:

Capsule body: Gelatin, titanium dioxide (E171), yellow iron oxide (E 172).

Capsule cap: Gelatin, titanium dioxide (E 171), red iron oxide (E 172).

Ink:

White ink on capsule cap: Titanium dioxide (E171), Shellac, Soya lecithin, Antifoam DC 1510

Brown ink on capsule body: Shellac, Iron oxide, red (E172), Iron oxide, black (E172), Titanium dioxide, (E171), Propylene glycol

What Fluvastatin looks like and contents of the pack

20mg:

Capsule cap: orange, opaque marked with white imprint "20"

Capsule body: ivory, opaque marked with brown imprint "FST"

40mg:

Capsule cap: orange, opaque marked with white imprint "40"

Capsule body: yellow, opaque marked with brown imprint "FST"

Blister packs.

HDPE container with desiccant (silica gel), closed with a sealed plastic cap.

Pack sizes:

Blister packs: 10, 14, 20, 28, 30, 50, 56, 60, 98 and 100 capsules

HDPE bottle with desiccant and plastic cap: 28, 30, 56 and 60 capsules

Not all pack sizes may be marketed

Marketing Authorisation Holder

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