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Package leaflet: Information for the patient

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, pharmacist or nurse.
- 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 (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
5. How to store Fluvastatin Capsules
6. Contents of the pack and other information

1. What Fluvastatin Capsules are and what they are used for

Fluvastatin 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.

- Fluvastain 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 had a heart catheterisation, with an intervention in the heart vessel.

If you have any questions about how Fluvastatin works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Fluvastatin Capsules

Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

Read the following explanations before you take Fluvastatin.

Do not take Fluvastatin Capsules:
- if you are allergic (hypersensitive) to fluvastatin or any of the other ingredients of this medicine (listed in section 6).
- 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 Capsules
- 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).
- if you are allergic to soya or peanut.
- 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 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 have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).

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 Fluvastatin:
- 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.

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.

If during treatment with Fluvastatin, 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.

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 Capsules

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

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using Fluvastatin. 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.

Fluvastatin can be taken on its own or with other cholesterol-lowering medicines prescribed by your doctor.

After intake of a resin, e.g. cholestyramines (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:
- 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).

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.

Take adequate precaution against pregnancy while 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.

Fluvastatin Capsules contain soya oil

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

Fluvastatin Capsules contain mannitol

This medicine contains mannitol and may have a mild laxative effect.

Information on sodium content

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

3. 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.

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

Recommended doses in adults

The dose range of fluvastatin 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.

Use in children and adolescents

For children (aged 9 years and older) the usual starting dose is 20 mg of fluvastatin 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 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 per 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 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 much Fluvastatin, 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 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, 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 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 decreasednumber 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 erythematous-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, abnormal blood test values for muscle and liver.

Very rare:
Tingling or numbness of the hands or feet disturbed or decreased sensitivity

Not known:
- Impotence, muscle weakness that is constant, breathing problems including persistent cough and/or shortness of breath or fever.
- Diarrhoea
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Other possible side effects
- Sleep disturbances, including insomnia and nightmares.
- Memory loss
- Sexual difficulties
- Depression
- 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.
- Inflammation, swelling, and irritation of a tendon.

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

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 carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package to protect from light and moisture.

Leave your capsules in the original packaging, and only remove them when it is time for you to take your medicine.

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 Capsules contain

The active substance is Fluvastatin sodium.

The other ingredients are:
- Capsule contents – Mannitol, Talc, Magnesium stearate
- Capsule shell – Gelatine, Titanium dioxide (E171), Red iron oxide (E172), Yellow iron oxide (E172)
- Printing Ink:
  White ink on capsule cap: Shellac, Titanium dioxide (E171), 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 Capsules look like and contents of the pack

The Capsules are available in two strengths providing either 20 mg or 40 mg Fluvastatin.

The 20mg capsules contain pale yellow powder. One half of the capsule is orange and has the number "20" has been printed on it. The other half of the capsule is ivory coloured and has the letters "FST" printed on it.

The 40mg capsules contain pale yellow powder. One half of the capsule is orange and has the number "40" has been printed on it. The other half of the capsule is yellow and has the letters "FST" printed on it.

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Fluvastatin capsules are available in packs of 14, 28, 30, 50, 56, 60, and 100 Capsules. *Only marketed pack sizes will be printed on the leaflet.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Torrent Pharma (UK) Ltd,
3rd Floor, Nexus Building, 4 Gatwick Road,
Crawley, West Sussex, RH10 9BG, United Kingdom

Manufacturer

Actavis hf,
Reykjavikurvegur 78, IS – 220 Hafnarfjordur, Iceland

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PHARMACODE xxxxxx

Pharmacode Reading Direction

185 mm

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