

# 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 or pharmacist. This includes any possible side effects not listed in this leaflet.
- Your doctor may have given you this medicine before from another company and it may have looked slightly different. Either brand will have the same effect

## 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
6. Contents of the pack and other information

## 1. WHAT FLUVASTATIN IS AND WHAT IT IS USED FOR

The name of your medicine is Fluvastatin 20mg or 40mg Capsules (called fluvastatin throughout this leaflet). It belongs to a group of medicines called "statins".

Fluvastatin contains the active ingredient 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 some types of surgery.

## 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 (hypersensitive) to fluvastatin or any of the other ingredients of this medicine listed in section 6 of this leaflet.
- 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, breast-feeding and fertility").

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

### Warnings and precautions

#### Talk to your doctor 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 kidney disease.
- if you have thyroid disease (hypothyroidism).
- if you have a medical history of muscle diseases affecting you or other members of 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.

#### Fluvastatin and children/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 may 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:

- 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).

#### Fluvastatin with food and drink

You can take fluvastatin with or without food.

#### Pregnancy, breast-feeding and fertility

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 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.

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 capsules contain castor oil.

This can cause stomach upset and diarrhoea.

### 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. 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.

#### How much fluvastatin to take

- 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 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 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 capsules once a day, take your dose in the evening or at bedtime.

If you are taking fluvastatin capsules twice a 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 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 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 or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

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

Serious side effects are rare (affecting less than 1 in 1000 patients) or very rare (affecting less than 1 in 10,000 patients).

#### The following are all serious side effects. You may need urgent medical attention if you have any of them.

- 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 (affects less than 1 in every 10 people):

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

##### Very rare (affects less than 1 in 10,000 people):

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

### 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
- Do not store above 25°C
- Do not throw away any medicines via waste water 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 20mg and 40mg Capsules contain

Each capsule contains fluvastatin sodium equivalent to 20mg or 40mg of fluvastatin. The other ingredients are:

Capsule content: mannitol, cellulose microcrystalline, calcium lactate pentahydrate, carmellose calcium, calcium phosphate, calcium hydrogen phosphate dihydrate, castor oil hydrogenated, magnesium stearate, silica colloidal anhydrous.

Capsule shell: titanium dioxide E 171, gelatine, red iron oxide E 172, yellow iron oxide E 172.

#### What Fluvastatin 20mg and 40mg Capsules look like and contents of the pack

Fluvastatin 20mg Capsules are white opaque/orange opaque.

Fluvastatin 40mg Capsules are white opaque/flesh opaque.

The 20mg capsules are contained in packs of 28.

The 40mg capsules are contained in packs of 28.

#### Marketing Authorization Holder and Manufacturer

##### The marketing authorisation holder is:

Zentiva  
One Onslow Street,  
Guildford  
Surrey, GU1 4YS, UK

##### The manufacturer is:

Sanofi-Aventis Sp. z o.o.,  
Drug Production and Distribution Plant  
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