

## **Package leaflet: Information for the patient**

Statease XL 80 mg prolonged-release tablets

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 Statease XL is and what it is used for
2. What you need to know before you take Statease XL
3. How to take Statease XL
4. Possible side effects
5. How to store Statease XL
6. Contents of the pack and other information

### **1. What Statease XL is and what it is used for**

Statease XL 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 Statease XL 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 Statease XL**

Follow all the doctor’s instructions carefully. They may differ from the general information contained in this leaflet.

Read the following explanations before you take Statease XL.

#### **Do not take Statease XL:**

- 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, breast-feeding and fertility”).

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Statease XL

- If you previously had a liver disease. Liver function tests will normally be done before you start Statease XL, when the 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 have 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.

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 taking Statease XL.**

Your doctor will take a blood test before prescribing Statease XL.

If during treatment with Statease XL, 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 muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

### **Statease XL 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 Statease XL**

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

Statease XL 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 Statease XL.

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

- medicines used to suppress the immune system (e.g. ciclosporin)
- 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, erythromycin or fusidic acid (medicines used to treat bacterial infections)
- 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, breast-feeding and fertility**

Do not take Statease XL 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 (e.g. use reliable contraception) against pregnancy while taking Statease XL.

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

#### **Fertility**

In animal studies no effects on male and female fertility were observed.

### **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 Statease XL**

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 Statease XL.

#### **How much Statease XL to take**

- The recommended dose range for adults is 20 to 80 mg fluvastatin 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 tablets of Statease XL to take.

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

Please note that you cannot use Statease XL 80 mg prolonged-release tablets for all the above dosages. Statease XL is only available as 80 mg prolonged-release tablets. For lower doses (20 mg and 40 mg) your doctor will prescribe other fluvastatin medicines.

### **When to take Statease XL**

If you are taking Statease XL you can take your dose at any time of the day.

Statease XL can be taken with or without meals. Swallow whole with a glass of water; do not divide, chew or crush the tablet.

### **Use in children and adolescents**

For children (aged 9 years and older) the recommended starting dose is 20 mg fluvastatin 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 Statease XL than you should**

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

### **If you forget to take Statease XL**

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 Statease XL**

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

**Rare:** may affect up to 1 in 1,000 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).

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

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- 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 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 have skin swelling, difficulty in breathing, dizziness (signs of severe allergic reaction).
- If you have signs of skin reactions such as skin rash, hives, redness, itching, swelling of the face, eyelids and lips.

**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 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.

#### **Other possible side effects**

**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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Statease XL**

Keep this medicine out of the sight and reach of children.

Blister packs: Keep the blisters in the outer carton in order to protect from light.

Tablet bottle (glass and plastic bottles): Keep the container tightly closed in order to protect from moisture and light.

Do not store above 30°C.

Do not use this medicine after the expiry date, which is stated on the blister, carton and tablet bottle, respectively, 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 further information**

### **What Statease XL contains:**

- The active substance is: fluvastatin. Each prolonged-release tablet contains 80 mg fluvastatin (as fluvastatin sodium).
- The other ingredients are:  
Tablet core:  
Povidone, microcrystalline cellulose, hydroxyethyl cellulose, mannitol, magnesium stearate  
Film-coating:  
Hypromellose 50, macrogol 6000, iron oxide yellow (E172), titanium dioxide (E171).

### **What Statease XL looks like and contents of the pack**

Statease XL are yellow, round, biconvex prolonged release tablets and are available in pack sizes of:  
Blister (OPA/Alu/PVC-Alu): 10, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 and 490 prolonged-release tablets.  
HDPE bottle with desiccant (Do not eat the desiccant) and snap-on cap (LDPE) with a tamper evident ring.  
Pack sizes of 250 prolonged-release tablets.  
Glass bottle with desiccant (Do not eat the desiccant) and HDPE cap: 28, 98, 100, 250 and 500 prolonged release tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

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McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

#### **Manufacturers**

Actavis hf., Reykjavikurvegi 78, IS-222 Hafnarfjörður, Iceland.  
Actavis Ltd., BLB016, Bulebel Industrial Estate, Zejtun ZTN 3000, Malta.  
McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.  
Mylan Hungary Kft., H-2900 Komárom, Mylan utca 1, Hungary.

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium: Fluvastatine Retard Mylan 80 mg tabletten met verlengde afgifte  
Czech Republic: Fluvastatin Mylan 80 mg  
Denmark: Fluvastatin Mylan 80 mg depottabletter  
Finland: Fluvastatin Mylan 80 mg depottabletti  
France: Fluvastatine Mylan L.P. 80 mg, comprimé pelliculé à libération prolongée  
Hungary: Fluvastatin -Generics (UK) 80 mg retard tabletta  
Ireland: Statease XL 80 mg prolonged-release tablets  
Italy: Fluvastatina Mylan Generics  
Netherlands: Fluvastatine Retard Mylan 80 mg, tabletten met verlengde afgifte

Poland: Fluvagen

Portugal: Fluvastatina Mylan 80 mg comprimidos de libertação prolongada

Slovakia: Fluvastatin Mylan 80 mg

Spain: Fluvastatina MYLAN 80 mg comprimidos de liberación prolongada EFG

UK: Pinmactil 80mg prolonged release tablets

**This leaflet was last revised in 02/2016**