

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

VATICOL XL 80 mg

Fluvastatin sodium

Film-coated tablet

Sugar free

Read all of this leaflet carefully before you start taking VATICOL XL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VATICOL XL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What VATICOL XL is and what it is used for

Fluvastatin belongs to a group of medicines called HMG-CoA reductase inhibitors or

'statins'. It works by blocking an enzyme that is needed by the body to make cholesterol.

This reduces the amount of cholesterol that is made by the body. VATICOL XL is used to lower the levels of cholesterol and other fats in the blood. To reduce the risk of undergoing treatments or procedures that restore blood flow to areas of your heart (coronary revascularization).

Before prescribing medicines to lower your cholesterol, your doctor should try to control your condition by recommending a special diet and exercise. Many people are able to control their condition by carefully following the recommended diet and undertaking an exercise program. VATICOL XL is prescribed only when these measures are not effective enough on their own.

2. What you need to know before you take VATICOL XL

Do not take VATICOL XL:

- If you are hypersensitive (allergic) to fluvastatin or to any of the other ingredients of VATICOL XL (see section 6).
- If you have liver disease as VATICOL XL may make liver problems worse.
- If you have severe kidney disease.
- If you are pregnant as VATICOL XL must not be used in pregnancy and should be discontinued if pregnancy occurs during treatment.
- If you are breastfeeding.
- If you are taking other medicines for high cholesterol such as fibrates or gemfibrozil.

VATICOL XL has not been tested in children and must therefore not be used in children under 18 years of age.

Warnings and precautions

Take special care with VATICOL XL:

- If you experience weakness and rapid fatigue of muscles as this may be symptoms of myasthenia gravis.
- If you experience double vision (seeing two images instead of one), trouble focusing, and drooping eyelids as these may be symptoms of ocular myasthenia gravis a condition that affects the muscles that move the eyes and eyelids.
- If you experience unexplained muscle pain, muscle tenderness or muscle weakness, particularly if accompanied by malaise (discomfort) or fever as these may be symptoms of rhabdomyolysis (often called rhabdo) is a serious medical condition that can be fatal or result in permanent disability.
- Your treating doctor will monitor you carefully if:
 - you have kidney problems or an underactive thyroid function
 - you have a personal or family history of muscle disorders or previous history of muscle toxicity with the use of a statin, such as VATICOL XL or a fibrate (used to treat high cholesterol)
 - you abuse alcohol, have an acute infection, low blood pressure, exercise excessively, are having major surgery (including dental surgery)/trauma or uncontrolled seizures
 - you have severe metabolic, hormonal or electrolyte disorders
 - you are an elderly patient (age > 70 years).
- If you have had an organ transplant and/or are taking medicines to prevent transplant rejection as VATICOL XL may increase the chance of certain side effects occurring.
- If you take fusidic acid, an antibiotic used to treat bacterial infections.
- If you experience difficulty to breathe, a non-productive cough and deterioration in general health (fatigue, weight loss and fever) as these may be symptoms of a serious lung condition.
- If you suffer from diabetes mellitus.

Children and adolescents

VATICOL XL tablets are not recommended for use in children under the age of 18 (see Do not take VATICOL XL).

Other medicines and VATICOL XL

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you take any of the following medicines:

- Fibrates (such as gemfibrozil or fenofibrate) and niacin: Used in the treatment of high cholesterol as this may cause muscle damage and should not be taken together (see Do not take VATICOL XL).
- Colchicine: Used to treat gout, as this may cause muscle damage.
- Ciclosporin: Used in organ transplant, as your treating doctor may need to consider a lower dose of fluvastatin.
- Warfarin: Used to thin your blood, as your treating doctor will need to monitor you for an increased risk of bleeding.
- Rifampicin: Used to treat tuberculosis (TB), as your treating doctor may need to adjust your fluvastatin dose.
- Oral antidiabetic medicines: Used to treat diabetes, as your doctor will need to monitor you.
- Bile acid sequestrants (e.g. colestyramine): Used to lower your cholesterol. VATICOL XL should be taken at least 4 hours after colestyramine.
- Fluconazole: Used to treat fungal infections as the concentration of VATICOL XL in your blood may increase.
- Medicines used to treat ulcers in the digestive tract: E.g. cimetidine, ranitidine or omeprazole may increase the concentration of VATICOL XL in your blood.



- Phenytoin: Used to treat fits, as your doctor may need to monitor the concentration of phenytoin in your blood.
- Itraconazole and erythromycin: Used to treat infections as your doctor may decide to monitor the concentration of VATICOL XL in your blood.
- Fusidic acid: An antibiotic used to treat bacterial infections as the risk of muscle damage is increased when used together with VATICOL XL.

VATICOL XL with food, drink and alcohol

VATICOL XL may be taken with food or on an empty stomach. VATICOL XL should be swallowed whole with a full glass of water.

Pregnancy and breastfeeding

VATICOL XL must not be used in pregnancy and should be discontinued if pregnancy occurs during treatment. Women of childbearing potential should use an effective contraceptive during treatment with VATICOL XL.

VATICOL XL must not be used during breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking VATICOL XL.

Driving and using machines

VATICOL XL is not expected to interfere with the ability to drive or use machines.

It is not always possible to predict to what extent VATICOL XL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which VATICOL XL affects you (see section 4).

3. How to take VATICOL XL

Do not share medicines prescribed for you with any other person.

Always take VATICOL XL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Before prescribing medicines to lower your cholesterol, your doctor may try to control your condition by recommending a special diet and exercise. This medicine is prescribed only when these measures are not effective enough on their own.

The usual dose of VATICOL XL is one film-coated tablet (80 mg) taken once daily at night.

VATICOL XL should be taken in the evening or at bedtime. It may be taken with food or on an empty stomach and should be swallowed whole with a full glass of water.

If you have the impression that the effect of VATICOL XL is too strong or too weak, talk to your doctor or pharmacist.

Your doctor may check your cholesterol levels four weeks after you start taking VATICOL XL and at regular intervals thereafter. It is important that your doctor checks your progress at regular visits.

If you take more VATICOL XL than you should

In the event of overdose, consult a doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take VATICOL XL

Do not take a double dose to make up for forgotten individual doses.

If you miss a dose of VATICOL XL, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule.

If you stop taking VATICOL XL

Do not stop taking VATICOL XL without speaking to your doctor. When you stop taking VATICOL XL, your blood cholesterol levels may increase again. Your doctor may want you to follow a special diet to prevent this from happening.

4. Possible side effects

VATICOL XL can have side effects.

Not all side effects reported for VATICOL XL are included in this leaflet. Should your general health worsen while taking VATICOL XL or if you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking VATICOL XL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, eyes, lips and mouth, tongue or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VATICOL XL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital

if you notice any of the following:

- Upper abdominal pain, nausea and vomiting as these may be symptoms of inflammation of the pancreas (pancreatitis).
- Nausea, vomiting, loss of appetite, easy bruising or bleeding, yellowing of skin or the whites of your eyes as this could be signs of problems with your liver (hepatitis and reversible increases in liver enzymes). Your doctor may note the increase in liver enzymes on your laboratory results.
- Muscle and joint pain (sometimes with swelling), flu-like symptoms, fatigue and fever as these may be symptoms of lupus like syndrome.
- Fever, muscle aches or cramps and muscle weakness as these may be symptoms of muscle damage including a condition referred to as immune-mediated necrotising myopathy. Your doctor may note an increase in what is referred to as creatinine phosphokinase on your laboratory results.
- If you have trouble to breathe, a non-productive cough and deterioration in general health (fatigue, weight loss and fever) as these may be symptoms of a serious lung condition.
- Fever, tiredness, weight loss and muscle/joint pain as these may be symptoms of inflammation of the blood vessels (vasculitis).
- Decreased urinary output, swelling due to fluid retention, nausea, fatigue and shortness of breath as these may be symptoms of acute kidney failure.
- Bruising, abnormal bleeding (nose bleeds, bleeding gums, heavy periods), blood in the stool or urine, feeling tired as these may be symptoms associated with a low blood platelet count (thrombocytopenia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache;
- trouble in sleeping (insomnia);
- heartburn (dyspepsia);
- nausea;
- stomach pain.

Less frequent side effects:

- A burning or prickling sensation that is usually felt in the hands, arms, legs, or feet, but can also occur in other parts of the body (paraesthesia);
- an unpleasant, abnormal sense of touch (dysesthesia);
- numbness (hypoesthesia).

Side effects with an unknown frequency:

- Erectile dysfunction,
- diarrhoea.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA**: via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>



Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of VATICOL XL.

5. How to store VATICOL XL

Store all medicines out of reach of children.

Store in a dry and cool place at or below 30 °C. Protect from light and moisture.

Keep the blisters in the carton until required for use.

Do not store in bathrooms.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VATICOL XL contains:

The active ingredient in each VATICOL XL film-coated tablet is fluvastatin 80 mg as fluvastatin sodium.

The other ingredients are gelcarin, hydroxypropyl cellulose, hypromellose, iron oxide red (C.I. 77491), iron oxide yellow (C.I. 77492), macrogol, magnesium stearate, titanium dioxide (C.I. 77891), viscarin.

Sugar free

What VATICOL XL looks like and contents of the pack:

VATICOL XL is a dark yellow, round, biconvex film-coated tablet or a dark yellow, round, biconvex, film-coated tablet with “C 27” debossed on one side and plain on the other side. 28 or 30 tablets are packed into silver, opaque, aluminium/aluminium blisters composed of polyamide/aluminium/polyvinylchloride. The blisters are packed in an outer cardboard carton along with a printed leaflet.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:



E-mail: Medinfo@aspenpharma.com

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