

ELLANCO TABLET

Lovastatin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ELLANCO. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ELLANCO against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ELLANCO is used for

ELLANCO is used together with a proper diet to treat high cholesterol levels in the blood. Using ELLANCO may help prevent medical problems caused by such substances clogging the blood vessels. ELLANCO may also be used to prevent certain types of heart problems in patients with risk factors for heart problems.

ELLANCO contains lovastatin which belongs to the group of medicines called 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors. It works by blocking an enzyme that is needed by the body to make cholesterol, thereby reducing the amount of cholesterol in the blood.

ELLANCO is available only with your doctor's prescription.

Before you take ELLANCO

When you must not take it

Do not take ELLANCO if:

- **you have an allergy to ELLANCO or other brands of simvastatin, or to any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the tongue or face, or painful joints.

- **you are pregnant or breastfeeding**

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

- **you have liver disease**
- **you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides**
- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking ELLANCO, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 1. you intend to become pregnant or plan to breast feed**

ELLANCO should not be used during pregnancy or while breastfeeding.

- 2. you have ever had liver disease**

Your doctor will do a blood test to make sure you have no problems with your liver.

- 3. you have kidney disease or any other medical problems**

- 4. you drink alcohol regularly**

- 5. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you take any ELLANCO.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines should not be taken with ELLANCO as they may increase the risk of muscle side effects with ELLANCO. It is particularly important to tell your doctor if you are taking:

- nefazodone, used to treat depression
- protease inhibitors, used to treat HIV infection, including indinavir, nelfinavir, ritonavir, saquinavir
- erythromycin, clarithromycin and fusidic acid antibiotics used to treat infections

- ketoconazole and itraconazole, used to treat certain fungal infections

If you are taking any of the above, your doctor may suggest stopping ELLANCO temporarily or permanently.

Some medicines and ELLANCO may interfere with each other. Because taking ELLANCO with any of the following drugs can increase the risk of muscle problems, it is particularly important

to tell your doctor if you are taking:

- other medicines to lower cholesterol levels, for example, fibric acid derivatives (such as gemfibrozil and bezafibrate)
- cyclosporin, used to suppress the immune system
- danazol
- verapamil, diltiazem or amlodipine, used to treat high blood pressure, angina or other heart conditions
- amiodarone, used to treat irregular heart beat

It is also important to tell your doctor if you are taking anticoagulants (drugs that prevent blood clots, such as warfarin, nicotinic acid (also known as niacin) or fenofibrate, another fibric acid derivative.

Also tell your doctor if you are taking niacin or a niacin-containing product and you are Chinese.

These medicines may be affected by ELLANCO, may affect how well it works, or may increase the risk of side effects with ELLANCO. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ELLANCO.

How to take ELLANCO

How much to take

Take ELLANCO only when prescribed by your doctor.

Your doctor will tell you how many tablets you need to take each day. This depends on your cholesterol and triglyceride levels and other factors, such as kidney disease.

For adults, the recommended starting dose is 20 mg per day, taken in the evening, which may need to be increased up to 80 mg daily to have the best effect.

For children (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.

Swallow ELLANCO with a glass of water.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

When to take it

Take ELLANCO once a day in the evening.

The liver produces its greatest amount of cholesterol when the body is at rest and when there is no dietary intake. For most people this is at night when asleep. Therefore, ELLANCO is more effective when taken in the evening. A good time would be after your evening meal. However, it does not matter whether you take it before or after food.

Take ELLANCO at about the same time each evening.

Taking your tablet(s) at the same time each evening will have the best effect. It will also help you remember when to take the tablets.

How long to take it

ELLANCO helps lower your cholesterol. It does not cure your condition. Therefore, you must

continue to take it as directed by your doctor if you expect to lower your cholesterol and keep it down. You may have to take cholesterol lowering medicine for the rest of your life. If you stop taking ELLANCO, your cholesterol levels may rise again.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ELLANCO. Do this even if there are no signs of discomfort or poisoning.

While you are using ELLANCO

Things you must do

If you become pregnant while you are taking ELLANCO, stop taking it and contact your doctor immediately.

Have your blood fats checked when your doctor says, to make sure ELLANCO is working.

If you are about to be started on any new medicine tell your

doctor and pharmacist that you are taking ELLANCO.

If you are about to have elective surgery, tell your doctor that you are taking ELLANCO.

Your doctor may suggest stopping the tablets a few days before surgery.

Things you must not do

Do not give ELLANCO to anyone else, even if they have the same condition as you.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of ELLANCO causing liver problems.

Avoid drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including ELLANCO. Therefore, drinking very large quantities (over 1 litre) of grapefruit juice each day increases your chance of ELLANCO causing side effects. These include aching muscles, muscle tenderness or weakness, not caused by exercise.

However, one glass (250mL) of grapefruit juice each day has not been shown to have any significant effect.

Be careful driving or operating machinery until you know how ELLANCO affects you.

ELLANCO generally does not cause any problems with your ability to drive a car or operate machinery.

However, as with many other medicines, ELLANCO may cause dizziness in some people. Make sure you know how you react to ELLANCO before you drive a car or operate machinery.

Changes to lifestyle that may help reduce the chance of coronary heart disease

Lowering high cholesterol can help reduce your chances of having coronary heart disease (CHD).

However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking, diabetes, excess weight, family history of CHD, being a male and being a woman who has reached menopause.

Some self help measures suggested below may help your condition and help reduce your chances of having CHD. Talk to your doctor, pharmacist, or dietician about these measures and for more information.

• Diet

- continue the low fat diet recommended by your doctor, dietician or pharmacist.

• Weight

- your doctor may advise you to lose weight if you are overweight.

• Exercise

- make exercise a part of your routine - walking is good. Ask your doctor for advice before starting exercise.

• Smoking

- your doctor may advise you to stop smoking or at least cut down.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ELLANCO.

ELLANCO helps most people with high cholesterol, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation, diarrhoea, wind
- stomach upset or pain, feeling sick (nausea)
- headache
- dizziness

These are the more common side effects of ELLANCO. For the most part these have been mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- aching muscles, muscle tenderness or weakness, not caused by exercise
- brown/black coloured urine

On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

The risk of muscle problems is greater for:

- patients taking higher doses of ELLANCO.
- older patients (65 years of age and older)
- female patients
- patients with abnormal kidney function
- patients with thyroid problems.

Tell your doctor immediately if you notice any of the following:

- tingling in the hands or feet
- yellowing of the skin and/or eyes, also called jaundice
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- fever, generally feeling unwell
- skin rash, itchiness
- pinkish, itchy swellings on the skin, also called hives or nettle rash

- painful, swollen joints
- bruising more easily than normal
- larger breasts than normal in men

These may be serious side effects of ELLANCO. Some of these may be symptoms of an allergic reaction to ELLANCO. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- shortness of breath

These are serious side effects. If you have them, you may have had a serious allergic reaction to ELLANCO. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Also, tell your doctor if you notice:

- hair loss
- muscle cramps
- trouble sleeping
- poor memory
- feelings of depression
- erectile dysfunction
- breathing problems including persistent cough and/or shortness of breath or fever

These are other side effects that have been reported with ELLANCO.

Liver problems can also occur and may be serious. Your doctor will do blood tests to check your liver.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not

experience any of them.

After using ELLANCO

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep ELLANCO in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking ELLANCO or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ELLANCO 20mg – A round scored tablet, white in colour with markings "DUO 2" and a "Flower".

Ingredients

Active ingredient:

ELLANCO 20mg contains 20mg lovastatin per tablet

Manufacturer / Distributor

ELLANCO is manufactured and distributed in Malaysia by:

DUOPHARMA (M) SDN. BHD. (42491-M)

WHOLLY OWNED BY CCM DUOPHARMA BIOTECH BERHAD (524271-W)

Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Marketing Authorization Holder

DUOPHARMA (M) SDN. BHD. (42491-M)

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