

LIPEX[®]

simvastatin

10 mg, 20 mg, 40 mg & 80 mg tablet

What is in this leaflet

This leaflet answers some common questions about LIPEX. 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 LIPEX 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 LIPEX is used for

LIPEX helps to lower high cholesterol and triglyceride levels.

Everyone has cholesterol and triglycerides in their blood. They are types of blood fat needed by the body for many things.

Your doctor has prescribed LIPEX to reduce the health risks associated with coronary heart disease (CHD).

If you have CHD, diabetes, history of stroke, or other vessel disease (regardless of the amount of cholesterol in your blood), LIPEX:

- can prolong your life by reducing the risk of heart attack or stroke
- reduces the need for surgery to increase blood flow to the legs and major organs such as the heart
- reduces the need for hospitalisation for chest pain (called angina).

Cholesterol

Some of the reasons cholesterol is needed by the body include; building cell walls, making bile acids (which help to digest food) and certain hormones. However, too much cholesterol can be a problem.

Your body makes cholesterol, but it also comes from food.

Normally the body balances the cholesterol it makes with the cholesterol it gets from food. This means if more cholesterol comes from food, less is made by the body. However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol, it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas, called plaque, on the walls of blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and angina), and stroke.

In patients with coronary heart disease (CHD) accompanied by high cholesterol levels, LIPEX may slow down the hardening of blood vessels and may reduce the development of new plaques.

There are different types of cholesterol, called LDL and HDL cholesterol. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol, on the other hand, is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

Triglycerides

Triglycerides are an energy source for the body. However, as with cholesterol, too much triglycerides can be a problem.

How LIPEX Works

LIPEX belongs to a group of medicines known as HMG-CoA reductase inhibitors or statins. It works by reducing the amount of cholesterol made by the liver. In terms of good and bad cholesterol, in most patients, LIPEX reduces the bad cholesterol and can actually raise the good cholesterol.

LIPEX does not reduce the cholesterol that comes from fat in food. Therefore, when you are taking LIPEX, you also need to follow a low fat diet and other measures, such as exercise and weight control.

In most people, there are no symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test.

LIPEX is not recommended for use in children under the age of 10. Safety and effectiveness have been studied in 10-17 year old boys and in girls, who had started their menstrual period at least one year before (see How to take LIPEX). LIPEX has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Your doctor may have prescribed LIPEX for another reason. Ask your doctor if you have any questions about why LIPEX has been prescribed for you.

LIPEX is not addictive.

Before you take LIPEX

When you must not take it

Do not take LIPEX if:

- you have an allergy to LIPEX or ZOCOR[®] (which are both a brand 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, trying to get pregnant, suspect that you are pregnant or breast-feeding.
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 LIPEX, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you intend to become pregnant or plan to breast feed. LIPEX should not be used during pregnancy or while breast-feeding
- you have ever had liver disease. Your doctor will do a blood test to make sure you have no problems with your liver.
- you have kidney disease or any other medical problems
- you have severe lung disease
- you drink alcohol regularly
- 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 LIPEX.

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. You should also tell your doctor who is prescribing a new medication for you that you are taking LIPEX.

Because taking LIPEX with any of the following medicines can increase the risk of muscle problems (see Adverse Effects), it is particularly important to tell your doctor if you are taking:

- fibric acid derivatives such as gemfibrozil and bezafibrate
- erythromycin, clarithromycin, telithromycin, and fusidic acid, antibiotics used to treat infections
- ketoconazole and itraconazole, medicines used to treat certain fungal infections
- cyclosporin, a medicine used to suppress the immune system
- danazol, a hormone used to treat gynaecological problems
- nefazodone, a medicine used to treat depression
- amiodarone, a medicine used to treat an irregular heartbeat
- verapamil, diltiazem, or amlodipine (medicines used to treat high blood pressure, angina, or other heart conditions)
- protease inhibitors, used to treat HIV infection, including indinavir, nelfinavir, ritonavir, saquinavir

It is also important to tell your doctor if you are taking anticoagulants, (medicines used to prevent blood clots such as warfarin, phenprocoumon or acenocoumarol), or niacin. Also tell your doctor if you are taking niacin or a niacin-containing product and are ethnic Chinese.

These medicines may be affected by LIPEX, or may affect how well it works. 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 LIPEX.

How to take LIPEX

How much to take

Take LIPEX 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 level and other factors, such as kidney disease.

For adults the usual starting dose is 20 mg or 40 mg per day, given as a single dose in the evening. Your doctor may adjust your dose to a maximum of 80 mg a day, given as a single dose in the evening.

The 80 mg dose is only for patients who have not reached their cholesterol goal on the 40 mg dose.

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.

Your doctor may prescribe lower doses, particularly if you are taking some of the medications listed above (see Taking Other Medicines) or have certain kidney conditions.

Swallow LIPEX 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 on the box, ask your doctor or pharmacist for help.

When to take it

Take LIPEX 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, LIPEX 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 LIPEX 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

LIPEX 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 LIPEX, 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 the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much LIPEX. Do this even if there are no signs of discomfort or poisoning.

While you are using LIPEX

Things you must do

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

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

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking LIPEX.

If you are about to have elective surgery, tell your doctor that you are taking LIPEX. Your doctor may suggest stopping the tablets a few days before surgery.

Things you must not do

Do not give LIPEX 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 LIPEX causing liver problems.

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

LIPEX generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, LIPEX may cause dizziness in some people. Make sure you know how you react to LIPEX before you drive a car or operate machinery.

Things that would be helpful for lowering your cholesterol

Changes to lifestyle 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.

Adverse Effects

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

LIPEX helps most people with high cholesterol, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse 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 adverse effects of LIPEX. 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
- 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 nettlerash
- painful, swollen joints
- bruising more easily than normal
- larger breasts than normal in men
- breathing problems including persistent cough and/or shortness of breath or fever

These may be serious adverse effects of LIPEX. Some of these may be symptoms of an allergic reaction to LIPEX. On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage. The risk of muscle breakdown is greater for patients taking higher doses of LIPEX. The risk of muscle breakdown is greater for older patients (65 years of age and older), female patients, patients with abnormal kidney function and patients with thyroid problems. You may need urgent medical attention. Serious adverse 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 adverse effects. If you have them, you may have had a serious allergic reaction to LIPEX. You may need urgent medical attention or hospitalisation. Serious adverse effects are rare.

Also, tell your doctor if you notice:

- hair loss
- muscle cramps

- poor memory
- trouble sleeping
- depression
- erectile dysfunction

These are other adverse effects that have been reported with LIPEX.

Possible adverse effects reported with some statins:

- sleep disturbances, including trouble sleeping and nightmares
- memory loss
- sexual difficulties
- depression
- breathing problems including persistent cough and/or shortness of breath or fever

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

Other adverse 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 adverse effects. You may not experience any of them.

After using LIPEX

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 LIPEX in a cool dry place where the temperature stays below 30°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 LIPEX 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

LIPEX comes in four types of tablets:

- LIPEX 10 mg - peach coloured, oval-shaped tablet with "MSD 735" marked on one side
- LIPEX 20 mg - tan coloured, oval-shaped tablet with "MSD 740" marked on one side
- LIPEX 40 mg - brick-red coloured, oval-shaped tablet with "MSD 749" marked on one side
- LIPEX 80 mg – brick red coloured, capsule shaped tablet with 543 marked on one side and 80 on the other.

A box of LIPEX contains 30 tablets.

Ingredients

Active ingredient:

- LIPEX 10 mg - 10 mg simvastatin per tablet
- LIPEX 20 mg - 20 mg simvastatin per tablet
- LIPEX 40 mg - 40 mg simvastatin per tablet
- LIPEX 80 mg – 80 mg simvastatin per tablet

Inactive ingredients:

- butylated hydroxyanisole
- ascorbic acid
- citric acid monohydrate
- cellulose
- starch - pregelatinised maize
- magnesium stearate
- lactose
- hypromellose
- hydroxypropylcellulose
- titanium dioxide
- talc
- iron oxide yellow CI77492 (10 mg and 20 mg tablets)
- iron oxide red CI77491 (10 mg, 20 mg and 40 mg tablets)

LIPEX does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

LIPEX is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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