

NEW ZEALAND CONSUMER MEDICINE INFORMATION

VYTORIN[®]

ezetimibe/simvastatin

10/10 mg, 10/20 mg, 10/40 mg & 10/80 mg tablets

What is in this leaflet

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

VYTORIN helps to lower high LDL (bad) cholesterol and triglyceride levels, and raises levels of HDL (good) cholesterol). VYTORIN is for adults and adolescents (10 to 17 years of age) who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

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

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.

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 VYTORIN Works

VYTORIN is a combination of ezetimibe a medicine that reduces the cholesterol absorbed in your digestive tract, and simvastatin an HMG-CoA reductase inhibitor (a statin) that works by reducing the amount of cholesterol made by the liver.

VYTORIN does not help to lose weight.

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

VYTORIN is not recommended for use in children under 10 years of age.

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

VYTORIN is not addictive.

Before you take VYTORIN

When you must not take it

Do not take VYTORIN if:

- you have an allergy to VYTORIN or LIPEX (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 kidney disease or any other medical problems
- you are taking any of the following medicines
 - certain antifungal medicines (such as itraconazole, ketoconazole, or posaconazole)
 - HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir and saquinavir)
 - certain antibiotics (such as erythromycin, clarithromycin, or telithromycin)
 - the antidepressant nefazodone
 - gemfibrozil (a fibric acid medicine for lowering cholesterol)
 - cyclosporine
 - danazol

Ask your doctor if you are not sure if your medicine is listed above.

- 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 VYTORIN, talk to your doctor.

Before you start to take it

Tell your doctor promptly if:

- You have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides
- you intend to become pregnant or plan to breast feed.
VYTORIN 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 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 VYTORIN.

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 any doctor who is prescribing a new medication for you that you are taking VYTORIN.

Because taking VYTORIN 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:

- other medicines to lower cholesterol levels, for example gemfibrozil or other fibrates
- erythromycin, clarithromycin, telithromycin, and fusidic acid, antibiotics used to treat infections
- medicines used to treat certain fungal infections (such as ketoconazole, itraconazole or posaconazole)
- cyclosporin, a medicine used to suppress the immune system
- danazol, a hormone used to treat gynaecological problems
- nefazodone, a medicine used to treat depression
- verapamil, diltiazem, or amlodipine (medicines used to treat high blood pressure and angina)
- protease inhibitors, used to treat HIV infection, including indinavir, nelfinavir, ritonavir, saquinavir
- amiodarone, a medicine used to treat cardiac arrhythmia

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

Some of these have already been listed in the above section "When you must not take it"

If your doctor has prescribed VYTORIN along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, VYTORIN should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

These medicines may be affected by VYTORIN, 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 VYTORIN.

How to take VYTORIN

How much to take

Adults: Take VYTORIN only when prescribed by your doctor.

Take one VYTORIN 10/10, 10/20, 10/40 or 10/80 tablet by mouth each day with a glass of water, in the evening.

Because of the increased risk of muscle problems, the VYTORIN 10/80 tablet is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

Adolescents (10 to 17 years of age): Take one VYTORIN 10/10, 10/20, or 10/40 tablet by mouth each day, in the evening.

VYTORIN can be taken with or without food.

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 VYTORIN 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, the simvastatin component of VYTORIN 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 VYTORIN at about the same time each evening.

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

How long to take it

VYTORIN 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 VYTORIN, 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 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 tablet, 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 VYTORIN. Do this even if there are no signs of discomfort or poisoning.

While you are using VYTORIN

Things you must do

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

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

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

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

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.

- The risk of muscle breakdown is greater at higher doses of VYTORIN, particularly the 10/80 mg dose.
- The risk of muscle breakdown is also greater for older patients (65 years of age and older), female patients, patients with kidney problems, and patients with thyroid problems

Things you must not do

Do not give VYTORIN 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 VYTORIN causing liver problems.

Avoid drinking large quantities of grapefruit juice (over 1 litre daily), this can affect the manner in which VYTORIN is absorbed into the blood stream.

Be careful driving or operating machinery until you know how VYTORIN affects you. There have been side effects reported with VYTORIN that may affect your ability to drive or operate machinery. Individual responses to VYTORIN may vary. (See Adverse Effects.) As with many other medicines, VYTORIN may cause dizziness in some people. Make sure you know how you react to VYTORIN before you drive a car or operate machinery.

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 VYTORIN. 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.

In clinical studies, VYTORIN was generally well tolerated. The adverse effects were usually mild, temporary, and similar in type and frequency to adverse effects in patients who were given ezetimibe alone or simvastatin alone (the active ingredients of VYTORIN) (see Before you take VYTORIN and While you are using VYTORIN).

The following common adverse effects were reported: muscle aches; elevations in laboratory blood tests of liver (transaminases) and/or muscle (CK) function.

These are the more common adverse effects of VYTORIN. For the most part these have been mild and short lived.

The following uncommon adverse effects were reported: elevations in blood tests of liver function; elevations in blood uric acid; elevations in the time it takes for blood to clot; protein in urine; weight decreased; dizziness; headache; tingling sensation in the hands or feet; stomach pain; indigestion; flatulence (wind); feeling sick (nausea); vomiting; stomach bloating; diarrhoea; dry mouth; heartburn; rash; itching; hives; painful, swollen joints; muscle pain, tenderness, weakness or spasms; neck pain; pain in arms and legs; back pain; unusual tiredness or weakness; feeling tired; chest pain; swelling, especially in the hands and feet; sleep disorder; trouble sleeping.

Additionally, the following adverse effects have been reported during clinical studies and/or general use with either VYTORIN, ezetimibe or simvastatin tablets (tablets that contain the active ingredients of VYTORIN).

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

- constipation
- inflammation of the pancreas
- gallstones
- inflammation of the gallbladder
- poor memory
- erectile dysfunction

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

- aching muscles, muscle cramps, tenderness or weakness, not caused by exercise
- yellowing of the skin and/or eyes, also called jaundice, which may indicate hepatitis or other liver problems (sometimes serious)
- depression
- 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
- raised red rash, sometimes with target-shaped lesions
- bruising more easily than normal
- breathing problems including persistent cough and/or shortness of breath or fever

These may be serious adverse effects of VYTORIN. Some of these may be symptoms of an allergic reaction to VYTORIN. 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 VYTORIN. 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 VYTORIN. You may need urgent medical attention or hospitalisation. Serious adverse effects are rare.

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

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 VYTORIN

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 VYTORIN 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 VYTORIN 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

VYTORIN comes in four types of tablets:

- VYTORIN 10/10 mg - a white to off white, capsule shaped, biconvex compressed tablet marked 311 on one side
- VYTORIN 10/20 mg – a white to off white, capsule shaped, biconvex compressed tablet marked 312 on one side
- VYTORIN 10/40 mg - a white to off white, capsule shaped, biconvex compressed tablet marked 313 on one side
- VYTORIN 10/80 mg - a white to off white, capsule shaped, biconvex compressed tablet marked 315 on one side

A box of VYTORIN contains 30 tablets.

Ingredients

Active ingredient:

- VYTORIN 10/10 mg - 10 mg ezetimibe & 10 mg simvastatin per tablet
- VYTORIN 10/20 mg - 10 mg ezetimibe & 20 mg simvastatin per tablet
- VYTORIN 10/40 mg - 10 mg ezetimibe & 40 mg simvastatin per tablet
- VYTORIN 10/80 mg - 10 mg ezetimibe & 80 mg simvastatin per tablet

Inactive ingredients:

- butylated hydroxyanisole
- citric acid monohydrate
- croscarmellose sodium
- hydroxypropyl methylcellulose
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- propyl gallate

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

Supplier

VYTORIN is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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