

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## SIMVASTATIN MYLAN

*Simvastatin film-coated tablets 10mg, 20mg, 40mg & 80mg*



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### What is in this leaflet

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Please read this leaflet carefully before you start taking Simvastatin Mylan.

This leaflet answers some common questions about Simvastatin Mylan.

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 Simvastatin Mylan 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.

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### What Simvastatin Mylan is used for

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Simvastatin Mylan helps to lower high cholesterol and triglyceride levels, and is used to reduce the health risks associated with coronary heart disease (CHD).

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

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

#### **Cholesterol**

Everyone has cholesterol and triglycerides in their blood. They are the types of blood fat needed by the body for building cell walls, making bile acids (which help to digest food) and certain hormones, and other functions.

There are different types of cholesterol, for example, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

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, especially the LDL.

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. In most people, there are no symptoms of high cholesterol at early stage and it would only be shown in blood test. After a certain length of time, the built-up of cholesterol 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 CHD accompanied by high cholesterol levels, simvastatin may slow down the hardening of blood vessels and may reduce the development of new plaques.

#### **Triglycerides**

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

Simvastatin Mylan contains the active ingredient simvastatin, which belongs to a group of medicines known as HMG-CoA reductase inhibitors.

It works by reducing the amount of cholesterol made by the liver. In most patients, simvastatin reduces the bad cholesterol and can raise the good cholesterol.

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

Your doctor may have prescribed this medicine for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

This medicine is available only with a doctor's prescription.

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### Before you take Simvastatin Mylan

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#### ***When you must not take it***

**Do not take Simvastatin Mylan if you have an allergy to:**

- any medicine containing simvastatin

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take Simvastatin Mylan if you have, or have had, the following medical conditions:**

- active liver disease
- muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.

**Do not take this medicine if you are taking any of the following medicines:**

- itraconazole, ketoconazole, posaconazole and voriconazole, used to treat certain fungal infections
- indinavir, nelfinavir, ritonavir and saquinavir, protease inhibitors used to treat HIV infection
- boceprevir and telaprevir, antiviral agents used to treat hepatitis C
- erythromycin, clarithromycin and telithromycin, antibiotics used to treat infections
- nefazodone, used to treat depression
- medicines containing cobicistat (used in the treatment of HIV infection)
- gemfibrozil, used to treat high cholesterol levels
- cyclosporin, used to suppress the immune system
- danazol, used to treat gynaecological problems.

**Do not take Simvastatin Mylan if you are pregnant, intend to become pregnant, or are breast-feeding.**

It may affect your baby.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged,

return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you intend to become pregnant or breastfeed.** Simvastatin Mylan should not be used during pregnancy or while breast-feeding.

**Tell your doctor if you:**

- have liver disease (your doctor will need to do a blood test to check your liver function)
- have kidney disease or any other medical conditions
- have severe breathing problems
- drink alcohol regularly.

**If you have not told your doctor about any of the above, tell them before you start taking Simvastatin Mylan.**

### ***Taking other medicines***

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Simvastatin Mylan.

Some medicines may interfere with Simvastatin Mylan. These include:

- amiodarone, used to treat an irregular heart beat
- verapamil, diltiazem or amlodipine, used to treat high blood pressure, angina or other heart conditions
- lomitapide, used to treat a serious and rare genetic cholesterol condition
- nicotinic acid (also known as niacin), used to lower cholesterol levels.

- fusidic acid, an antibiotic used to treat infections
- elbasvir and grazoprevir, used to treat hepatitis C
- warfarin, or other anticoagulants used to prevent blood clots
- colchicine, used for gout
- digoxin, used to treat heart failure
- daptomycin, a medicine used to treat complicated skin and skin structure infections.

These medicines may be affected by Simvastatin Mylan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## **How to take Simvastatin Mylan**

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**Follow all directions given to you by your doctor or 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.**

### ***How much to take***

**Take Simvastatin Mylan 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.

**Adults:** the usual starting dose is 20 mg or 40 mg per day, which may need to be increased up to 80 mg daily.

**Children (10 – 17 years old):** the usual starting dose is 10 mg per day. The maximum daily dose is 40 mg.

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 and liver problems.

## ***How to take it***

**Swallow the tablets whole with a full glass of water.**

## ***When to take it***

**Take Simvastatin Mylan 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, Simvastatin Mylan 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 this medicine before or after food.

**Take your medicine at about the same time each evening.**

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

## ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps lower your cholesterol but does not cure your condition. You may have to take cholesterol-lowering medicine for the rest of your life. If you stop taking Simvastatin Mylan, 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 medicine as you would normally.**

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

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

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

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## **While you are taking Simvastatin Mylan**

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### ***Things you must do***

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Your doctor may suggest stopping Simvastatin Mylan a few days before surgery.

**If you become pregnant while taking Simvastatin Mylan, stop taking it and tell your doctor immediately.**

Keep all your doctor’s appointments so that your progress can be checked.

Your doctor may request some tests to check your blood cholesterol levels to make sure the medicine is working properly, and to prevent unwanted side effects.

### ***Things you must not do***

**Do not stop taking Simvastatin Mylan without checking with your doctor.**

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

**Do not use Simvastatin Mylan to treat any other medical complaints, unless your doctor tells you to.**

### ***Things to be careful of***

**Avoid drinking large quantities of alcohol.**

Drinking large quantities of alcohol may increase your chance of simvastatin 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 simvastatin. Therefore, drinking very large quantities (over 1 litre) of grapefruit juice each day increases your chance of simvastatin causing side effects. These include aching muscles, muscle tenderness or weakness, which is not caused by exercise.

**Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking this medicine until you know how it affects you.**

Simvastatin Mylan generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause dizziness in some people.

## ***Things that would be helpful for lowering your cholesterol***

Lowering high cholesterol can help reduce your chance of having 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** - eat a healthy low-fat diet, which includes plenty of fresh fruit, vegetables, bread, cereals and fish. Also, eat less sugar. Check with your doctor, dietician or pharmacist for a suitable diet program.

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

**Exercise** - regular exercise helps reduce cholesterol levels and helps the heart get fitter, but it is important not to overdo it. Walking is a good exercise. Try to find a route that is fairly flat. Before starting, ask your doctor for the most suitable exercise program for you.

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

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## In case of overdose

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### *If you take too much (overdose)*

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Simvastatin Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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## Side effects

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

This medicine 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 attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

**Tell your doctor or pharmacist 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 some of the more common side effects of Simvastatin Mylan. They are usually mild and short-lived.

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

- aching muscles, muscle tenderness or weakness, which is 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 nettle-rash
- painful, swollen joints
- bruising more easily than normal
- larger breasts than normal in men.

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

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 simvastatin
- patients 65 years of age or older
- female patients
- patients with abnormal kidney function
- patients with thyroid problems.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

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

The above list includes very serious side effects. If you have them, you may have had a serious allergic reaction to Simvastatin Mylan. You may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people. Some of these side effects, for example, changes in liver function, can only be found when your doctor does tests from time to time to check your progress.

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## After taking Simvastatin Mylan

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### **Storage**

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

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

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

Do not store Simvastatin Mylan or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any that are left over.

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## Product description

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### **What it looks like**

Simvastatin Mylan film coated tablets come in four strengths:

Simvastatin Mylan 10 mg - pinkish brown coloured, oval, biconvex, film coated tablets with 'BL' debossed on one side and '10' debossed on the other side.

Simvastatin Mylan 20 mg - peach coloured, oval, biconvex, film coated tablets with 'BL' debossed on one side and '20' debossed on the other side.

Simvastatin Mylan 40 mg - dull pink coloured, oval, biconvex,

film coated tablets with 'BL'  
debossed on one side and '40'  
debossed on the other side.

Simvastatin Mylan 80 mg -  
pink coloured, capsule shaped,  
biconvex, film coated tablets with  
'80' debossed on one side.

## ***Ingredients***

### **Active ingredient**

The active ingredient in Simvastatin Mylan tablets is simvastatin.

Each Simvastatin Mylan 10 mg film coated tablet contains 10 mg of simvastatin.

Each Simvastatin Mylan 20 mg film coated tablet contains 20 mg of simvastatin.

Each Simvastatin Mylan 40 mg film coated tablet contains 40 mg of simvastatin.

Each Simvastatin Mylan 80 mg film coated tablet contains 80 mg of simvastatin.

Each film coated tablet also contains:

- lactose monohydrate
- maize starch
- microcrystalline cellulose
- sodium starch glycolate
- ascorbic acid
- citric acid monohydrate
- pregelatinised maize starch
- colloidal silicon dioxide
- magnesium stearate
- butylated hydroxytoluene
- isopropyl alcohol
- purified water
- hypromellose
- purified talc
- titanium dioxide
- macrogol 400
- red iron oxide
- yellow iron oxide (10 mg and 20 mg tablets only).

Simvastatin Mylan tablets do not contain sucrose or gluten.

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## **If you want to know more**

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

## ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Eilerslie,  
Auckland.

Telephone: (09) 579 2792

## ***Date of Information***

26 July 2019

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