

# NOUMED SIMVASTATIN

*simvastatin tablets*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about NOUMED SIMVASTATIN.

It does not contain all of 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 taking this medicine against the benefits it is expected to 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 NOUMED SIMVASTATIN is used for

NOUMED SIMVASTATIN tablets contain the active ingredient simvastatin.

Simvastatin belongs to a group of medicines called HMG-CoA reductase inhibitors or 'statins'. These are drugs that help people control their high cholesterol and triglyceride levels.

It is also used in people who have coronary heart disease (CHD), or who are at high risk of CHD, for example those with diabetes, a history of stroke or other blood vessel disease, regardless of their cholesterol level. If you are in this group, NOUMED SIMVASTATIN may be prescribed by your doctor to:

- help prolong life by reducing the risk of a heart attack
- reduce the risk of stroke
- reduce the need for surgery to increase blood flow to the heart
- reduce the need for hospitalisation because of angina (chest pain).

#### Cholesterol

Everyone has cholesterol in their blood. It is a type of blood fat needed by the body for many things, such as building cell walls, making bile acids (which help to digest food) and certain hormones.

Cholesterol is present in many foods and is also made in your body by the liver. If your body does not balance the amount of cholesterol it makes with the amount of cholesterol taken from food, then your cholesterol levels become too high.

There are two main types of cholesterol, known as LDL and HDL. LDL is the 'bad' cholesterol that can block your blood vessels, while HDL is the 'good' cholesterol that is thought to remove the 'bad' cholesterol from the blood vessels.

When you have high levels of cholesterol, some LDL may 'stick' to the inside walls 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 your blood vessels. This hardening and narrowing of your blood vessels make it more difficult for blood to flow, which can lead to heart disease (causing heart attacks and angina), and stroke (where blood flow to the brain is interrupted).

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

#### Triglycerides

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

#### How simvastatin works

Simvastatin lowers 'bad' cholesterol (LDL) and raises 'good' cholesterol (HDL) levels. It works by reducing the amount of cholesterol made by the liver in your body.

Simvastatin does not reduce cholesterol and triglycerides that come from fats in food. Therefore, NOUMED SIMVASTATIN treatment should be accompanied by a diet that is low in fat (preferably unsaturated and of vegetable origin), and other lifestyle measures (such as exercise and weight control).

In patients with CHD and high cholesterol levels, simvastatin may slow down the hardening of blood vessels and reduces the risk of new plaque development.

In most people, there are no symptoms of high cholesterol or triglycerides. You may not realise it until your doctor organises a blood test to measure LDL, HDL, total cholesterol and triglycerides.

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

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

NOUMED SIMVASTATIN is not recommended in children and adolescents, since there are limited data on its effects in these age groups.

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## Before you take it

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### *When you must not take it*

**Do not take this medicine if you have an allergy to simvastatin, or to any of the inactive ingredients listed at the end of this leaflet under Product Description.**

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

**Do not take this medicine if you are, or plan to be, 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.

It may affect your developing baby if you take it during pregnancy.

**Do not take this medicine if you have or have had any of the following medical conditions:**

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

**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 you take it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return the pack 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 intend to become pregnant or plan to breast feed. NOUMED SIMVASTATIN should not be used during pregnancy or while breast-feeding.
- you have unexplained muscle pain, tenderness or weakness not caused by exercise. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death. Your doctor may do a blood test to check for certain muscle problems.
- you have, or had ever had, liver disease. Your doctor will do a blood test to make sure you have no problems with your liver.
- you have kidney problems
- you drink alcohol regularly
- you have allergies to the ingredients in this medicine, any other medicines especially if they are in the same drug class as simvastatin, any other medicines, foods, preservatives or dyes.

**If you have not told your doctor about any of the above, tell him/her before you start taking NOUMED SIMVASTATIN.**

### **Taking other medicines**

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

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

- nefazodone, used for depression
- medicines containing cobicistat (a drug used in the treatment of HIV infection)
- protease inhibitors used to treat HIV infection, including

indinavir, nelfinavir, ritonavir and saquinavir

- certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
- gemfibrozil, used to treat high cholesterol levels
- ciclosporin, used to suppress the immune system
- danazol
- erythromycin, clarithromycin, telithromycin and fusidic acid (antibiotics for infections)
- ketoconazole, itraconazole, posaconazole and voriconazole, used to treat certain fungal infection.

If you are taking any of the medicines listed above, your doctor may suggest stopping NOUMED SIMVASTATIN temporarily or permanently.

Other medicines and NOUMED SIMVASTATIN may interfere with each other. It is particularly important to tell your doctor if you are taking any of the following medicines because taking NOUMED SIMVASTATIN with these medicines can increase the risk of muscle problems.

- other medicines used to lower cholesterol levels, e.g. fibric acid derivatives (such as gemfibrozil) or nicotinic acid (also known as niacin)

If you are taking medicines containing niacin, also tell you doctor if you are of Chinese or Asian origin.

- warfarin, or other drugs used to prevent blood clots
- colchicine, used to treat gout
- verapamil, diltiazem or amlodipine, used to treat high blood pressure, angina or other heart conditions
- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)

- amiodarone, used to treat irregular heartbeat.
- digoxin, used to treat heart failure.
- daptomycin, a drug used to treat complicated skin and skin structure infections and bacteraemia

These medicines may be affected by NOUMED SIMVASTATIN, or may affect how well it works. You may need to take different amounts of your medicine 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 NOUMED SIMVASTATIN.

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## How to take NOUMED SIMVASTATIN

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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, ask your doctor or pharmacist for help.**

### **How much to take**

The amount of NOUMED SIMVASTATIN to be taken depends on your cholesterol and triglyceride levels and other factors, such as kidney disease.

The recommended starting dose for adults is 10 mg or 20 mg per day, which may be increased to achieve the best effect.

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

For people with CHD or risk factors for CHD, the usual starting dose is 40mg per day.

Your doctor may have prescribed a different dose.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

If you take the wrong dose, NOUMED SIMVASTATIN may not work as well and your problem may not improve.

### **How to take it**

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

If you need to break the tablet in two, hold it with both hands and snap along the break line.

### **When to take it**

**Take your medicine 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 they are asleep.

Therefore, NOUMED SIMVASTATIN is more effective when taken in the evening. It does not matter whether you take it with or without food, but a good time would be after your evening meal.

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

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

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

Your doctor will determine how long you have to take NOUMED SIMVASTATIN.

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

This medicine helps to lower your cholesterol levels, but 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 medicines for the rest of your life. If you stop taking this medicine, your cholesterol levels may rise again.

### **If you forget to take it**

**Take your dose as soon as you remember, and continue to take it as you would normally.**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**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.**

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

**Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else has taken too much NOUMED SIMVASTATIN. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Keep this telephone number handy.

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## While you are taking it

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### **Things you must do**

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

**Have your blood fats checked when your doctor says so, to make sure this medicine is working.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NOUMED SIMVASTATIN.**

**If you are going to have surgery, tell your doctor that you are taking NOUMED SIMVASTATIN.**

Your doctor may advise you to stop taking this medicine a few days before surgery.

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

**Do not stop taking NOUMED SIMVASTATIN without checking with your doctor.**

**Do not take NOUMED SIMVASTATIN to treat any other complaints unless your doctor tells you to.**

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

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

**Avoid drinking large quantities of alcohol.**

It may increase the chance of NOUMED SIMVASTATIN causing liver problems.

**Avoid drinking grapefruit juice.**

Grapefruit juice contains some components that influence the metabolism of medicines, including NOUMED SIMVASTATIN. This increases the risk of side effects, such as aching muscles, muscle tenderness or weakness, not caused by exercise.

**Be careful driving or operating machinery until you know how NOUMED SIMVASTATIN affects you.**

As with many other medicines, NOUMED SIMVASTATIN may cause dizziness or light-headedness in some people.

***Lifestyle changes that may help reduce the chance of having CHD***

Lowering high cholesterol levels 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, and a family history of CHD. Men, and menopausal women are also at higher risk.

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

- a low fat diet
- losing weight if you are overweight
- moderate exercise as part of your routine. Before starting, you should ask your doctor about the most suitable exercises for you.
- Stop or cut down on smoking.

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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 NOUMED SIMVASTATIN.**

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.**

**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 the more common side effects of NOUMED SIMVASTATIN. Mostly, these are 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.

In very rare cases, this may not go away after stopping NOUMED SIMVASTATIN

- brown/black coloured urine..  
These are signs of rare but serious muscle problems or breakdown resulting in kidney damage that can lead to death. The risk of muscle problems is higher in patients taking higher doses of simvastatin (particularly the 80mg dose); older patients (65 years of age and older); female patients; patients with abnormal kidney function; and patients with thyroid problems.
- tingling in the hands or feet
- 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 usual
- in men, larger breasts than normal (gynaecomastia)
- muscle rupture
- skin rashes and mouth sores (called lichenoid drug eruptions)

These may be serious side effects of NOUMED SIMVASTATIN. You may need urgent medical attention. Serious side effects are rare.

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

- sudden signs of an allergic reaction such as rash, itching or hives (pinkish, raised areas) on the skin, swelling of the face, lips, tongue or other parts of the body,

shortness of breath, wheezing or trouble breathing

Other side effects have been reported with simvastatin.

**Tell your doctor if you notice:**

- hair loss
- muscle cramps
- trouble sleeping
- poor memory, memory loss, confusion
- feelings of depression
- blurred or impaired vision
- erectile dysfunction
- 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 regular blood tests to check your liver.

**Tell your doctor immediately if you have the following symptoms:**

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes

Other side effects not listed above may also occur in some people.

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

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## After taking it

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### Storage

**Keep your medicine in the original container until it is time to take them.**

If you take the tablets out of its container, they may not keep well.

**Keep your medicine in a cool, dry place, protected from light, 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 on a windowsill or in the car.

Heat and dampness can destroy some medicines.

**Keep this medicine 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 its expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

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## Product description

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### What it looks like

NOUMED SIMVASTATIN is available in 3 strengths that are supplied in blister packs of 30 tablets each.

10 mg: pale pink, oval, scored, convex, film-coated tablets with 'SIM 10' marked on one side.

20 mg: orange, oval, scored, convex, film-coated tablets with 'SIM 20' marked on one side.

40 mg: pink, oval, scored, convex, film-coated tablets with 'SIM 40' marked on one side.

### Ingredients

#### Active ingredient

NOUMED SIMVASTATIN tablets contain either 10 mg, 20 mg or 40 mg of simvastatin.

#### Inactive ingredients

- lactose monohydrate
- pregelatinized maize starch
- microcrystalline cellulose
- hypromellose
- ascorbic acid
- citric acid monohydrate
- butylated hydroxyanisole

- magnesium stearate
- purified talc
- titanium dioxide
- iron oxide red
- iron oxide yellow (10 mg and 20mg tablets only)

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

### Sponsor

Avallon Pharmaceuticals Pty Ltd  
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### Australian registration numbers

10 mg: AUST R 298189  
20 mg: AUST R 298190  
40 mg: AUST R 298191

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