

# Simvastatin: why your dose or treatment may have recently changed

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## Key messages

Simvastatin is a medicine used to lower cholesterol and reduce the risk of heart problems and strokes.

- As with any medicine, simvastatin may cause side effects in some people. Most side effects are mild, but very rarely they can be serious
- Some medical studies have found that taking high doses of simvastatin together with the medicines amlodipine or diltiazem may increase the risk of side effects such as muscle pain or cramps, and rarer serious muscle effects
- Your doctor may have reduced the dose of your simvastatin treatment or changed your treatment to another statin because you are taking another medicine, such as amlodipine or diltiazem
- Stop taking simvastatin and see your doctor as soon as possible if you experience muscle pain or cramps whilst taking this medicine, whether or not you are also taking amlodipine or diltiazem



**Your doctor may change your simvastatin treatment if you are taking some other medicines. If you experience muscle pain or cramps while taking simvastatin, stop taking it and see your doctor as soon as possible.**

## What is simvastatin and what does it do?

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Simvastatin belongs to a widely used group of medicines called statins which are used in adults to lower their cholesterol levels. It is given to people with:

- high levels of cholesterol or fats in their blood
- an inherited illness called familial hypercholesterolaemia that increases cholesterol levels
- coronary heart disease (eg. heart attacks, angina), diabetes, a history of stroke, or other blood vessel diseases

Cholesterol is a chemical produced in the body and also contained in food. A certain amount is necessary for good health, but too much cholesterol in the blood can

cause a build-up of fat in the blood vessels, which increases the risk of heart disease and stroke.

Therefore it is important to lower cholesterol levels to the correct amount. Taking simvastatin as your doctor has recommended can help to lower cholesterol levels and decrease the risk of having a heart attack and/or stroke. You should stay on a cholesterol-lowering diet while taking simvastatin.

In the UK, simvastatin is available on prescription, and can also be bought over-the-counter from pharmacies. Your medicine may just have the name 'simvastatin', or it may have a brand name. The brand names of simvastatin medicines available in the UK are:

- Inegy
- Simvador
- Zocor

It is estimated that around 2.9 million patients in the UK were prescribed simvastatin 40 mg in 2011<sup>1</sup>. You can find out more information about simvastatin from the medicine's [patient information leaflet](#) and from [NHS Choices](#).

### **What is the new safety information for simvastatin?**

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As with any medicine, simvastatin may cause side effects (adverse drug reactions) in some people. Muscle problems such as pain, tenderness, weakness and cramps are one known side effect of simvastatin. On rare occasions (occurring in less than 1 out of 1000 patients), these muscle problems may be serious, including muscle breakdown leading to kidney damage.

It is already known that taking certain other medicines with simvastatin may increase the risk of side effects such as muscle problems. We recently looked at medical and scientific research on simvastatin when it is given with other medicines.

Two of the other medicines that were looked at were amlodipine and diltiazem. These are used to treat high blood pressure and chest pain associated with heart disease, and they are often prescribed with simvastatin.

Your medicine may just have the name 'amlodipine' or 'diltiazem', or it may have a brand name. The brand names of amlodipine are: Amlostin, Exforge, Istin, and Sevikar. The brand names of diltiazem are: Adizem, Angitil, Dilzem, Kenzem, Retalzem, Slozem, Tildiem, Viazem.

The research showed that taking high doses (more than 20 mg) of simvastatin with amlodipine or diltiazem slightly increased the risk of muscle problems.

- Because of this finding, **we now recommend to doctors that the maximum dose of simvastatin with amlodipine or diltiazem should not exceed 20 mg per day**. This will ensure that patients are less likely to suffer from side effects but still benefit from most of the cholesterol-reducing effect of simvastatin.

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<sup>1</sup> Estimate from CPRD data

Because of this new information, your doctor may have changed your simvastatin treatment. It is important to take simvastatin exactly as your doctor has recommended, but you should stop taking simvastatin and seek medical attention as soon as possible if you experience any muscle-related problems.

### **What should I do if I am taking simvastatin?**

**If you are taking simvastatin and also taking amlodipine or diltiazem your doctor will review your treatment at your next routine appointment.** You should not stop taking simvastatin.

- Your doctor may lower the dose of simvastatin you take or change your treatment to another statin. This will reduce the chances of you having side effects but ensure that you still benefit from most of the cholesterol-lowering effects of a statin.
- It is important to tell your doctor about any other medicines that you are taking, including any obtained without a prescription

**If you experience any muscle pain, weakness or cramps whilst taking simvastatin, you should stop taking simvastatin and see your doctor as soon as possible.**

- Please report any suspected side effects to a medicine or vaccine to the Yellow Card Scheme: <http://yellowcard.mhra.gov.uk/>