

## Simvastatin 10, 20 and 40mg Tablets

Simvastatin

### PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Simvastatin Tablets are and what they are used for
2. What you need to know before you take Simvastatin Tablets
3. How to take Simvastatin Tablets
4. Possible side effects
5. How to store Simvastatin Tablets
6. Contents of the pack and other information

#### 1. What Simvastatin Tablets are and what they are used for

Simvastatin is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Simvastatin raises levels of "good" cholesterol (HDL cholesterol). Simvastatin is a member of the class of medicines called statins.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called "bad" cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called "good" cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease. Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

You should stay on a cholesterol-lowering diet while taking this medicine.

Simvastatin is used in addition to your cholesterol-lowering diet if you have:

- A raised cholesterol level in your blood (primary hypercholesterolaemia) or elevated fat levels in your blood (mixed hyperlipidaemia).
- A hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments.
- Coronary heart disease (CHD) or are at high risk of CHD (because you have diabetes, history of stroke, or other blood vessel disease). Simvastatin may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

In most people, there are no immediate symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, keep track of your cholesterol, and discuss your goals with your doctor.

#### 2. What you need to know before you take Simvastatin Tablets

Do not take Simvastatin Tablets:

- If you are hypersensitive (allergic) to simvastatin or any of the ingredients in these tablets (see section 6).
- If you have active liver disease.
- If you are taking *mibefradil*, a drug for the treatment of hypertension and angina.
- If you have a rare inherited disease called porphyria.
- If you are pregnant or breastfeeding. See Pregnancy and Breastfeeding section.
- If you had severe respiratory failure.
- If you are taking any of the below medicines:
  - Itraconazole, ketoconazole, posaconazole or voriconazole (medicines for fungal infections).
  - Erythromycin, clarithromycin, telithromycin (antibiotics for infections).
  - Nefazodone (a medicine for depression).
- If you are taking HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections).
- Gemfibrozil used to lower cholesterol levels, ciclosporin used after organ transplant, danazol used to treat endometriosis.
- Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.
- If you are taking or, in the last 7 days, have taken or been given a medicine called fusidic acid (used to treat bacterial infection) Do not take more than 40 mg Simvastatin if you are taking lomitapide (used to treat a serious and rare genetic cholesterol condition)

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

**Warnings and precautions**  
Talk to your doctor or pharmacist or nurse before taking this medicine:

- About all your medical conditions including allergies.
- If you drink large amounts of alcohol.

- If you have ever had liver disease. Simvastatin Tablets may not be right for you.
- If you are due to have an operation. You may need to stop taking Simvastatin Tablets for a short time.
- Your doctor should do a blood test before you start taking Simvastatin Tablets. This is to check how well your liver is working.
- If you are Asian, because a different dose may be applicable to you.
- Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Simvastatin Tablets.
- If you have severe lung disease.
- If you have high blood pressure or high levels of fats and sugars in your blood or if you have a body mass index of more than 30kg/m<sup>2</sup>. You may be more at risk of developing diabetes. Your doctor will monitor you closely if this applies to you.

Contact your doctor immediately 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; and very rare deaths have occurred.

The risk of muscle breakdown is greater at higher doses of Simvastatin Tablets. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- You consume large amounts of alcohol.
- You have kidney problems.
- You have thyroid problems.
- You are 65 years or older.
- You are female.
- You have ever had muscle problems during treatment with cholesterol-lowering medicines called "statins" or fibrates.
- You or a close family member have a hereditary muscle disorder.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

Simvastatin is not recommended for children.

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 SIMVASTATIN). Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Other medicines and Simvastatin Tablets

It is particularly important to tell your doctor if you are taking any of the following drugs. Taking Simvastatin Tablets with any of these drugs can increase the risk of muscle problems (some of these have already been listed in the above section "Do not take Simvastatin Tablets").

- Ciclosporin (a medicine often used in organ transplant patients).
- Danazol (a man-made hormone used to treat endometriosis) a condition in while the lining of the uterus grows outside the uterus.
- Medicines like itraconazole, ketoconazole, fluconazole, voriconazole, or posaconazole (medicines for fungal infections).
- Fibrates like gemfibrozil and bezafibrate (medicines for lowering cholesterol).
- Erythromycin, clarithromycin, telithromycin, or fusidic acid (medicines for bacterial infections). Do not take fusidic acid while using this medicine. Also see section 4 of this leaflet.
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (medicines for AIDS).
- Nefazodone (a medicine for depression).
- Amiodarone (a medicine for an irregular heartbeat).
- Verapamil, diltiazem, or amlodipine (medicines for high blood pressure, chest pain associated with heart disease, or other heart conditions).
- Boceprevir (used to treat hepatitis C virus infection)
- Colchicine (used to treat gout)
- medicines with the active ingredient cobicistat
- lomitapide (used to treat a serious and rare genetic cholesterol condition)

- As well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular, tell your doctor if you are taking any of the following:
  - Medicines to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)
  - Fenofibrate (another medicine for lowering cholesterol).
  - Niacin (another medicine for lowering cholesterol).
  - Rifampicin (used to treat tuberculosis).

You should also tell any doctor who is prescribing a new medicine for you that you are taking Simvastatin.

Simvastatin Tablets with food, drink and alcohol

Grapefruit juice has one or more components that alter the metabolism of some medications including Simvastatin. Large volumes of grapefruit juice (more than 1 litre) may have adverse effects however typical consumption (one 250 ml glass daily) is unlikely to cause problems. If you are unsure ask your doctor for advice.

Your doctor will have told you to keep alcohol to a minimum. If you are concerned about how much alcohol you can drink you should discuss this with your doctor.

**Pregnancy and Breastfeeding**

Tell your doctor if you are, you think you might be or are planning to become pregnant, or if you are breast feeding.

- If you are planning to become pregnant. You should stop taking Simvastatin at least one month before trying to become pregnant.
- If you discover you are pregnant while taking Simvastatin you should stop taking Simvastatin immediately.
- If you are a woman who could bear children unless you are using a reliable form of contraception other than the pill (you may want to discuss this with your doctor).

Do not take Simvastatin if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

**Driving and using machines**

Simvastatin Tablets are not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people get dizzy after taking Simvastatin Tablets.

**Simvastatin Tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### 3. How to take Simvastatin Tablets

Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment and your personal risk status.

Always take Simvastatin Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You should stay on a cholesterol-lowering diet while taking Simvastatin.

**Usual Dose:**

- To be taken orally, whole with a glass of water:
- 10 mg daily for high cholesterol levels.
- 20 mg daily for coronary heart disease, taken as a single dose in the evening.
- Some patients with mild to moderate hypercholesterolaemia may be treated with an initial dose of 5 mg of Simvastatin.

**Children (10-17 years old):**

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 adjust the dose to a maximum daily dose of 80 mg, taken as a single dose in the evening. Your doctor may prescribe lower doses, especially if you are taking ciclosporin or suffer from certain kidney disorders. Continue taking Simvastatin until your doctor tells you to stop treatment.

**If you take more Simvastatin Tablets than you should**

If you swallow too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

**If you forget to take Simvastatin Tablets**

Try to take Simvastatin Tablets daily as prescribed. However, if you miss a dose wait until the next dose is due then continue as before. Do not take a double dose to make up for the forgotten one.

**If you stop taking Simvastatin Tablets**

If you stop taking Simvastatin your cholesterol levels may rise again. Do not stop taking Simvastatin Tablets without first discussing it with your doctor.

If you have any further questions on the use of Simvastatin Tablets ask your doctor or pharmacist.

#### 4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The following terms are used to describe how often side effects have been reported:  
Rare (less than 1 of 1000 users)  
Very rare (occurring in less than 1 of 10,000 users).  
Frequency not known (cannot be estimated from the available data)

The following rare serious side effects were reported:

**If any of these serious side effects happen, stop taking the medicine and tell your doctor immediately or go to the emergency room at your nearest hospital.**

- Muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- Hypersensitivity (allergic) reactions including:
  - Swelling of the face, tongue and throat which may cause difficulty in breathing (angioedema).
  - Severe muscle pain usually in the shoulders and hips.
  - Rash with weakness of limbs and neck muscles
  - Pain or inflammation of the joints (polymyalgia rheumatica).
  - Inflammation of the blood vessels (vasculitis).
  - Unusual bruising, skin eruptions and swelling (dermatomyositis), hives, itchiness, skin sensitivity to the sun, fever, flushing.
  - Shortness of breath (dyspnoea) and feeling unwell.
  - Lupus-like disease picture (including rash, joint disorders, and effects on blood cells).
- Inflammation of the liver with yellowing of the eyes and/or skin, itchiness of the skin, dark-coloured urine or pale-coloured stools,

feeling tired or weak, loss of appetite: liver failure (very rare, may affect up to 1 in 10,000 people).

- Pancreatitis (inflammation of the pancreas) often with severe abdominal pain.

The following side effects have also been reported rarely:

- Anaemia (a condition in which the body does not have enough healthy red blood cells) which can lead to pale skin and cause weakness or breathlessness
- Headache, dizziness, numbness or weakness in the arms and legs, tingling sensation (pins and needles)
- Sickness, vomiting, constipation, diarrhoea, flatulence, indigestion and abdominal pain
- Rash, itching, hair loss
- Weakness
- Trouble sleeping (very rare)
- Poor memory (very rare) memory loss, confusion.

The following very rare serious side effect was reported:

- A serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis).

The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):

- Erectile dysfunction
- Depression
- Inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever.
- Tendon problems, sometimes complicated by rupture of the tendon
- Erectile dysfunction
- Muscle weakness that is constant
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine
- Muscle pain, tenderness, or weakness that is constant that may not go away after stopping Simvastatin (frequency not known).

Additional possible side effects reported with some statins:

- Sleep disturbances, including nightmares
- Memory loss
- Sexual difficulties

Laboratory values

Elevations in some laboratory blood tests of liver function and a muscle enzyme (creatine kinase) have been observed.

Your doctor may want to do simple blood tests to check your muscle enzyme levels and if your liver is working properly before and during your treatment with Simvastatin Tablets.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Simvastatin Tablets

**Keep out of the sight and reach of children**  
Store in the original packaging.

Do not store above 30°C.

Do not use after the expiry date stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

#### 6. Contents of the pack and other information

**What Simvastatin Tablets contain**

The active substance in this medicine is simvastatin which is available in 3 strengths, 10, 20 and 40mg per tablet.

The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, butylated hydroxyanisole (E320), ascorbic acid, anhydrous citric acid, colloidal anhydrous silica, talc, magnesium stearate, hypromellose, red iron oxide (E172), yellow iron oxide (E172), triethylcitrate, titanium dioxide (E171), povidone.

**What Simvastatin Tablets look like and contents of the pack**

Simvastatin 10mg Tablets are peach coloured oval shaped.  
Simvastatin 20mg Tablets are tan coloured oval shaped.  
Simvastatin 40mg Tablets are brick red coloured.

Simvastatin 10 mg Tablets are supplied in blister packs of 28 tablets.  
Simvastatin 20 mg Tablets and Simvastatin 40 mg Tablets are supplied in blister packs of 14 tablets. Two blister packs per carton.

**Marketing Authorisation Holder and Manufacturer**

Relonchem Limited  
Cheshire House, Gorse Lane, Widnes,  
Cheshire,  
WA8 0RP,UK

[POM]

PL 20395/0004  
PL 20395/0005  
PL 20395/0006

This leaflet was last revised in April 2018