

# Simvastatin 10mg, 20mg and 40mg Tablets

## Read all of this leaflet carefully before you start taking this medicine

- *Keep this leaflet. You may need to read it again*
- *If you have any further questions, ask your doctor or pharmacist*
- *This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours*
- *If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

### In this leaflet:

1. What Simvastatin is and what it is used for.
2. Before you take Simvastatin.
3. How to take Simvastatin.
4. Possible side effects.
5. How to store Simvastatin.
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### 1. WHAT SIMVASTATIN IS AND WHAT IT IS USED FOR

Simvastatin belongs to a group of medicines known as statins. These work by reducing the amount of cholesterol and certain fatty substances called triglycerides in your blood.

#### Simvastatin is used:

- to lower cholesterol and triglycerides in the blood when a low fat diet and other measures (such as exercise, weight loss) have failed.
- to lower inherited high levels of cholesterol in your blood (homozygous familial hypercholesterolemia), together with dieting and other treatments (e.g. LDL-apheresis), or when such treatments are not appropriate.
- to reduce the risk of coronary heart disease if you have hardening of the arteries (arteriosclerosis) or diabetes, even if your cholesterol levels are normal, together with dieting and other treatments.

### 2. BEFORE YOU TAKE SIMVASTATIN

#### Do not take Simvastatin:

- if you are allergic (hypersensitive) to simvastatin or to any of the other ingredients of the tablet

- if you have liver problems or a continuous high level of certain liver enzymes (serum transaminases)
- if you are pregnant or breast-feeding
- if you are taking the following medicines (see also the section "Taking other medicines" below):
  - certain antifungals (ketoconazole or itraconazole, fluconazole, posaconazole)
  - certain medicines for the treatment of AIDS (HIV-protease inhibitors, such as indinavir, nelfinavir, ritonavir and saquinavir)
  - certain antibiotics (erythromycin, clarithromycin or telithromycin)
  - the antidepressant nefazodone

#### Take special care with Simvastatin:

- if while being treated with simvastatin you experience unexplained muscle pain, sensitivity to pressure or muscle weakness. Simvastatin may cause muscle problems and sometimes muscle breakdown with muscle cramps, fever and red-brown discolouration of urine. The risk of muscle breakdown is greater at higher doses. Contact your doctor immediately if you experience muscle pain, tenderness or weakness.
- if any of the following applies to you, as you may have a greater risk of muscle breakdown:
  - you are more than 70 years old
  - you have kidney problems
  - you have thyroid problems (and are not taking medicine for it)
  - you or close family members have a hereditary muscle disorder
  - you have ever had muscle problems during treatment with simvastatin or other statins or fibrates (other cholesterol lowering medicines).
- if you have severe respiratory failure
- if you are taking certain other medicines: see the section "Taking other medicines" below.
- if you consume large amounts of alcohol or have had liver problems or liver disease in the past. Simvastatin can affect your liver without you noticing it directly. Your doctor may conduct some blood tests to check your liver before and after starting treatment.

Consult your doctor if any of the above applies to you or has applied to you in the past.

### Taking other medicines

*Please note that the following statements may also apply to products you took some time ago or may take at some time in the future.*

The risk of muscle problems can be greater if simvastatin is taken with the following medicines: (some of these have already been listed in the above section "Do not take Simvastatin")

- Fibrates (other cholesterol-lowering medicines, such as gemfibrozil, bezafibrate) (the dose of simvastatin should not exceed 10 mg daily).
- Niacin (another medicine for lowering cholesterol) (the dose of simvastatin should not exceed 10mg daily)
- Ciclosporin (drug used to suppress the immune system) (the dose of simvastatin should not exceed 10 mg daily).
- Certain antifungals (such as itraconazole or ketoconazole, fluconazole, posaconazole)
- The antibiotics erythromycin, clarithromycin and telithromycin
- Certain medicines for the treatment of AIDS (HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir)
- Danazol (medicine used to treat endometriosis and breast cysts in women) (the dose of simvastatin should not exceed 10 mg daily).
- The antidepressant nefazodone
- Amiodarone, a medicine used for irregular heart beat (the dose of simvastatin should not exceed 20 mg daily).
- Verapamil and diltiazem (medicine used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions). If you take Verapamil the dose of simvastatin should not exceed 20 mg daily, if you take diltiazem the dose of simvastatin should not exceed 40 mg daily *unless your doctor considers that the clinical effects is likely to outweigh the increased risk of muscle problems*
- Fusidic acid as a tablet or infusion (a medicine used to treat bacterial infections)
- Colchicine (a medicine to treat gout)

You should also tell your doctor if you take

- medicines that prevent blood clots (anticoagulants, such as acenocoumarol and warfarin). Simvastatin may increase the effect of these medicines.
- Rifampicin (antibiotic used to treat tuberculosis)
- Amlodipine (a medicine to treat high blood pressure and chest pain (angina pectoris))

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

### Taking Simvastatin with food and drink:

Grapefruit juice contains one or more components which may increase the amount of simvastatin in the blood. Therefore, you should not drink grapefruit juice as it could increase the risk of muscle damage.

### Pregnancy and breast-feeding

Do not take simvastatin if you are pregnant, trying to become pregnant or suspect you may be pregnant, as the safety in pregnant women has not been established. If you become pregnant while using simvastatin, you must stop taking the tablets immediately and contact your doctor.

No data on the excretion of simvastatin in breast milk are available. Because many medicinal products are excreted in human milk and because of the potential for serious side effects, you must not breast-feed your infant while taking simvastatin.

*Ask your doctor or pharmacist for advice before taking any medicine.*

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

### Driving and using machines:

Simvastatin has no effect or only a negligible effect on the ability to drive or use machines. However, there have been rare cases of dizziness reported in patients taking simvastatin tablets (see section 4). Do not drive vehicles or operate machines that require attention if you experience this side-effect.

### Important information about some of the ingredients of Simvastatin:

Amongst other ingredients, Simvastatin tablets contain lactose monohydrate. If your doctor has informed you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

### 3. HOW TO TAKE SIMVASTATIN?

Always take your tablets exactly as your doctor has instructed you. You should check with your

doctor or pharmacist if you are unsure. You should stay on a cholesterol lowering diet while taking Simvastatin.

The dose is 1 simvastatin 10mg, 20mg 40mg or 80 mg tablet by mouth once a day in the evening.

The 80mg dose is only recommended in adult patients with very high cholesterol levels and at high risk of heart disease problems.

If needed, your doctor can increase the dose at intervals of at least 4 weeks to a maximum of 80mg per day as a single dose in the evening.

If you have been prescribed simvastatin because your need to lower inherited high levels of cholesterol in your blood (homozygous familial hypercholesterolemia), your doctor will instruct you to take simvastatin 40mg/day in the evening or 80 mg/day in 3 divided doses of 20 mg, 20 mg and an evening dose of 40 mg.

If your doctor has prescribed a bile acid sequestrant (another medicine for lowering cholesterol such as colestyramine) along with simvastatin you should take simvastatin at least two hours before or four hours after taking the bile acid sequestrant.

#### **Children and adolescents (10-17 years of age)**

For children (10 -17 years old) with a hereditary illness called familial hypercholesterolaemia, the recommended usual starting dose is 10mg a day in the evening. The maximum recommended dose is 40mg a day.

#### **Elderly patients**

The dose of simvastatin does not need to be changed for elderly patients

#### **Instructions for use**

Simvastatin tablets should be taken with water. Take the tablets either on an empty stomach or after a meal.

#### **Duration of treatment:**

You will have to take simvastatin over a long period of time. Your doctor will tell you how long you need to take simvastatin.

*If you have the impression that the effect of simvastatin is too strong or too weak, talk to your doctor or pharmacist.*

#### **If you take more Simvastatin than you should:**

Although no specific information about simvastatin overdose is available, any medication taken in excess can have serious

consequences. If you take too many tablets by mistake, contact a doctor or pharmacist immediately.

#### **If you forget to take Simvastatin:**

If you realise you have forgotten to take a dose soon after its due time, take it as soon as possible. However, if it is almost time to take the next dose, omit the forgotten dose and take the next one when it is due. Ask your doctor or pharmacist in case of doubt.

Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking Simvastatin:**

If you suddenly stop taking this medicine, your cholesterol may rise again. It is therefore important that you consult a doctor before stopping treatment, even if you suffer from physical complaints. He/she can tell you if you can stop and the best way to do so.

*If you have any further questions on the use of this product, ask your doctor or pharmacist.*

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Simvastatin can have side effects, although not everybody will have them. For the most part side effects have been mild and short lived.

#### **If any of the following serious side effects**

**happen, stop taking the medicine and tell your doctor immediately or go to the emergency room at your nearest hospital:**

- **Muscle aches and pains, tenderness, weakness or cramps.** This is because on rare occasions, muscle damage can be serious (see section 2 "Take special care with Simvastatin").
- A rapid swelling of the face, tongue or throat occurs (angio-oedema), which may cause great difficulty in breathing. Hives can develop simultaneously and the swelling can be itchy.

The following side effects were reported uncommonly (1 to 10 users in 1,000)

- Sleep disturbances, including sleeplessness and nightmares
- Memory loss
- Depression
- Sexual dysfunction

The following side effects were reported rarely (1 to 10 users in 10,000).

- anaemia,
- stomach upsets (such as sickness, constipation, abdominal pain, flatulence, nausea, indigestion, diarrhoea, vomiting),
- inflammation of the pancreas (severe

abdominal pain radiating to the back, nausea and vomiting),

- headache, dizziness, weakness, numbness or loss of sensation in the arms and legs,
- hair loss, rash, itchiness,
- Muscle aches and pains, tenderness, weakness or cramps, dark coloured urine, pale coloured stools (see above and section 2).
- liver disease (possibly presenting as yellowing of the eyes and/or skin)
- increase in blood levels of liver enzymes
- An allergic reaction that may include some of the following symptoms: sudden swelling of face, tongue or throat (angio oedema, see below), a certain skin disease (lupus-like syndrome) with rash, fever and joint pain, joint and blood vessel inflammation, high levels of white blood cells, (eosinophilia), joint pains, unusual bruising, skin eruptions, swelling, hives, skin sensitivity to the sun, a high temperature, flushing, difficulty in breathing or tiredness. (see above and section 2)

The following side effects were reported very rarely (less than 1 user in 10,000)

- Breathing problems including persistent cough and/or shortness of breath or fever
- Liver failure

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacists

## 5. HOW TO STORE SIMVASTATIN?

Keep out of the reach and sight of children.

Store the tablets in the original package, in order to protect from light and moisture. Do not store above 30°C. Do not use the tablets after the "do not use after" or "exp". date stated on the packaging. The wording "exp" means: "expiry date". The first 2 digits denote the month, the last digits the year.

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 to protect the environment.

## 6. FURTHER INFORMATION

### What Simvastatin contains:

The active substance is: Simvastatin, 10 mg, 20mg or 40mg

The other ingredients are:

Tablet core: Lactose monohydrate, cellulose, microcrystalline (E460), Starch (maize) pregelatinised 1500 butylhydroxyanisole (E320), 50418261

Butylhydroxytoluene (E321), ascorbic acid (E300), Citric acid (E330), silica, colloidal anhydrous (E551), talc (E553b), magnesium stearate (E470b).

Film-coating: Hypromellose (E464), iron oxide, red (E172), iron oxide, yellow (E172), triethylcitrate (E1505), titanium dioxide (E171), talc (E553b), povidone.

### What Simvastatin looks like and contents of pack

Simvastatin 10mg is a peach-coloured, oval, biconvex, film-coated tablet, scored on one side; The tablets can be divided into equal halves along the score line.

Simvastatin 20 mg is a tan-coloured, oval, biconvex, film-coated tablet, scored on one side; The tablets can be divided into equal halves along the score line.

Simvastatin 40mg is a brick red-coloured, oval, biconvex, film-coated tablet, scored on one side; The tablets can be divided into equal halves along the score line.

The tablets are packed in blisters in a carton box, containing 28 tablets.

### Marketing Authorisation Holder and Manufacturer

Actavis Group PTC ehf.  
Reykjavíkurvegur 76-78  
220 Hafnarfjörður  
Iceland

### Manufacturer

Actavis Nordic A/S  
Ørnegårdsvej 16  
DK-2820 Gentofte  
Denmark

Actavis UK Ltd  
Barnstaple  
EX32 8NS  
UK

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If you would like a leaflet with larger text, please contact 01271 311257.



Actavis, Barnstaple, EX32 8NS, UK