

SIMTIN[®]

Simvastatin 10 mg and 20 mg

What is in this leaflet

- What Simtin[®] is used for
- How Simtin[®] works
- Before you take Simtin[®]
- How to take Simtin[®]
- While you are using Simtin[®]
- Side Effects
- Storage and disposal of Simtin[®]
- Product description

What Simtin[®] is used for

Simtin[®] is used along with 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). Simtin[®] 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.

How Simtin[®] works

Simtin[®] is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Simtin[®] raises levels of “good” cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking this medicine. Simtin[®] is a member of the class of drugs called statins.

Before you take Simtin[®]

When you must not take it

- Hypersensitivity to any ingredient of the tablets (see also “Ingredients”).
- Current liver disease or unexplained persistent elevations of serum transaminases.
- Pregnancy and nursing.
- if you are taking one or more of the following drugs at the same time:
 - itraconazole, ketoconazole, or posaconazole (medicines for fungal infections)
 - erythromycin, clarithromycin, or telithromycin (antibiotics for infections)
 - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections)

- nefazodone (a medicine for depression)
- Simtin[®] is not recommended in children.

Before you start to take it

- Tell your doctor about all your medical conditions including allergies.
- Tell your doctor if you drink large amounts of alcohol.
- Tell your doctor if you have ever had liver disease. Simtin[®] may not be right for you.
- Tell your doctor if you are due to have an operation. You may need to stop taking Simtin[®] tablets for a short time.
- Your doctor should do a blood test before you start taking Simtin[®]. This is to check how well your liver is working.
- Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Simtin[®].
- Tell your doctor if you have severe lung disease.

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 Simtin[®] and is 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 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.

Taking other medicines

It is particularly important to tell your doctor if you are taking any of the following drugs. Taking Simtin[®] with any of these drugs can increase the risk of muscle problems.

- ciclosporin (a medicine often used in organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis)
- medicines like itraconazole, ketoconazole, fluconazole, 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)
- 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)

- colchicine (a medicine used to treat gout).

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)
- rifamapicin (a medicine used to treat tuberculosis).

How to take Simtin[®]

How much to take

Always take Simtin[®] exactly as your doctor has told you.

The usual dose is one Simtin[®] tablet of 10 mg or 20 mg by mouth once daily, as prescribed by your doctor. Your doctor may increase the dose depending on your condition.

When to take it

Simtin[®] is usually taken in the evening.

How long to take it

Treatment with Simtin[®] is normally a long-term therapy.

If you forget to take it

If you forget to take a dose, do not take a double dose to make up for forgotten doses.

If you take too much (overdose)

Contact your doctor if you have taken too much Simtin[®].

While you are using Simtin[®]

Things you must do

Stay on a cholesterol-lowering diet as directed by your doctor.

Things you must not do

Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including Simtin[®]. Consuming grapefruit juice should be avoided.

Things to be careful of

If your doctor has prescribed Simtin[®] along with any bile acid sequestrant (medicines for lowering cholesterol), you should take Simtin[®] at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Your ability to drive or use machinery may be impaired if you get dizzy after taking Simtin[®].

Side Effects

Like all medicines, Simtin[®] can cause side effects, although not everybody gets them. The following terms are used to describe how often side effects have been reported:

- Rare (occurring in 1 or more of 10,000 and less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 10,000 patients treated).
- Frequency not known

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
 - severe muscle pain usually in the shoulders and hips
 - rash with weakness of limbs and neck muscles
 - pain or inflammation of the joints
 - inflammation of the blood vessels
- unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, flushing
- shortness of breath and feeling unwell
- lupus-like disease picture (including rash, joint disorders, and effects on blood cells)
- inflammation of the liver with yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, liver failure (very rare)
- inflammation of the pancreas often with severe abdominal pain.

The following side effects have also been reported rarely:

- low red blood cell count (anaemia)
- numbness or weakness of the arms and legs
- headache, tingling sensation, dizziness
- digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting)
- rash, itching, hair loss
- weakness
- trouble sleeping (very rare)
- poor memory (very rare).

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.

After using Simtin[®]

Storage

Keep out of reach of children!

Store in a cool, dry place below 25°C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product description

What it looks like

SIMTIN[®]-10: Light yellow coloured, circular, film-coated tablets.

SIMTIN[®]-20: Orange coloured, circular, film-coated tablets.

Ingredients

Simtin[®]-10: Each tablet contains Simvastatin 10 mg, lactose anhydrous, starch, microcrystalline cellulose, vitamin c coated, butylated hydroxy toluene, colloidal silicon dioxide, talc, magnesium stearate, hydroxy propyl methyl cellulose, methylene chloride, titanium dioxide, propylene glycol, iron oxide yellow.

Simtin[®]-20: Each tablet contains Simvastatin 10 mg, lactose anhydrous, starch, microcrystalline cellulose, vitamin c coated, butylated hydroxy toluene, colloidal silicon dioxide, talc, magnesium stearate, tabcoat-tc-2052 orange, methylene chloride.

MAL No.:

Simtin[®]-10: MAL05092209AC

Simtin[®]-20: MAL05092211AC

Manufacturer

Micro Labs Limited (Hosur, India)

Marketing Authorization Holder

Apex pharmacy marketing Sdn Bhd (Selangor, Malaysia)

Date of Revision

May 2011