

SIMVASTATIN 10 MG TABLETS

SIMVASTATIN 20 MG TABLETS

SIMVASTATIN 40 MG 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 further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What SIMVASTATIN TABLETS are and what they are used for.
2. Before you take SIMVASTATIN TABLETS.
3. How to take SIMVASTATIN TABLETS.
4. Possible side effects.
5. Storing SIMVASTATIN TABLETS

Simvastatin 10, 20 & 40 mg Film-coated Tablets contain the active substance simvastatin 10mg, 20mg or 40mg. The other ingredients are: lactose monohydrate, pregelatinised maize starch, ascorbic acid (E300), citric acid monohydrate (E330), microcrystalline cellulose (E460(i)), butylhydroxyanisole (E320), croscarmellose sodium, magnesium stearate (E572). The film coating materials contain hydroxypropylcellulose (E463), hypromellose 15cP (E464), titanium dioxide (E171), talc (E553(b)), iron oxide yellow (E172), iron oxide red (E172) and iron oxide black (E172).

Marketing Authorization Holder/Manufacturer: Dexcel®-Pharma Limited, 1 Cottesbrooke Park, Heartlands Business Park, Daventry, Northamptonshire NN11 8YL, England.

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

Simvastatin Film-coated Tablets belong to the group of medicines called LIPID-LOWERING medicines. These medicines are also known as "statins". They work by lowering lipids (fats) such as cholesterol and triglycerides in your blood when non-medicinal measures, such as a low-fat diet, exercise and lifestyle changes, alone have failed.

There are three tablet strengths available:

Simvastatin 10 mg Tablets are peach coloured, film coated, oval shaped tablets.

Simvastatin 20 mg Tablets are tan coloured, film coated, oval shaped tablets.

Simvastatin 40 mg Tablets are salmon-pink coloured, film coated, oval shaped tablets.

Simvastatin Tablets are available in calendar packs, as blister strips of 28 tablets in a carton.

Simvastatin Tablets are recommended for patients with high cholesterol and triglyceride levels, and for patients with cardiovascular diseases (heart and blood vessels diseases) and/or diabetes mellitus with either high or normal cholesterol levels.

If you have any of these conditions, this medicine along with dietary control can help prolong your life and reduce the risk of cardiovascular diseases.

2. Before you take Simvastatin Tablets Do not take Simvastatin Tablets:

If you are allergic to simvastatin, to similar medicines or to any of the other ingredients of Simvastatin Tablets;

If you have liver problems; If you are pregnant, plan to become pregnant or are breastfeeding; If you are taking any of the following medicines: nefazodone (an antidepressant); certain anti-HIV medicines called protease inhibitors (indinavir, ritonavir, saquinavir, nelfinavir); antifungal agents (e.g. itraconazole, ketoconazole); erythromycin, clarithromycin or telithromycin (antibiotics called "macrolides"). If you think any of these apply to you, do not take the tablets, go and talk to your doctor first and follow the advice given.

Take special care with Simvastatin Tablets:

These tablets can cause muscle problems. The risk of muscle problems is greater at higher doses of Simvastatin Tablets and in certain groups of patients. Tell your doctor: About all your medical conditions including allergies; If you have severe respiratory failure (severe breathing problems). If you have kidney problems; If you have or ever had muscle pain, cramps, tenderness or weakness; if you or close family member have a hereditary muscle disorder or a previous history of muscle problems with other cholesterol lowering drugs (e.g. "statins" or fibrates); If you consume substantial quantities of alcohol or if you have a past history of liver disease; If you have thyroid problems; If you are over 70 years of age; If you are awaiting surgery or when any medical or surgical condition is unexpectedly required. Tell your doctor **immediately if you experience unexplained muscle pain, tenderness or weakness**. This is because on rare occasions, there is a risk of muscle problems which may be serious, including muscle breakdown which can result in kidney damage. The doctor may perform a blood test to check the condition of your muscles before and after starting treatment.

Taking Simvastatin Tablets with food and drink: You should avoid drinking grapefruit juice during treatment with Simvastatin since it could increase your risk of muscle damage. Alcohol can affect the action of simvastatin and your doctor should have advised you to always keep your alcohol intake to a minimum while you are on these tablets. If you are concerned about how much alcohol you may drink while taking simvastatin, discuss this with your doctor.

Pregnancy: Do not use Simvastatin Tablets if you are pregnant, trying to become pregnant or suspect you may be pregnant. If you become pregnant while taking Simvastatin Tablets, stop taking them immediately and contact your doctor.

Breastfeeding: Do not use Simvastatin Tablets if you are breastfeeding. Consult your doctor before taking the tablets if you are breastfeeding, or planning to breastfeed.

Use in children: Simvastatin Tablets are not recommended for use in children.

Driving and using machines: Simvastatin Tablets are not expected to affect your ability to drive a car or to operate machinery. However, when driving vehicles or operating machinery, it should be taken into account that dizziness has rarely been reported.

Important information about some of the ingredients of Simvastatin Tablets: This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines: Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed. The risk of muscle problems can be greater if Simvastatin Tablets are taken with certain medicines – see below and tell your doctor if you are taking any of these: (some of these medicines have already been listed in the above section “Do not take Simvastatin Tablets”): Antifungal agents (such as itraconazole or ketoconazole); the antibiotics erythromycin, clarithromycin or telithromycin; Nefazodone, an antidepressant; HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir); Ciclosporin (a drug used to suppress the immune system); Fibrates (other lipid-lowering medicines such as gemfibrozil, and bezafibrate); Amiodarone, a medicine used for irregular heart beat; Verapamil or diltiazem (drugs used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions); Nicotinic acid (lipid-lowering medicine) in large doses (i.e. greater than or equal to 1 g per day).

It is also important to tell your doctor if you are taking anticoagulants (drugs that prevent blood clots, such as warfarin) or fenofibrate.

3. How to take Simvastatin Tablets

Always take Simvastatin Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual starting dose is 20 or 40 mg a day, given as a single dose in the evening. It is recommended that Simvastatin Tablets are taken in the evening, or at night, so that they will be working when the body is producing the most cholesterol. Your doctor may adjust your dose to a maximum of 80 mg per day, given as a single dose in the evening. The 80 mg dose is only recommended in patients with severe hypercholesterolaemia and high risk cardiovascular complications. Your doctor may prescribe lower doses, particularly if you are taking certain medications listed above or have certain kidney conditions. Your doctor may need to change this dose in order to have the best effect. Do not take more or less than your doctor has prescribed. Keep taking your tablets for as long as your doctor has asked you to. If you stop taking Simvastatin Tablets, your cholesterol may rise again.

If you take more Simvastatin Tablets than you should: Do not take more medicine than prescribed by your doctor. If you ever take too much, go to the nearest hospital casualty department or tell your doctor immediately.

If you forget to take Simvastatin Tablets: If you miss a dose, just carry on with the next one as normal. Do not take an extra one to make up. Do not take two doses at the same time.

4. Possible side effects

Like all medicines, Simvastatin Tablets may occasionally cause side effects in some patients. For the most part side effects have been mild and short-lived.

The following side effects were reported rarely (between 1 in 1000 and 1 in 10,000 people are likely to be affected):
Blood system disorders: anaemia,

Nervous system disorders: headache, dizziness, numbness or loss of sensation in the arms and legs,

Gastrointestinal disorders: stomach upsets (such as sickness, constipation, diarrhoea, flatulence, indigestion and abdominal pain), pancreatitis,

Hepato-biliary disorders: liver disease (possibly presenting as yellowing of the eyes and/or skin, itchiness of the skin, dark colored urine, pale colored stools),

Skin and subcutaneous tissue disorders: hair loss, rash, itchiness,

Musculoskeletal, connective tissue and bone disorders: muscle damage (see below),

General disorders: weakness,

Allergic reaction to Simvastatin Tablets. The allergic reaction may include some of the following: swelling of the face,

tongue or throat (in which case you should contact your doctor immediately), joint pains, joint and blood vessel inflammation, unusual bruising, skin eruptions, swelling, hives, skin sensitivity to the sun, a high temperature, flushing, difficulty in breathing, or tiredness.

Contact your doctor immediately if you experience muscle aches and pains, tenderness, weakness, or cramps. This is because on rare occasions, muscle damage can be serious. (See section headed "Before you take Simvastatin Tablets").

In addition the following side effects may occur:

Sleep disturbances, including insomnia (difficulty sleeping) and nightmares

Memory loss

Sexual difficulties

Depression

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

If any of these happen, or you have any other unusual symptoms or feelings, stop taking the tablets and contact your doctor immediately.

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

5. Storing Simvastatin Tablets

Do not use after the expiry date stated on the label.

Do not store above 25°C. Store in the original package. If your doctor tells you to stop taking the tablets, please take them back to the pharmacist.

Keep your medicine out of the reach and sight of children.

This leaflet was last approved in November 2009.