

<b>PATIENT INFORMATION</b> simvastatin (sim-va-STAT-in) tablets, for oral use
<p>Read this Patient Information before you start taking simvastatin tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.</p>
<p><b>What are simvastatin tablets?</b>  Simvastatin tablets is a prescription medicine that contains the cholesterol lowering medicine, simvastatin.  Simvastatin tablets is used to lower:</p> <ul style="list-style-type: none"> <li>the risk of death by lowering the risk of heart disease death.</li> <li>the risk of heart attacks and strokes.</li> <li>the need for certain types of heart and blood vessel procedures to improve blood flow called arterial revascularization in people with known heart, cerebrovascular disease (conditions that affect blood flow and the blood vessels in the brain), peripheral vascular disease (a blood circulation disorder that causes the blood vessels outside of your heart and brain to narrow, block, or spasm), and diabetes, who are at high risk for heart disease problems.</li> </ul> <p>Simvastatin tablets are used along with diet to:</p> <ul style="list-style-type: none"> <li>lower the level of low-density lipoprotein (LDL) cholesterol or “bad” cholesterol in adults with hyperlipidemia (high levels of fat in the blood), and in adults and children 10 years of age and older with heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL).</li> <li>treat adults with a type of high cholesterol called primary dysbetalipoproteinemia.</li> <li>lower the level of triglycerides (type of fat in the blood) in adults.</li> </ul> <p>Simvastatin tablets are used along with other cholesterol lowering treatments to lower the level of low-density lipoprotein (LDL) in adults with a type of high cholesterol called homozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL).  The safety and effectiveness of simvastatin tablets has not been established in children younger than 10 years of age with heterozygous familial hypercholesterolemia (HeFH) or other types of hyperlipidemia (high levels of fat in the blood).</p>
<p><b>Do not take simvastatin tablets if you:</b></p> <ul style="list-style-type: none"> <li>take certain medicines called CYP3A4 inhibitors such as: <ul style="list-style-type: none"> <li>certain antifungal medicines (such as itraconazole, ketoconazole, posaconazole, voriconazole).</li> <li>certain antibiotics (including erythromycin, clarithromycin).</li> <li>HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and darunavir/ritonavir) and cobicistat-containing products such as (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate).</li> <li>certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir).</li> <li>the antidepressant nefazodone.</li> </ul> </li> <li>take medicines called cyclosporine, danazol, or gemfibrozil.</li> <li>have liver problems.</li> <li>are allergic to simvastatin or any of the ingredients in simvastatin tablets. See the end of this Patient Information leaflet for a complete list of ingredients in simvastatin tablets.</li> </ul> <p>Ask your healthcare provider or pharmacist if you are not sure if your medicine is listed above.</p>
<p><b>Before you take simvastatin tablets, tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"> <li>have unexplained muscle aches or weakness.</li> <li>have or have had myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used for breathing), ocular myasthenia (a disease causing eye muscle weakness).</li> <li>have kidney problems.</li> <li>have liver problems or drink more than 2 glasses of alcohol daily.</li> <li>have thyroid problems.</li> <li>are 65 years of age or older.</li> <li>are of Chinese descent.</li> <li>are pregnant or plan to become pregnant. If you become pregnant while taking simvastatin tablets, call your healthcare provider right away to discuss stopping simvastatin tablets.</li> <li>are breastfeeding or plan to breastfeed. It is not known if simvastatin passes into your breast milk. Do not breastfeed while taking simvastatin tablets.</li> </ul>
<p><b>Tell your healthcare provider about all the medicines you take,</b> including prescription and over-the-counter medicines, vitamins, and herbal supplements. Talk to your healthcare provider before you start taking any new medicines.  Tell your healthcare provider who prescribes simvastatin tablets if another healthcare provider increases the dose of another medicine you are taking.  Simvastatin tablets may affect the way other medicines work, and other medicines may affect how simvastatin tablets works. Especially tell your healthcare provider if you take:</p> <ul style="list-style-type: none"> <li>digoxin (a drug used to treat irregular heartbeat).</li> <li>coumarin anticoagulants (drugs that prevent blood clots, such as warfarin).</li> </ul> <p>Taking simvastatin tablets with certain substances can also increase the risk of muscle problems. Especially tell your healthcare provider if you take:</p> <ul style="list-style-type: none"> <li>amiodarone or dronedarone (medicines used to treat an irregular heartbeat).</li> <li>verapamil, diltiazem, amlodipine, or ranolazine (medicines used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions).</li> <li>lomitapide (a medicine used to treat a serious and rare genetic cholesterol condition).</li> <li>daptomycin (a drug used to treat complicated skin and bloodstream infections).</li> <li>large doses of niacin or nicotinic acid, especially if you are of Chinese descent.</li> <li>fibric acid derivatives (such as fenofibrate).</li> <li>colchicine (a medicine used to treat gout).</li> <li>grapefruit juice.</li> </ul> <p>Ask your healthcare provider or pharmacist for a list of medicines if you are not sure. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.</p>

<p><b>How should I take Simvastatin tablets?</b></p> <ul style="list-style-type: none"> <li>Take simvastatin tablets exactly as your healthcare provider tells you to take it.</li> <li><b>Do not</b> change your dose or stop taking simvastatin tablets without talking to your healthcare provider.</li> <li>Take simvastatin tablets 1 time each day in the evening.</li> <li>If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take 2 doses of simvastatin tablets at the same time. Talk with your healthcare provider if you have questions about a missed dose.</li> <li>While taking simvastatin tablets, continue to follow your cholesterol-lowering diet and to exercise as your healthcare provider told you to.</li> <li>Your healthcare provider may do blood tests to check your cholesterol while you take simvastatin tablets. Your healthcare provider may change your dose of simvastatin tablets if needed.</li> <li>In case of overdose, get medical help or contact a live Poison Center expert right away at 1-800-222-1222. Advice is also available online at poisonhelp.org</li> </ul>
<p>What are the possible side effects of simvastatin tablets?  <b>Simvastatin tablets may cause serious side effects including:</b></p> <ul style="list-style-type: none"> <li><b>Muscle pain, tenderness, and weakness (myopathy).</b> Muscle problems, including muscle breakdown, can be serious in some people and rarely cause kidney damage that can lead to death.  <b>Tell your healthcare provider right away if:</b> <ul style="list-style-type: none"> <li><b>you have unexplained muscle pain, tenderness, or weakness, especially if you have a fever or feel more tired than usual, while you take simvastatin tablets.</b></li> <li>you have muscle problems that do not go away even after your healthcare provider has advised you to stop taking simvastatin tablets. Your healthcare provider may do further tests to diagnose the cause of your muscle problems.</li> </ul> </li> </ul> <p>Your chances of getting muscle problems are higher if you:</p> <ul style="list-style-type: none"> <li>are taking certain other medicines while you take simvastatin tablets.</li> <li>are 65 years of age or older.</li> <li>are female.</li> <li>have thyroid problems (hypothyroidism) that are not controlled.</li> <li>have kidney problems.</li> <li>are taking higher doses of simvastatin tablets.</li> <li>are Chinese.</li> </ul> <ul style="list-style-type: none"> <li><b>Liver problems.</b> Your healthcare provider should do blood tests to check your liver before you start taking simvastatin tablets and if you have any symptoms of liver problems while you take simvastatin tablets. Call your healthcare provider right away if you have the following symptoms of liver problems: <ul style="list-style-type: none"> <li>feeling tired or weak</li> <li>loss of appetite</li> <li>right-sided upper belly pain</li> <li>dark urine</li> <li>yellowing of your skin or the whites of your eyes</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li><b>Increase in blood sugar (glucose) levels.</b> simvastatin tablets may cause an increase in your blood sugar levels.</li> </ul>
<p><b>The most common side effects of simvastatin tablets include:</b></p> <ul style="list-style-type: none"> <li>upper respiratory infection</li> <li>headache</li> <li>stomach (abdominal) pain</li> <li>constipation</li> <li>nausea</li> </ul> <p>Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of simvastatin tablets.  Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>
<p><b>How should I store simvastatin tablets?</b></p> <ul style="list-style-type: none"> <li>Store simvastatin tablets between 20 to 25°C (68 to 77°F).</li> </ul>
<p><b>Keep simvastatin tablets and all medicines out of the reach of children.</b></p>
<p><b>General information about safe and effective use of simvastatin tablets.</b>  Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use simvastatin tablets for a condition for which it was not prescribed. Do not give simvastatin tablets to other people, even if they have the same symptoms that you have. It may harm them.  You can ask your pharmacist or healthcare provider for information about simvastatin tablets that is written for health professionals.</p>
<p><b>What are the ingredients in simvastatin tablets?</b>  <b>Active ingredient(s): simvastatin.</b>  <b>Inactive ingredient(s):</b> alcohol, anhydrous citric acid, ascorbic acid, colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch (maize), purified water, talc, titanium dioxide, triethyl citrate, and butylated hydroxyanisole is added as a preservative.  Simvastatin 10mg, 20mg, and 40 mg contains red and yellow ferric oxide. Simvastatin 80 mg contains red ferric oxide.</p>
<p><b>Manufactured for:</b>  Biocon Pharma Inc.,  Iselin, New Jersey, 08830-3009  United States of America</p>
<p><b>Manufactured by:</b>  Biocon Generics Inc.  1 Duncan Drive,  Cranbury, NJ 08512</p>

This Patient Information has been approved by the U.S. Food and Drug Administration.