**Simvastatin 10 mg, 20mg, 40mg film-coated tablets**

**What is simvastatin sandoz and what is it used for?**Simvastatin Sandoz contains the active ingredient simvastatin. Simvastatin Sandoz is a medicine used to lower the levels of total cholesterol, 'bad' cholesterol (LDL-cholesterol), and fatty substances called triglycerides in the blood. It also increases the concentration of 'good' cholesterol (HDL-cholesterol).

Simvastatin Sandoz belongs to a group of medicines called statins.

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

LDL-cholesterol is often referred to as 'bad' cholesterol because it can build up on the walls of your blood vessels, forming 'plaque.' Over time, this plaque can grow and lead to narrowing of the blood vessels. This narrowing can slow down or block the blood flow to vital organs such as the heart or brain, potentially causing a heart attack or stroke.

HDL-cholesterol is often referred to as 'good' cholesterol because it helps prevent the accumulation of bad cholesterol in the blood vessels, thus protecting against heart and vascular diseases.

Triglycerides are another form of fat in your blood vessels that increase the risk of heart and vascular diseases.

When using this medicine, you should continue your cholesterol-lowering diet.

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

• have an elevated concentration of cholesterol in your blood (primary hypercholesterolemia) or a high level of fats in your blood (mixed hyperlipidemia).

• have a hereditary condition (homozygous familial hypercholesterolemia) that increases the concentration of cholesterol in your blood. You may also receive other treatments.

• have coronary heart disease (CHD) or are at risk of getting it (due to having diabetes, a stroke, or another vascular condition). Simvastatin Sandoz can prolong your life by reducing the risk of heart and vascular complications, regardless of the amount of cholesterol in your blood.

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

**When should you not use this medicine or take extra precautions?  
When should you not use this medicine?**

* You are allergic to any of the substances in this medicine..
* You currently have liver problems.
* You are pregnant or breastfeeding:
  + You are using medicines containing one or more of the following active ingredients:
  + Itraconazole, ketoconazole, posaconazole, or voriconazole (antifungal agents)
  + Erythromycin, clarithromycin, or telithromycin (antibiotics)
  + HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used in HIV infections)
  + Boceprevir or telaprevir (used against hepatitis C virus infections)
  + Nefazodone (used in the treatment of depression)
  + Cobicistat
  + Gemfibrozil (used to lower cholesterol)
  + Ciclosporin (used in patients who have undergone an organ transplant)
  + Danazol (a synthetic hormone used for the treatment of endometriosis, a condition where the uterine lining grows outside the uterus)
  + Do not use more than 40 mg of Simvastatin Sandoz if you are using lomitapide (used to treat a severe and rare genetic cholesterol disorder).
  + If you are not sure whether you are using any of the above medicines, ask your doctor.

**When should you take extra precautions with this medicine?**Contact your doctor or pharmacist before using this medicine if you:

* have any medical conditions, including allergies to certain substances (allergies).
* consume large amounts of alcohol.
* have ever had liver disease. This medicine may not be suitable for you.
* are currently using, or have used in the last 7 days, a medicine called fusidic acid (a medicine used to treat bacterial infections) orally or through injection. The combination of fusidic acid with Simvastatin Sandoz can lead to severe muscle problems (rhabdomyolysis).
* If you need to undergo surgery, it may be necessary to temporarily discontinue Simvastatin Sandoz tablets.
* If you have myasthenia (a condition causing general muscle weakness, sometimes affecting the muscles used for breathing) or ocular myasthenia (a condition causing weakness of the eye muscles) or have had these conditions, as statins can sometimes worsen the condition or lead to the occurrence of myasthenia (see section 4).
* If you are of Asian descent, a different dosage may be applicable to you.

Your doctor should perform blood tests before you start using Simvastatin Sandoz and if you experience any symptoms of liver problems while using Simvastatin Sandoz. This examination is necessary to check if your liver is functioning properly.

Your doctor may also conduct blood tests after you have started taking Simvastatin Sandoz to monitor the function of your liver.

During the period of using this medicine, your doctor will closely monitor whether you have diabetes or are at an increased risk of developing diabetes. You may have an increased risk of developing diabetes if you have high sugar and fat levels in your blood, if you are overweight, and if you have high blood pressure.

Inform your doctor if you have a severe lung disease.

If, for unexplained reasons, you experience muscle pain, tenderness, or weakness after using this medicine, contact your doctor immediately. This is because muscle problems can be severe in rare cases, including muscle breakdown leading to kidney damage; in very rare cases, there have been fatalities.

Also, contact your doctor or pharmacist if you constantly experience muscle weakness. Additional tests and medications may be necessary to diagnose and treat this condition.

The risk of muscle breakdown is higher at higher doses of Simvastatin Sandoz, especially at a dosage of 80 mg. The risk of muscle breakdown is also higher in certain patients. If any of the following points apply to you, inform your doctor:

* You consume large amounts of alcohol.
* You have kidney problems.
* You have thyroid problems.
* You are 65 years or older.
* You are a woman.
* You have experienced muscle problems during treatment with cholesterol-lowering medicines called 'statins' or fibrates.
* You or a close family member have a hereditary muscle disease.

**Children and adolescents up to 18 years:**

The safety and efficacy of this medicine have been studied in boys aged 10-17 years and girls of the same age whose menstruation began at least a year before this medicine has not been studied in children under 10 years old. Consult your doctor for more information.

**Are you using any other medicines?**

If you are using or have recently used other medicines or if there is a possibility that you will use other medicines in the near future, please inform your doctor or pharmacist.

The use of Simvastatin Sandoz together with any of the following medicines may increase the risk of muscle problems (some of which have already been mentioned in the section above, "When should you not use this medicine"):

* If you are taking oral fusidic acid to treat a bacterial infection, you must temporarily stop using this medicine. Your doctor will tell you when it is safe to start Simvastatin Sandoz again. Concurrent use of Simvastatin Sandoz with fusidic acid can, in rare cases, lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See section 4 for further information on rhabdomyolysis.
* Ciclosporin (often used in patients who have undergone an organ transplant)
* Danazol (a synthetic hormone used for the treatment of endometriosis, a condition where the uterine lining grows outside the uterus)
* Medicines containing active ingredients such as itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (antifungal agents)
* Fibrates containing active ingredients such as gemfibrozil and bezafibrate (used to lower cholesterol in the blood)
* Erythromycin, clarithromycin, or telithromycin (antibiotics)
* HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used in the treatment of AIDS)
* Antiviral agents against hepatitis C, such as boceprevir, telaprevir, elbasvir, or grazoprevir (used against hepatitis C virus infections)
* Nefazodone (used in the treatment of depression)
* Medicines containing the active ingredient cobicistat
* Amiodarone (used for the treatment of irregular heartbeat)
* Verapamil, diltiazem, or amlodipine (used for high blood pressure, chest pain in heart disease, or other heart conditions)
* Lomitapide (used for the treatment of a severe and rare genetic cholesterol disorder)
* Daptomycin (a medicine used for the treatment of difficult-to-treat skin and skin structure infections and bacteremia (presence of bacteria in your blood)). Side effects affecting the muscles may worsen if this medicine is taken during treatment with simvastatin. Your doctor may decide to temporarily stop the use of simvastatin.
* Colchicine (used for the treatment of gout)
* Ticagrelor (used in patients who have had a heart attack or angina or chest pain that is not well controlled). If you are using ticagrelor, do not exceed 40 mg of simvastatin daily.

As with the above-mentioned medicines, you should inform your doctor or pharmacist if you are using or have recently used other medicines, including those available without a prescription. You should particularly inform your doctor about the use of medicines containing the following active ingredients:

* Medicines containing active ingredients that prevent blood clots, such as warfarin, phenprocoumon, or acenocoumarol (anticoagulants)
* Fenofibrate (also used to lower cholesterol in the blood)
* Niacin (also used to lower cholesterol in the blood)
* Rifampicin (used for the treatment of tuberculosis)

Inform any doctor who prescribes you a new medicine that you are using Simvastatin Sandoz.

**What to consider with food, drink, and alcohol?**Grapefruit juice contains one or more components that can affect the processing of certain medicines (including Simvastatin Sandoz) by the body. Therefore, drinking grapefruit juice should be avoided. Inform your doctor if you consume larger amounts of alcohol.

**Pregnancy and breastfeeding:** If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, contact your doctor or pharmacist before using this medicine.

Do not use Simvastatin Sandoz if you are pregnant or think you might be pregnant, or if you are planning to become pregnant. If you become pregnant while using this medicine, stop taking it immediately and inform your doctor.

Do not use Simvastatin Sandoz if you are breastfeeding because it is not known whether this medicine passes into breast milk.

**Driving and using machines:** This medicine is not expected to affect driving ability and the ability to use machines. However, be aware that some people may experience dizziness after using this medicine.

**Simvastatin Sandoz contains lactose:** If your doctor has told you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

**How to use this medicine?**Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and personal risk. Always use this medicine exactly as your doctor has told you. If you are unsure about the correct usage, contact your doctor or pharmacist. Continue your cholesterol-lowering diet while using Simvastatin Sandoz.

The recommended dosage is 1 tablet, once daily, taken orally.

**Adults:** The recommended starting dose is 10, 20, or, in some cases, 40 mg per day. Your doctor may adjust the dose to a maximum of 80 mg per day after a minimum of 4 weeks. Do not take more than 80 mg per day.

Your doctor may prescribe lower doses, especially if you are using any of the medicines mentioned above or if you have kidney problems.

The 80 mg dose is only recommended for adult patients with severely elevated cholesterol levels in the blood and a high risk of heart and vascular complications who have not achieved their cholesterol target levels with lower doses.

**Use in children and adolescents up to 18 years:** For children (10-17 years), the usual recommended starting dose is 10 mg once daily, to be taken in the evening. The maximum recommended dose is 40 mg once daily.

**Method of administration and duration of treatment:** Take this medicine in the evening. You can take it with or without food. Continue taking this medicine unless your doctor tells you to stop. The tablet can be divided into equal doses. If your doctor has prescribed Simvastatin Sandoz together with another cholesterol-lowering medicine containing a bile acid sequestrant, take Simvastatin Sandoz at least 2 hours before or 4 hours after administration of the bile acid sequestrant.

**Have you taken too much of this medicine:** Immediately consult your doctor. In case of an overdose, your doctor will take symptomatic and supportive measures.

**Did you forget to take this medicine:** Do not take a double dose to make up for a missed dose but continue with the prescribed dosage.

**If you stop using this medicine:** Contact your doctor or pharmacist as your cholesterol levels may rise again.

Do you have any other questions about the use of this medicine? Then, please contact your doctor or pharmacist.

**Possible side effects:**Like any medicine, this medicine can cause side effects, although not everybody gets them.

If you experience any of these serious side effects, stop using this medicine and immediately consult your doctor or go to the emergency department of the nearest hospital.The following rare serious side effects have been reported:

* Muscle pain, tenderness, weakness, or cramps. In rare cases, these muscle problems can be severe, including a serious muscle condition that can reduce kidney function, and in very rare cases, death has been reported.
* Hypersensitivity reactions (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 the limbs and neck muscles.
* Joint pain or inflammation (polymyalgia rheumatica)
* Inflammation of blood vessels (vasculitis)
* Unusual bruising, blisters, and swelling (dermatomyositis), hives, sun sensitivity, fever, flushing
* Shortness of breath (dyspnea) and feeling unwell
* Lupus-like syndrome (with skin rash, joint disorders, and effects on blood cells)

Inflammation of the liver with the following symptoms: yellowing of the skin and eyes (jaundice), itching, dark-colored urine, or pale stools, feeling tired or weak, loss of appetite, very rarely liver failure

Inflammation of the pancreas, often with severe abdominal pain

**The following very rare serious side effects have been reported:**

* Severe allergic reaction that may cause difficulty breathing or dizziness (anaphylaxis)
* Breast enlargement in men (gynecomastia)
* Skin rash or mouth ulcers (lichenoid drug eruptions)
* Muscle rupture

**Other side effects:**

**Rare (affect less than 1 in 1000 users):**

* Low red blood cell count (anemia)
* Numbness or weakness in the arms and legs
* Headache, tingling, dizziness
* Blurred vision and decreased visual acuity
* Digestive disorders (abdominal pain, constipation, flatulence, indigestion, diarrhea, nausea, vomiting)
* Skin rash, itching, hair loss
* Weakness
* Increase in certain laboratory results of blood tests for liver function and muscle enzyme (creatine kinase)
* Memory loss, confusion

**Very rare (affect less than 1 in 10,000 users):**

* Insomnia
* Poor memory

**Unknown frequency (frequency cannot be determined from available data):**

* Erectile problems
* Depression
* Pneumonia causing breathing problems, including persistent cough and/or shortness of breath or fever
* Tendon problems, sometimes with rupture as a complication
* Constant muscle weakness
* Myasthenia gravis (a disease that causes generalized muscle weakness, sometimes in the muscles used for breathing)
* Ocular myasthenia (a disease that causes weakness in the eye muscles)

Contact your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision, drooping eyelids, difficulty swallowing, or shortness of breath.

**The following possible side effects have been reported with various statins:**

* Sleep disturbances, including nightmares
* Sexual problems
* Diabetes. You have a greater risk of developing diabetes if you have high blood sugar and lipid levels, are overweight, and have high blood pressure. Your doctor will monitor you during the period you are using this medicine.

**How to store this medicine?**

* Keep out of sight and reach of children.
* Do not use this medicine after the expiry date which is stated on the blister, bottle, and carton after "EXP:". The expiry date refers to the last day of that month.
* Store below 30ºC.
* Store the blister in the outer packaging to protect it from light.
* Store in the original packaging to protect it from light.
* Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines that are no longer needed. These measures will help to protect the environment.

**Simvastatin 10 mg, 20mg, 40mg film-coated tablets**

**What is simvastatin sandoz and what is it used for?**Simvastatin Sandoz contains the active ingredient simvastatin. Simvastatin Sandoz is a medicine used to lower the levels of total cholesterol, 'bad' cholesterol (LDL-cholesterol), and fatty substances called triglycerides in the blood. It also increases the concentration of 'good' cholesterol (HDL-cholesterol).

Simvastatin Sandoz belongs to a group of medicines called statins.

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

LDL-cholesterol is often referred to as 'bad' cholesterol because it can build up on the walls of your blood vessels, forming 'plaque.' Over time, this plaque can grow and lead to narrowing of the blood vessels. This narrowing can slow down or block the blood flow to vital organs such as the heart or brain, potentially causing a heart attack or stroke.

HDL-cholesterol is often referred to as 'good' cholesterol because it helps prevent the accumulation of bad cholesterol in the blood vessels, thus protecting against heart and vascular diseases.

Triglycerides are another form of fat in your blood vessels that increase the risk of heart and vascular diseases.

When using this medicine, you should continue your cholesterol-lowering diet.

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

• have an elevated concentration of cholesterol in your blood (primary hypercholesterolemia) or a high level of fats in your blood (mixed hyperlipidemia).

• have a hereditary condition (homozygous familial hypercholesterolemia) that increases the concentration of cholesterol in your blood. You may also receive other treatments.

• have coronary heart disease (CHD) or are at risk of getting it (due to having diabetes, a stroke, or another vascular condition). Simvastatin Sandoz can prolong your life by reducing the risk of heart and vascular complications, regardless of the amount of cholesterol in your blood.

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

**When should you not use this medicine or take extra precautions?  
When should you not use this medicine?**

* You are allergic to any of the substances in this medicine..
* You currently have liver problems.
* You are pregnant or breastfeeding:
  + You are using medicines containing one or more of the following active ingredients:
  + Itraconazole, ketoconazole, posaconazole, or voriconazole (antifungal agents)
  + Erythromycin, clarithromycin, or telithromycin (antibiotics)
  + HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used in HIV infections)
  + Boceprevir or telaprevir (used against hepatitis C virus infections)
  + Nefazodone (used in the treatment of depression)
  + Cobicistat
  + Gemfibrozil (used to lower cholesterol)
  + Ciclosporin (used in patients who have undergone an organ transplant)
  + Danazol (a synthetic hormone used for the treatment of endometriosis, a condition where the uterine lining grows outside the uterus)
  + Do not use more than 40 mg of Simvastatin Sandoz if you are using lomitapide (used to treat a severe and rare genetic cholesterol disorder).
  + If you are not sure whether you are using any of the above medicines, ask your doctor.

**When should you take extra precautions with this medicine?**Contact your doctor or pharmacist before using this medicine if you:

* have any medical conditions, including allergies to certain substances (allergies).
* consume large amounts of alcohol.
* have ever had liver disease. This medicine may not be suitable for you.
* are currently using, or have used in the last 7 days, a medicine called fusidic acid (a medicine used to treat bacterial infections) orally or through injection. The combination of fusidic acid with Simvastatin Sandoz can lead to severe muscle problems (rhabdomyolysis).
* If you need to undergo surgery, it may be necessary to temporarily discontinue Simvastatin Sandoz tablets.
* If you have myasthenia (a condition causing general muscle weakness, sometimes affecting the muscles used for breathing) or ocular myasthenia (a condition causing weakness of the eye muscles) or have had these conditions, as statins can sometimes worsen the condition or lead to the occurrence of myasthenia (see section 4).
* If you are of Asian descent, a different dosage may be applicable to you.

Your doctor should perform blood tests before you start using Simvastatin Sandoz and if you experience any symptoms of liver problems while using Simvastatin Sandoz. This examination is necessary to check if your liver is functioning properly.

Your doctor may also conduct blood tests after you have started taking Simvastatin Sandoz to monitor the function of your liver.

During the period of using this medicine, your doctor will closely monitor whether you have diabetes or are at an increased risk of developing diabetes. You may have an increased risk of developing diabetes if you have high sugar and fat levels in your blood, if you are overweight, and if you have high blood pressure.

Inform your doctor if you have a severe lung disease.

If, for unexplained reasons, you experience muscle pain, tenderness, or weakness after using this medicine, contact your doctor immediately. This is because muscle problems can be severe in rare cases, including muscle breakdown leading to kidney damage; in very rare cases, there have been fatalities.

Also, contact your doctor or pharmacist if you constantly experience muscle weakness. Additional tests and medications may be necessary to diagnose and treat this condition.

The risk of muscle breakdown is higher at higher doses of Simvastatin Sandoz, especially at a dosage of 80 mg. The risk of muscle breakdown is also higher in certain patients. If any of the following points apply to you, inform your doctor:

* You consume large amounts of alcohol.
* You have kidney problems.
* You have thyroid problems.
* You are 65 years or older.
* You are a woman.
* You have experienced muscle problems during treatment with cholesterol-lowering medicines called 'statins' or fibrates.
* You or a close family member have a hereditary muscle disease.

**Children and adolescents up to 18 years:**

The safety and efficacy of this medicine have been studied in boys aged 10-17 years and girls of the same age whose menstruation began at least a year before this medicine has not been studied in children under 10 years old. Consult your doctor for more information.

**Are you using any other medicines?**

If you are using or have recently used other medicines or if there is a possibility that you will use other medicines in the near future, please inform your doctor or pharmacist.

The use of Simvastatin Sandoz together with any of the following medicines may increase the risk of muscle problems (some of which have already been mentioned in the section above, "When should you not use this medicine"):

* If you are taking oral fusidic acid to treat a bacterial infection, you must temporarily stop using this medicine. Your doctor will tell you when it is safe to start Simvastatin Sandoz again. Concurrent use of Simvastatin Sandoz with fusidic acid can, in rare cases, lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See section 4 for further information on rhabdomyolysis.
* Ciclosporin (often used in patients who have undergone an organ transplant)
* Danazol (a synthetic hormone used for the treatment of endometriosis, a condition where the uterine lining grows outside the uterus)
* Medicines containing active ingredients such as itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (antifungal agents)
* Fibrates containing active ingredients such as gemfibrozil and bezafibrate (used to lower cholesterol in the blood)
* Erythromycin, clarithromycin, or telithromycin (antibiotics)
* HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used in the treatment of AIDS)
* Antiviral agents against hepatitis C, such as boceprevir, telaprevir, elbasvir, or grazoprevir (used against hepatitis C virus infections)
* Nefazodone (used in the treatment of depression)
* Medicines containing the active ingredient cobicistat
* Amiodarone (used for the treatment of irregular heartbeat)
* Verapamil, diltiazem, or amlodipine (used for high blood pressure, chest pain in heart disease, or other heart conditions)
* Lomitapide (used for the treatment of a severe and rare genetic cholesterol disorder)
* Daptomycin (a medicine used for the treatment of difficult-to-treat skin and skin structure infections and bacteremia (presence of bacteria in your blood)). Side effects affecting the muscles may worsen if this medicine is taken during treatment with simvastatin. Your doctor may decide to temporarily stop the use of simvastatin.
* Colchicine (used for the treatment of gout)
* Ticagrelor (used in patients who have had a heart attack or angina or chest pain that is not well controlled). If you are using ticagrelor, do not exceed 40 mg of simvastatin daily.

As with the above-mentioned medicines, you should inform your doctor or pharmacist if you are using or have recently used other medicines, including those available without a prescription. You should particularly inform your doctor about the use of medicines containing the following active ingredients:

* Medicines containing active ingredients that prevent blood clots, such as warfarin, phenprocoumon, or acenocoumarol (anticoagulants)
* Fenofibrate (also used to lower cholesterol in the blood)
* Niacin (also used to lower cholesterol in the blood)
* Rifampicin (used for the treatment of tuberculosis)

Inform any doctor who prescribes you a new medicine that you are using Simvastatin Sandoz.

**What to consider with food, drink, and alcohol?**Grapefruit juice contains one or more components that can affect the processing of certain medicines (including Simvastatin Sandoz) by the body. Therefore, drinking grapefruit juice should be avoided. Inform your doctor if you consume larger amounts of alcohol.

**Pregnancy and breastfeeding:** If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, contact your doctor or pharmacist before using this medicine.

Do not use Simvastatin Sandoz if you are pregnant or think you might be pregnant, or if you are planning to become pregnant. If you become pregnant while using this medicine, stop taking it immediately and inform your doctor.

Do not use Simvastatin Sandoz if you are breastfeeding because it is not known whether this medicine passes into breast milk.

**Driving and using machines:** This medicine is not expected to affect driving ability and the ability to use machines. However, be aware that some people may experience dizziness after using this medicine.

**Simvastatin Sandoz contains lactose:** If your doctor has told you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

**How to use this medicine?**Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and personal risk. Always use this medicine exactly as your doctor has told you. If you are unsure about the correct usage, contact your doctor or pharmacist. Continue your cholesterol-lowering diet while using Simvastatin Sandoz.

The recommended dosage is 1 tablet, once daily, taken orally.

**Adults:** The recommended starting dose is 10, 20, or, in some cases, 40 mg per day. Your doctor may adjust the dose to a maximum of 80 mg per day after a minimum of 4 weeks. Do not take more than 80 mg per day.

Your doctor may prescribe lower doses, especially if you are using any of the medicines mentioned above or if you have kidney problems.

The 80 mg dose is only recommended for adult patients with severely elevated cholesterol levels in the blood and a high risk of heart and vascular complications who have not achieved their cholesterol target levels with lower doses.

**Use in children and adolescents up to 18 years:** For children (10-17 years), the usual recommended starting dose is 10 mg once daily, to be taken in the evening. The maximum recommended dose is 40 mg once daily.

**Method of administration and duration of treatment:** Take this medicine in the evening. You can take it with or without food. Continue taking this medicine unless your doctor tells you to stop. The tablet can be divided into equal doses. If your doctor has prescribed Simvastatin Sandoz together with another cholesterol-lowering medicine containing a bile acid sequestrant, take Simvastatin Sandoz at least 2 hours before or 4 hours after administration of the bile acid sequestrant.

**Have you taken too much of this medicine:** Immediately consult your doctor. In case of an overdose, your doctor will take symptomatic and supportive measures.

**Did you forget to take this medicine:** Do not take a double dose to make up for a missed dose but continue with the prescribed dosage.

**If you stop using this medicine:** Contact your doctor or pharmacist as your cholesterol levels may rise again.

Do you have any other questions about the use of this medicine? Then, please contact your doctor or pharmacist.

**Possible side effects:**Like any medicine, this medicine can cause side effects, although not everybody gets them.

If you experience any of these serious side effects, stop using this medicine and immediately consult your doctor or go to the emergency department of the nearest hospital.The following rare serious side effects have been reported:

* Muscle pain, tenderness, weakness, or cramps. In rare cases, these muscle problems can be severe, including a serious muscle condition that can reduce kidney function, and in very rare cases, death has been reported.
* Hypersensitivity reactions (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 the limbs and neck muscles.
* Joint pain or inflammation (polymyalgia rheumatica)
* Inflammation of blood vessels (vasculitis)
* Unusual bruising, blisters, and swelling (dermatomyositis), hives, sun sensitivity, fever, flushing
* Shortness of breath (dyspnea) and feeling unwell
* Lupus-like syndrome (with skin rash, joint disorders, and effects on blood cells)

Inflammation of the liver with the following symptoms: yellowing of the skin and eyes (jaundice), itching, dark-colored urine, or pale stools, feeling tired or weak, loss of appetite, very rarely liver failure

Inflammation of the pancreas, often with severe abdominal pain

**The following very rare serious side effects have been reported:**

* Severe allergic reaction that may cause difficulty breathing or dizziness (anaphylaxis)
* Breast enlargement in men (gynecomastia)
* Skin rash or mouth ulcers (lichenoid drug eruptions)
* Muscle rupture

**Other side effects:**

**Rare (affect less than 1 in 1000 users):**

* Low red blood cell count (anemia)
* Numbness or weakness in the arms and legs
* Headache, tingling, dizziness
* Blurred vision and decreased visual acuity
* Digestive disorders (abdominal pain, constipation, flatulence, indigestion, diarrhea, nausea, vomiting)
* Skin rash, itching, hair loss
* Weakness
* Increase in certain laboratory results of blood tests for liver function and muscle enzyme (creatine kinase)
* Memory loss, confusion

**Very rare (affect less than 1 in 10,000 users):**

* Insomnia
* Poor memory

**Unknown frequency (frequency cannot be determined from available data):**

* Erectile problems
* Depression
* Pneumonia causing breathing problems, including persistent cough and/or shortness of breath or fever
* Tendon problems, sometimes with rupture as a complication
* Constant muscle weakness
* Myasthenia gravis (a disease that causes generalized muscle weakness, sometimes in the muscles used for breathing)
* Ocular myasthenia (a disease that causes weakness in the eye muscles)

Contact your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision, drooping eyelids, difficulty swallowing, or shortness of breath.

**The following possible side effects have been reported with various statins:**

* Sleep disturbances, including nightmares
* Sexual problems
* Diabetes. You have a greater risk of developing diabetes if you have high blood sugar and lipid levels, are overweight, and have high blood pressure. Your doctor will monitor you during the period you are using this medicine.

**How to store this medicine?**

* Keep out of sight and reach of children.
* Do not use this medicine after the expiry date which is stated on the blister, bottle, and carton after "EXP:". The expiry date refers to the last day of that month.
* Store below 30ºC.
* Store the blister in the outer packaging to protect it from light.
* Store in the original packaging to protect it from light.
* Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines that are no longer needed. These measures will help to protect the environment.

**Simvastatin 10 mg, 20mg, 40mg film-coated tablets**

**What is simvastatin sandoz and what is it used for?**Simvastatin Sandoz contains the active ingredient simvastatin. Simvastatin Sandoz is a medicine used to lower the levels of total cholesterol, 'bad' cholesterol (LDL-cholesterol), and fatty substances called triglycerides in the blood. It also increases the concentration of 'good' cholesterol (HDL-cholesterol).

Simvastatin Sandoz belongs to a group of medicines called statins.

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

LDL-cholesterol is often referred to as 'bad' cholesterol because it can build up on the walls of your blood vessels, forming 'plaque.' Over time, this plaque can grow and lead to narrowing of the blood vessels. This narrowing can slow down or block the blood flow to vital organs such as the heart or brain, potentially causing a heart attack or stroke.

HDL-cholesterol is often referred to as 'good' cholesterol because it helps prevent the accumulation of bad cholesterol in the blood vessels, thus protecting against heart and vascular diseases.

Triglycerides are another form of fat in your blood vessels that increase the risk of heart and vascular diseases.

When using this medicine, you should continue your cholesterol-lowering diet.

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

• have an elevated concentration of cholesterol in your blood (primary hypercholesterolemia) or a high level of fats in your blood (mixed hyperlipidemia).

• have a hereditary condition (homozygous familial hypercholesterolemia) that increases the concentration of cholesterol in your blood. You may also receive other treatments.

• have coronary heart disease (CHD) or are at risk of getting it (due to having diabetes, a stroke, or another vascular condition). Simvastatin Sandoz can prolong your life by reducing the risk of heart and vascular complications, regardless of the amount of cholesterol in your blood.

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

**When should you not use this medicine or take extra precautions?  
When should you not use this medicine?**

* You are allergic to any of the substances in this medicine..
* You currently have liver problems.
* You are pregnant or breastfeeding:
  + You are using medicines containing one or more of the following active ingredients:
  + Itraconazole, ketoconazole, posaconazole, or voriconazole (antifungal agents)
  + Erythromycin, clarithromycin, or telithromycin (antibiotics)
  + HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used in HIV infections)
  + Boceprevir or telaprevir (used against hepatitis C virus infections)
  + Nefazodone (used in the treatment of depression)
  + Cobicistat
  + Gemfibrozil (used to lower cholesterol)
  + Ciclosporin (used in patients who have undergone an organ transplant)
  + Danazol (a synthetic hormone used for the treatment of endometriosis, a condition where the uterine lining grows outside the uterus)
  + Do not use more than 40 mg of Simvastatin Sandoz if you are using lomitapide (used to treat a severe and rare genetic cholesterol disorder).
  + If you are not sure whether you are using any of the above medicines, ask your doctor.

**When should you take extra precautions with this medicine?**Contact your doctor or pharmacist before using this medicine if you:

* have any medical conditions, including allergies to certain substances (allergies).
* consume large amounts of alcohol.
* have ever had liver disease. This medicine may not be suitable for you.
* are currently using, or have used in the last 7 days, a medicine called fusidic acid (a medicine used to treat bacterial infections) orally or through injection. The combination of fusidic acid with Simvastatin Sandoz can lead to severe muscle problems (rhabdomyolysis).
* If you need to undergo surgery, it may be necessary to temporarily discontinue Simvastatin Sandoz tablets.
* If you have myasthenia (a condition causing general muscle weakness, sometimes affecting the muscles used for breathing) or ocular myasthenia (a condition causing weakness of the eye muscles) or have had these conditions, as statins can sometimes worsen the condition or lead to the occurrence of myasthenia (see section 4).
* If you are of Asian descent, a different dosage may be applicable to you.

Your doctor should perform blood tests before you start using Simvastatin Sandoz and if you experience any symptoms of liver problems while using Simvastatin Sandoz. This examination is necessary to check if your liver is functioning properly.

Your doctor may also conduct blood tests after you have started taking Simvastatin Sandoz to monitor the function of your liver.

During the period of using this medicine, your doctor will closely monitor whether you have diabetes or are at an increased risk of developing diabetes. You may have an increased risk of developing diabetes if you have high sugar and fat levels in your blood, if you are overweight, and if you have high blood pressure.

Inform your doctor if you have a severe lung disease.

If, for unexplained reasons, you experience muscle pain, tenderness, or weakness after using this medicine, contact your doctor immediately. This is because muscle problems can be severe in rare cases, including muscle breakdown leading to kidney damage; in very rare cases, there have been fatalities.

Also, contact your doctor or pharmacist if you constantly experience muscle weakness. Additional tests and medications may be necessary to diagnose and treat this condition.

The risk of muscle breakdown is higher at higher doses of Simvastatin Sandoz, especially at a dosage of 80 mg. The risk of muscle breakdown is also higher in certain patients. If any of the following points apply to you, inform your doctor:

* You consume large amounts of alcohol.
* You have kidney problems.
* You have thyroid problems.
* You are 65 years or older.
* You are a woman.
* You have experienced muscle problems during treatment with cholesterol-lowering medicines called 'statins' or fibrates.
* You or a close family member have a hereditary muscle disease.

**Children and adolescents up to 18 years:**

The safety and efficacy of this medicine have been studied in boys aged 10-17 years and girls of the same age whose menstruation began at least a year before this medicine has not been studied in children under 10 years old. Consult your doctor for more information.

**Are you using any other medicines?**

If you are using or have recently used other medicines or if there is a possibility that you will use other medicines in the near future, please inform your doctor or pharmacist.

The use of Simvastatin Sandoz together with any of the following medicines may increase the risk of muscle problems (some of which have already been mentioned in the section above, "When should you not use this medicine"):

* If you are taking oral fusidic acid to treat a bacterial infection, you must temporarily stop using this medicine. Your doctor will tell you when it is safe to start Simvastatin Sandoz again. Concurrent use of Simvastatin Sandoz with fusidic acid can, in rare cases, lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See section 4 for further information on rhabdomyolysis.
* Ciclosporin (often used in patients who have undergone an organ transplant)
* Danazol (a synthetic hormone used for the treatment of endometriosis, a condition where the uterine lining grows outside the uterus)
* Medicines containing active ingredients such as itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (antifungal agents)
* Fibrates containing active ingredients such as gemfibrozil and bezafibrate (used to lower cholesterol in the blood)
* Erythromycin, clarithromycin, or telithromycin (antibiotics)
* HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used in the treatment of AIDS)
* Antiviral agents against hepatitis C, such as boceprevir, telaprevir, elbasvir, or grazoprevir (used against hepatitis C virus infections)
* Nefazodone (used in the treatment of depression)
* Medicines containing the active ingredient cobicistat
* Amiodarone (used for the treatment of irregular heartbeat)
* Verapamil, diltiazem, or amlodipine (used for high blood pressure, chest pain in heart disease, or other heart conditions)
* Lomitapide (used for the treatment of a severe and rare genetic cholesterol disorder)
* Daptomycin (a medicine used for the treatment of difficult-to-treat skin and skin structure infections and bacteremia (presence of bacteria in your blood)). Side effects affecting the muscles may worsen if this medicine is taken during treatment with simvastatin. Your doctor may decide to temporarily stop the use of simvastatin.
* Colchicine (used for the treatment of gout)
* Ticagrelor (used in patients who have had a heart attack or angina or chest pain that is not well controlled). If you are using ticagrelor, do not exceed 40 mg of simvastatin daily.

As with the above-mentioned medicines, you should inform your doctor or pharmacist if you are using or have recently used other medicines, including those available without a prescription. You should particularly inform your doctor about the use of medicines containing the following active ingredients:

* Medicines containing active ingredients that prevent blood clots, such as warfarin, phenprocoumon, or acenocoumarol (anticoagulants)
* Fenofibrate (also used to lower cholesterol in the blood)
* Niacin (also used to lower cholesterol in the blood)
* Rifampicin (used for the treatment of tuberculosis)

Inform any doctor who prescribes you a new medicine that you are using Simvastatin Sandoz.

**What to consider with food, drink, and alcohol?**Grapefruit juice contains one or more components that can affect the processing of certain medicines (including Simvastatin Sandoz) by the body. Therefore, drinking grapefruit juice should be avoided. Inform your doctor if you consume larger amounts of alcohol.

**Pregnancy and breastfeeding:** If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, contact your doctor or pharmacist before using this medicine.

Do not use Simvastatin Sandoz if you are pregnant or think you might be pregnant, or if you are planning to become pregnant. If you become pregnant while using this medicine, stop taking it immediately and inform your doctor.

Do not use Simvastatin Sandoz if you are breastfeeding because it is not known whether this medicine passes into breast milk.

**Driving and using machines:** This medicine is not expected to affect driving ability and the ability to use machines. However, be aware that some people may experience dizziness after using this medicine.

**Simvastatin Sandoz contains lactose:** If your doctor has told you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

**How to use this medicine?**Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and personal risk. Always use this medicine exactly as your doctor has told you. If you are unsure about the correct usage, contact your doctor or pharmacist. Continue your cholesterol-lowering diet while using Simvastatin Sandoz.

The recommended dosage is 1 tablet, once daily, taken orally.

**Adults:** The recommended starting dose is 10, 20, or, in some cases, 40 mg per day. Your doctor may adjust the dose to a maximum of 80 mg per day after a minimum of 4 weeks. Do not take more than 80 mg per day.

Your doctor may prescribe lower doses, especially if you are using any of the medicines mentioned above or if you have kidney problems.

The 80 mg dose is only recommended for adult patients with severely elevated cholesterol levels in the blood and a high risk of heart and vascular complications who have not achieved their cholesterol target levels with lower doses.

**Use in children and adolescents up to 18 years:** For children (10-17 years), the usual recommended starting dose is 10 mg once daily, to be taken in the evening. The maximum recommended dose is 40 mg once daily.

**Method of administration and duration of treatment:** Take this medicine in the evening. You can take it with or without food. Continue taking this medicine unless your doctor tells you to stop. The tablet can be divided into equal doses. If your doctor has prescribed Simvastatin Sandoz together with another cholesterol-lowering medicine containing a bile acid sequestrant, take Simvastatin Sandoz at least 2 hours before or 4 hours after administration of the bile acid sequestrant.

**Have you taken too much of this medicine:** Immediately consult your doctor. In case of an overdose, your doctor will take symptomatic and supportive measures.

**Did you forget to take this medicine:** Do not take a double dose to make up for a missed dose but continue with the prescribed dosage.

**If you stop using this medicine:** Contact your doctor or pharmacist as your cholesterol levels may rise again.

Do you have any other questions about the use of this medicine? Then, please contact your doctor or pharmacist.

**Possible side effects:**Like any medicine, this medicine can cause side effects, although not everybody gets them.

If you experience any of these serious side effects, stop using this medicine and immediately consult your doctor or go to the emergency department of the nearest hospital.The following rare serious side effects have been reported:

* Muscle pain, tenderness, weakness, or cramps. In rare cases, these muscle problems can be severe, including a serious muscle condition that can reduce kidney function, and in very rare cases, death has been reported.
* Hypersensitivity reactions (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 the limbs and neck muscles.
* Joint pain or inflammation (polymyalgia rheumatica)
* Inflammation of blood vessels (vasculitis)
* Unusual bruising, blisters, and swelling (dermatomyositis), hives, sun sensitivity, fever, flushing
* Shortness of breath (dyspnea) and feeling unwell
* Lupus-like syndrome (with skin rash, joint disorders, and effects on blood cells)

Inflammation of the liver with the following symptoms: yellowing of the skin and eyes (jaundice), itching, dark-colored urine, or pale stools, feeling tired or weak, loss of appetite, very rarely liver failure

Inflammation of the pancreas, often with severe abdominal pain

**The following very rare serious side effects have been reported:**

* Severe allergic reaction that may cause difficulty breathing or dizziness (anaphylaxis)
* Breast enlargement in men (gynecomastia)
* Skin rash or mouth ulcers (lichenoid drug eruptions)
* Muscle rupture

**Other side effects:**

**Rare (affect less than 1 in 1000 users):**

* Low red blood cell count (anemia)
* Numbness or weakness in the arms and legs
* Headache, tingling, dizziness
* Blurred vision and decreased visual acuity
* Digestive disorders (abdominal pain, constipation, flatulence, indigestion, diarrhea, nausea, vomiting)
* Skin rash, itching, hair loss
* Weakness
* Increase in certain laboratory results of blood tests for liver function and muscle enzyme (creatine kinase)
* Memory loss, confusion

**Very rare (affect less than 1 in 10,000 users):**

* Insomnia
* Poor memory

**Unknown frequency (frequency cannot be determined from available data):**

* Erectile problems
* Depression
* Pneumonia causing breathing problems, including persistent cough and/or shortness of breath or fever
* Tendon problems, sometimes with rupture as a complication
* Constant muscle weakness
* Myasthenia gravis (a disease that causes generalized muscle weakness, sometimes in the muscles used for breathing)
* Ocular myasthenia (a disease that causes weakness in the eye muscles)

Contact your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision, drooping eyelids, difficulty swallowing, or shortness of breath.

**The following possible side effects have been reported with various statins:**

* Sleep disturbances, including nightmares
* Sexual problems
* Diabetes. You have a greater risk of developing diabetes if you have high blood sugar and lipid levels, are overweight, and have high blood pressure. Your doctor will monitor you during the period you are using this medicine.

**How to store this medicine?**

* Keep out of sight and reach of children.
* Do not use this medicine after the expiry date which is stated on the blister, bottle, and carton after "EXP:". The expiry date refers to the last day of that month.
* Store below 30ºC.
* Store the blister in the outer packaging to protect it from light.
* Store in the original packaging to protect it from light.
* Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines that are no longer needed. These measures will help to protect the environment.

**Simvastatin 10 mg, 20mg, 40mg film-coated tablets**

**What is simvastatin sandoz and what is it used for?**Simvastatin Sandoz contains the active ingredient simvastatin. Simvastatin Sandoz is a medicine used to lower the levels of total cholesterol, 'bad' cholesterol (LDL-cholesterol), and fatty substances called triglycerides in the blood. It also increases the concentration of 'good' cholesterol (HDL-cholesterol).

Simvastatin Sandoz belongs to a group of medicines called statins.

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

LDL-cholesterol is often referred to as 'bad' cholesterol because it can build up on the walls of your blood vessels, forming 'plaque.' Over time, this plaque can grow and lead to narrowing of the blood vessels. This narrowing can slow down or block the blood flow to vital organs such as the heart or brain, potentially causing a heart attack or stroke.

HDL-cholesterol is often referred to as 'good' cholesterol because it helps prevent the accumulation of bad cholesterol in the blood vessels, thus protecting against heart and vascular diseases.

Triglycerides are another form of fat in your blood vessels that increase the risk of heart and vascular diseases.

When using this medicine, you should continue your cholesterol-lowering diet.

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

• have an elevated concentration of cholesterol in your blood (primary hypercholesterolemia) or a high level of fats in your blood (mixed hyperlipidemia).

• have a hereditary condition (homozygous familial hypercholesterolemia) that increases the concentration of cholesterol in your blood. You may also receive other treatments.

• have coronary heart disease (CHD) or are at risk of getting it (due to having diabetes, a stroke, or another vascular condition). Simvastatin Sandoz can prolong your life by reducing the risk of heart and vascular complications, regardless of the amount of cholesterol in your blood.

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

**When should you not use this medicine or take extra precautions?  
When should you not use this medicine?**

* You are allergic to any of the substances in this medicine..
* You currently have liver problems.
* You are pregnant or breastfeeding:
  + You are using medicines containing one or more of the following active ingredients:
  + Itraconazole, ketoconazole, posaconazole, or voriconazole (antifungal agents)
  + Erythromycin, clarithromycin, or telithromycin (antibiotics)
  + HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used in HIV infections)
  + Boceprevir or telaprevir (used against hepatitis C virus infections)
  + Nefazodone (used in the treatment of depression)
  + Cobicistat
  + Gemfibrozil (used to lower cholesterol)
  + Ciclosporin (used in patients who have undergone an organ transplant)
  + Danazol (a synthetic hormone used for the treatment of endometriosis, a condition where the uterine lining grows outside the uterus)
  + Do not use more than 40 mg of Simvastatin Sandoz if you are using lomitapide (used to treat a severe and rare genetic cholesterol disorder).
  + If you are not sure whether you are using any of the above medicines, ask your doctor.

**When should you take extra precautions with this medicine?**Contact your doctor or pharmacist before using this medicine if you:

* have any medical conditions, including allergies to certain substances (allergies).
* consume large amounts of alcohol.
* have ever had liver disease. This medicine may not be suitable for you.
* are currently using, or have used in the last 7 days, a medicine called fusidic acid (a medicine used to treat bacterial infections) orally or through injection. The combination of fusidic acid with Simvastatin Sandoz can lead to severe muscle problems (rhabdomyolysis).
* If you need to undergo surgery, it may be necessary to temporarily discontinue Simvastatin Sandoz tablets.
* If you have myasthenia (a condition causing general muscle weakness, sometimes affecting the muscles used for breathing) or ocular myasthenia (a condition causing weakness of the eye muscles) or have had these conditions, as statins can sometimes worsen the condition or lead to the occurrence of myasthenia (see section 4).
* If you are of Asian descent, a different dosage may be applicable to you.

Your doctor should perform blood tests before you start using Simvastatin Sandoz and if you experience any symptoms of liver problems while using Simvastatin Sandoz. This examination is necessary to check if your liver is functioning properly.

Your doctor may also conduct blood tests after you have started taking Simvastatin Sandoz to monitor the function of your liver.

During the period of using this medicine, your doctor will closely monitor whether you have diabetes or are at an increased risk of developing diabetes. You may have an increased risk of developing diabetes if you have high sugar and fat levels in your blood, if you are overweight, and if you have high blood pressure.

Inform your doctor if you have a severe lung disease.

If, for unexplained reasons, you experience muscle pain, tenderness, or weakness after using this medicine, contact your doctor immediately. This is because muscle problems can be severe in rare cases, including muscle breakdown leading to kidney damage; in very rare cases, there have been fatalities.

Also, contact your doctor or pharmacist if you constantly experience muscle weakness. Additional tests and medications may be necessary to diagnose and treat this condition.

The risk of muscle breakdown is higher at higher doses of Simvastatin Sandoz, especially at a dosage of 80 mg. The risk of muscle breakdown is also higher in certain patients. If any of the following points apply to you, inform your doctor:

* You consume large amounts of alcohol.
* You have kidney problems.
* You have thyroid problems.
* You are 65 years or older.
* You are a woman.
* You have experienced muscle problems during treatment with cholesterol-lowering medicines called 'statins' or fibrates.
* You or a close family member have a hereditary muscle disease.

**Children and adolescents up to 18 years:**

The safety and efficacy of this medicine have been studied in boys aged 10-17 years and girls of the same age whose menstruation began at least a year before this medicine has not been studied in children under 10 years old. Consult your doctor for more information.

**Are you using any other medicines?**

If you are using or have recently used other medicines or if there is a possibility that you will use other medicines in the near future, please inform your doctor or pharmacist.

The use of Simvastatin Sandoz together with any of the following medicines may increase the risk of muscle problems (some of which have already been mentioned in the section above, "When should you not use this medicine"):

* If you are taking oral fusidic acid to treat a bacterial infection, you must temporarily stop using this medicine. Your doctor will tell you when it is safe to start Simvastatin Sandoz again. Concurrent use of Simvastatin Sandoz with fusidic acid can, in rare cases, lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See section 4 for further information on rhabdomyolysis.
* Ciclosporin (often used in patients who have undergone an organ transplant)
* Danazol (a synthetic hormone used for the treatment of endometriosis, a condition where the uterine lining grows outside the uterus)
* Medicines containing active ingredients such as itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (antifungal agents)
* Fibrates containing active ingredients such as gemfibrozil and bezafibrate (used to lower cholesterol in the blood)
* Erythromycin, clarithromycin, or telithromycin (antibiotics)
* HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used in the treatment of AIDS)
* Antiviral agents against hepatitis C, such as boceprevir, telaprevir, elbasvir, or grazoprevir (used against hepatitis C virus infections)
* Nefazodone (used in the treatment of depression)
* Medicines containing the active ingredient cobicistat
* Amiodarone (used for the treatment of irregular heartbeat)
* Verapamil, diltiazem, or amlodipine (used for high blood pressure, chest pain in heart disease, or other heart conditions)
* Lomitapide (used for the treatment of a severe and rare genetic cholesterol disorder)
* Daptomycin (a medicine used for the treatment of difficult-to-treat skin and skin structure infections and bacteremia (presence of bacteria in your blood)). Side effects affecting the muscles may worsen if this medicine is taken during treatment with simvastatin. Your doctor may decide to temporarily stop the use of simvastatin.
* Colchicine (used for the treatment of gout)
* Ticagrelor (used in patients who have had a heart attack or angina or chest pain that is not well controlled). If you are using ticagrelor, do not exceed 40 mg of simvastatin daily.

As with the above-mentioned medicines, you should inform your doctor or pharmacist if you are using or have recently used other medicines, including those available without a prescription. You should particularly inform your doctor about the use of medicines containing the following active ingredients:

* Medicines containing active ingredients that prevent blood clots, such as warfarin, phenprocoumon, or acenocoumarol (anticoagulants)
* Fenofibrate (also used to lower cholesterol in the blood)
* Niacin (also used to lower cholesterol in the blood)
* Rifampicin (used for the treatment of tuberculosis)

Inform any doctor who prescribes you a new medicine that you are using Simvastatin Sandoz.

**What to consider with food, drink, and alcohol?**Grapefruit juice contains one or more components that can affect the processing of certain medicines (including Simvastatin Sandoz) by the body. Therefore, drinking grapefruit juice should be avoided. Inform your doctor if you consume larger amounts of alcohol.

**Pregnancy and breastfeeding:** If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, contact your doctor or pharmacist before using this medicine.

Do not use Simvastatin Sandoz if you are pregnant or think you might be pregnant, or if you are planning to become pregnant. If you become pregnant while using this medicine, stop taking it immediately and inform your doctor.

Do not use Simvastatin Sandoz if you are breastfeeding because it is not known whether this medicine passes into breast milk.

**Driving and using machines:** This medicine is not expected to affect driving ability and the ability to use machines. However, be aware that some people may experience dizziness after using this medicine.

**Simvastatin Sandoz contains lactose:** If your doctor has told you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

**How to use this medicine?**Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and personal risk. Always use this medicine exactly as your doctor has told you. If you are unsure about the correct usage, contact your doctor or pharmacist. Continue your cholesterol-lowering diet while using Simvastatin Sandoz.

The recommended dosage is 1 tablet, once daily, taken orally.

**Adults:** The recommended starting dose is 10, 20, or, in some cases, 40 mg per day. Your doctor may adjust the dose to a maximum of 80 mg per day after a minimum of 4 weeks. Do not take more than 80 mg per day.

Your doctor may prescribe lower doses, especially if you are using any of the medicines mentioned above or if you have kidney problems.

The 80 mg dose is only recommended for adult patients with severely elevated cholesterol levels in the blood and a high risk of heart and vascular complications who have not achieved their cholesterol target levels with lower doses.

**Use in children and adolescents up to 18 years:** For children (10-17 years), the usual recommended starting dose is 10 mg once daily, to be taken in the evening. The maximum recommended dose is 40 mg once daily.

**Method of administration and duration of treatment:** Take this medicine in the evening. You can take it with or without food. Continue taking this medicine unless your doctor tells you to stop. The tablet can be divided into equal doses. If your doctor has prescribed Simvastatin Sandoz together with another cholesterol-lowering medicine containing a bile acid sequestrant, take Simvastatin Sandoz at least 2 hours before or 4 hours after administration of the bile acid sequestrant.

**Have you taken too much of this medicine:** Immediately consult your doctor. In case of an overdose, your doctor will take symptomatic and supportive measures.

**Did you forget to take this medicine:** Do not take a double dose to make up for a missed dose but continue with the prescribed dosage.

**If you stop using this medicine:** Contact your doctor or pharmacist as your cholesterol levels may rise again.

Do you have any other questions about the use of this medicine? Then, please contact your doctor or pharmacist.

**Possible side effects:**Like any medicine, this medicine can cause side effects, although not everybody gets them.

If you experience any of these serious side effects, stop using this medicine and immediately consult your doctor or go to the emergency department of the nearest hospital.The following rare serious side effects have been reported:

* Muscle pain, tenderness, weakness, or cramps. In rare cases, these muscle problems can be severe, including a serious muscle condition that can reduce kidney function, and in very rare cases, death has been reported.
* Hypersensitivity reactions (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 the limbs and neck muscles.
* Joint pain or inflammation (polymyalgia rheumatica)
* Inflammation of blood vessels (vasculitis)
* Unusual bruising, blisters, and swelling (dermatomyositis), hives, sun sensitivity, fever, flushing
* Shortness of breath (dyspnea) and feeling unwell
* Lupus-like syndrome (with skin rash, joint disorders, and effects on blood cells)

Inflammation of the liver with the following symptoms: yellowing of the skin and eyes (jaundice), itching, dark-colored urine, or pale stools, feeling tired or weak, loss of appetite, very rarely liver failure

Inflammation of the pancreas, often with severe abdominal pain

**The following very rare serious side effects have been reported:**

* Severe allergic reaction that may cause difficulty breathing or dizziness (anaphylaxis)
* Breast enlargement in men (gynecomastia)
* Skin rash or mouth ulcers (lichenoid drug eruptions)
* Muscle rupture

**Other side effects:**

**Rare (affect less than 1 in 1000 users):**

* Low red blood cell count (anemia)
* Numbness or weakness in the arms and legs
* Headache, tingling, dizziness
* Blurred vision and decreased visual acuity
* Digestive disorders (abdominal pain, constipation, flatulence, indigestion, diarrhea, nausea, vomiting)
* Skin rash, itching, hair loss
* Weakness
* Increase in certain laboratory results of blood tests for liver function and muscle enzyme (creatine kinase)
* Memory loss, confusion

**Very rare (affect less than 1 in 10,000 users):**

* Insomnia
* Poor memory

**Unknown frequency (frequency cannot be determined from available data):**

* Erectile problems
* Depression
* Pneumonia causing breathing problems, including persistent cough and/or shortness of breath or fever
* Tendon problems, sometimes with rupture as a complication
* Constant muscle weakness
* Myasthenia gravis (a disease that causes generalized muscle weakness, sometimes in the muscles used for breathing)
* Ocular myasthenia (a disease that causes weakness in the eye muscles)

Contact your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision, drooping eyelids, difficulty swallowing, or shortness of breath.

**The following possible side effects have been reported with various statins:**

* Sleep disturbances, including nightmares
* Sexual problems
* Diabetes. You have a greater risk of developing diabetes if you have high blood sugar and lipid levels, are overweight, and have high blood pressure. Your doctor will monitor you during the period you are using this medicine.

**How to store this medicine?**

* Keep out of sight and reach of children.
* Do not use this medicine after the expiry date which is stated on the blister, bottle, and carton after "EXP:". The expiry date refers to the last day of that month.
* Store below 30ºC.
* Store the blister in the outer packaging to protect it from light.
* Store in the original packaging to protect it from light.
* Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines that are no longer needed. These measures will help to protect the environment.