

## **Package leaflet: Information for the user**

### **Simvastatin Normon 10 mg film-coated tablets**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

- 1. What Simvastatin Normon is and what it is used for**
- 2. What you need to know before you take Simvastatin Normon**
- 3. How to take Simvastatin Normon**
- 4. Possible side effects**
- 5. How to store Simvastatin Normon**
- 6. Contents of the pack and other information**

#### **1. What Simvastatin Normon is and what it is used for**

Simvastatin Normon contains the active substance simvastatin. This medicine is used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, it raises levels of “good” cholesterol (HDL cholesterol). This medicine belongs to a class of medicines called statins.

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

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

You should stay on a cholesterol-lowering diet while taking this medicine.

This medicine is used in addition to your cholesterol lowering diet if you have:

A raised cholesterol level in your blood (primary hypercholesterolaemia) or elevated fat levels in your blood (mixed hyperlipidaemia).

A hereditary illness (homozygous familial hypercholesterolemia) that increases the cholesterol level in your blood. You may also receive other treatments.

Coronary heart disease (CHD) or are at high risk of CHD (because you have diabetes, history of stroke, or other blood vessel disease). Simvastatin may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

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

## **2. What you need to know before you take Simvastatin Normon**

### **Do not take Simvastatin Normon**

- If you are allergic to simvastatin or any of the other ingredients of this medicine (listed in section 6).
- If you currently have liver problems.
- If you are pregnant or breast-feeding.
- If you are taking medicine(s) with one or more than one of the following active ingredients:
  - Itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections).
  - Erythromycin, clarithromycin or telithromycin (used to treat infections).
  - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (HIV protease inhibitors are used for HIV infections).
  - Boceprevir or telaprevir (used to treat hepatitis C virus infection).
  - Nefazodone (used to treat depression).
  - Cobicistat.
  - Gemfibrozil (used to lower cholesterol).
  - Ciclosporin (used in organ transplant patients).
  - Danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus).
- If you are taking or have taken, in the last 7 days, a medicine called fusidic acid (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and simvastatin may lead to serious muscle problems (rhabdomyolysis).
- Do not take more than 40 mg simvastatin if you are taking lomitapide (used to treat a serious and rare genetic cholesterol condition).

Ask your doctor if you are not sure if your medicine is listed above.

### **Warnings and precautions**

Talk to your doctor or pharmacist before you start taking this medicine.

Talk to your doctor:

- About all your medical conditions including allergies.
- If you drink large amounts of alcohol.
- If you have ever had liver disease. Simvastatin may not be right for you.
- If you are due to have an operation. You may need to stop taking simvastatin tablets for a short time.
- If you are Asian because a different dose may be applicable to you.

Your doctor should do a blood test before you start taking this medicine and if you have any symptoms of liver problems while you take this medicine. This is to check how well your liver is working.

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking this medicine.

While you are on this medicine, your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Tell your doctor if you have severe lung disease.

**Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.**

The risk of muscle breakdown is greater at higher doses of simvastatin, particularly the 80 mg dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- You consume large amounts of alcohol.
- You have kidney problems.
- You have thyroid problems.
- You are 65 years or older.
- You are female.
- You have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” or fibrates.
- You or a close family member have a hereditary muscle disorder.

Also talk to your doctor or pharmacist if you have constant muscle weakness. Additional tests and medicines may be necessary to diagnose and treat this problem.

### **Children and adolescents**

Safety and effectiveness of treatment with simvastatin have been studied in 10–17-year-old boys and in girls who had started their menstrual period (menstruation) at least one year before (see section 3). Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

### **Other medicines and Simvastatin Normon**

Other medicines and Simvastatin Normon. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

Taking simvastatin with any of the following drugs can increase the risk of muscle problems (some of these have already been listed in the above section “Do not take Simvastatin Normon”).

- **If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart simvastatin use. Taking simvastatin with fusidic acid may rarely lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See section 4 for more information on rhabdomyolysis.**
- Ciclosporin (often used in organ transplant patients).
- Danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus).

- Medicines with an active ingredient like itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole (used to treat fungal infections).
- Fibrates with an active ingredient like gemfibrozil and bezafibrate (used to lower cholesterol).
- Erythromycin, clarithromycin, telithromycin (used to treat bacterial infections).
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (used to treat AIDS).
- Hepatitis C antiviral agents such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C virus infection).
- Nefazodone (used to treat depression).
- Medicines with the active ingredient cobicistat.
- Amiodarone (used to treat an irregular heartbeat).
- Verapamil, diltiazem, or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions).
- Lomitapide (used to treat a serious and rare genetic cholesterol condition).
- Daptomycin (a drug used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin. Your doctor may decide that you stop taking this medicine for a while.
- Colchicine (used to treat gout).
- Ticagrelor (antiplatelet medicine).

As well as the medicines listed above, tell your doctor if you are taking medicines with any of the following active ingredients:

- Medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon or acenocumarol (anticoagulants).
- Fenofibrate (also used to lower cholesterol).
- Niacin (also used to lower cholesterol).
- Rifampicin (used to treat tuberculosis).

You should also tell any doctor who is prescribing a new medicine for you that you are taking simvastatin.

### **Simvastatin Normon with food and drink**

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

### **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you get pregnant while taking this medicine, stop taking it immediately and contact your doctor. Do not take this medicine if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

Ask your doctor or pharmacist for advice before using any medicine.

### **Driving and using machines**

Simvastatin not expected to interfere with your ability to drive or operate machinery. However, it should be taken into account that some people get dizzy after taking simvastatin.

### **Simvastatin Normon contains lactose**

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.

### **3. How to take Simvastatin Normon**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment, and your personal risk status.

Before starting this medicine, you should be on a diet to lower your cholesterol.

Posology:

The recommended dose is 1 tablet by mouth once a day.

Adults:

The usual starting dose is 10, 20 or, in some cases, 40 mg a day. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day. **Do not take more than 80 mg a day.**

Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have certain kidney conditions.

The 80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

### **Use in children and adolescents**

For children and adolescents (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended daily dose is 40 mg.

Method of administration:

Take this medicine in the evening. You can take it with or without food. Keep taking it unless your doctor tells you to stop.

If your doctor has prescribed simvastatin with another medicine for lowering cholesterol containing any bile acid sequestrant, you should take simvastatin at least 2 hours before or at least 4 hours after taking the bile acid sequestrant.

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

In case of overdose or accidental intake, immediately talk to your doctor or pharmacist, or go to the nearest hospital, indicating the medicine and the amount taken.

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

Do not take a double dose to make up for a forgotten dose. Just take your normal amount of this medicine at the usual time the next day.

### **If you stop taking Simvastatin Normon**

Talk to your doctor or pharmacist because your cholesterol may rise again.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following terms are used to describe how often side effects have been reported:

- Rare (may affect up to 1 in 1,000 patients).
- Very rare (may affect up to 1 in 10,000 people).
- Not known (frequency cannot be estimated from the available data).

**If any of the below mentioned serious side effects happen, stop taking the medicine and tell your doctor immediately or go to the emergency room at your nearest hospital.**

The following **rare** serious side effects were reported:

- Muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- Hypersensitivity (allergic) reactions including:
  - Swelling of the face, tongue and throat which may cause difficulty in breathing (angioedema).
  - Severe muscle pain usually in the shoulders and hips, rash with weakness of limbs and neck muscles, pain or inflammation of the joints (polymyalgia rheumatica), inflammation of the blood vessels (vasculitis), unusual bruising, skin eruptions and swelling (dermatomyositis), hives, skin sensitivity to the sun, fever, flushing, shortness of breath (dyspnoea) and feeling unwell, lupus-like disease picture (including rash, joint disorders, and effects on blood cells).
- Inflammation of the liver with the following symptoms: yellowing of the skin and eyes, itching, dark-coloured urine, or pale-coloured stool, feeling tired or weak.
- Loss of appetite.
- Liver failure (very rare).
- Inflammation of the pancreas often with severe abdominal pain.

The following rare serious side effects were reported:

- A severe allergic reaction that causes breathing difficulties or dizziness (anaphylactic reaction).
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions).
- Muscle rupture.
- Gynecomastia (breast enlargement in men).

The following side effects have also been reported rarely:

- Low red blood cell count (anaemia).
- Numbness or weakness of the arms and legs.
- Headache, tingling sensation, dizziness.
- Blurred vision; impaired vision.

- Digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting).
- Rash, itching, hair loss.
- Weakness.
- Trouble sleeping (very rare).
- Poor memory (very rare), memory loss, confusion.

The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):

- Erectile dysfunction.
- Depression.
- Inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever.
- Tendon problems, sometimes complicated by rupture of the tendon.

Additional possible side effects reported with some statins:

- Sleep disturbances, including nightmares.
- Sexual dysfunction.
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.
- Muscle pain, tenderness, or weakness that is constant that may not go away after stopping treatment with simvastatin (frequency not known).

#### *Complementary tests*

Elevations in some laboratory blood tests of liver function (transaminases) and a muscle enzyme (creatine kinase) have been observed.

#### **Reporting of side effects**

If you get any adverse effects talk to your doctor, pharmacist, or nurse. This includes any possible adverse effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Simvastatin Normon**

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

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original packaging in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

##### **What Simvastatin Normon contains**

The active substance is simvastatin. Each tablet contains 10 mg of simvastatin.

The other ingredients (excipients) are: pregelatinised maize starch, microcrystalline cellulose, lactose monohydrate, butylated hydroxyanisole (E-320), magnesium stearate, ascorbic acid, citric acid, hypromellose, titanium dioxide (E-171), yellow iron oxide (E-172), red iron oxide (E-172), talc and macrogol 6000.

**What Simvastatin Normon looks like and contents of the pack**

Simvastatin Normon 10 mg film-coated tablets are pinkish, round, biconvex and scored tablets. Each pack contains 28 tablets.

**Marketing Authorisation Holder and Manufacturer**

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

**The text was last reviewed in:** June 2022

## **Package leaflet: Information for the user**

### **Simvastatin Normon 20 mg film-coated tablets**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.  
If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. You should not pass it on to others because it may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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#### **1. What Simvastatin Normon is and what it is used for**

Simvastatin Normon contains the active substance simvastatin. This medicine is used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, it raises levels of “good” cholesterol (HDL cholesterol). This medicine belongs to a class of medicines called statins.

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

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

You should stay on a cholesterol-lowering diet while taking this medicine.

This medicine is used in addition to your cholesterol lowering diet if you have:

A raised cholesterol level in your blood (primary hypercholesterolemia) or elevated fat levels in your blood (mixed hyperlipidaemia).

A hereditary illness (homozygous familial hypercholesterolemia) that increases the cholesterol level in your blood. You may also receive other treatments.

Coronary heart disease (CHD) or are at high risk of CHD (because you have diabetes, history of stroke, or other blood vessel disease). Simvastatin may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

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

## **2. What you need to know before you take Simvastatin Normon**

### **Do not take Simvastatin Normon**

- If you are allergic to simvastatin or any of the other ingredients of this medicine (listed in section 6).
- If you currently have liver problems.
- If you are pregnant or breastfeeding.
- If you are taking medicine(s) with one or more than one of the following active ingredients:
  - Itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections).
  - Erythromycin, clarithromycin or telithromycin (used to treat infections).
  - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (HIV protease inhibitors are used for HIV infections).
  - Boceprevir or telaprevir (used to treat hepatitis C virus infection).
  - Nefazodone (used to treat depression).
  - Cobicistat.
  - Gemfibrozil (used to lower cholesterol).
  - Ciclosporin (used in organ transplant patients).
  - Danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus).
- If you are taking or have taken, in the last 7 days, a medicine containing fusidic acid (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and simvastatin may lead to serious muscle problems (rhabdomyolysis).
- Do not take more than 40 mg simvastatin if you are taking lomitapide (used to treat a serious and rare genetic cholesterol condition).

Ask your doctor if you are not sure if your medicine is listed above.

### **Warnings and precautions**

Talk to your doctor or pharmacist before you start taking this medicine.

Talk to your doctor:

About all your medical conditions including allergies.

- If you drink large amounts of alcohol.
- If you have ever had liver disease. Simvastatin may not be right for you.
- If you are due to have an operation. You may need to stop taking simvastatin tablets for a short time.
- If you are Asian, because a different dose may be applicable to you.

Your doctor should do a blood test before you start taking this medicine and if you have any symptoms of liver problems while you take this medicine. This is to check how well your liver is working.

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking this medicine.

While you are on this medicine, your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Tell your doctor if you have severe lung disease.

**Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.**

The risk of muscle breakdown is greater at higher doses of simvastatin, particularly the 80 mg dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- You consume large amounts of alcohol.
- You have kidney problems.
- You have thyroid problems.
- You are 65 years or older.
- You are female.
- You have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” or fibrates.
- You or a close family member have a hereditary muscle disorder.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be necessary to diagnose and treat this problem.

### **Children and adolescents**

Safety and effectiveness of treatment with simvastatin have been studied in 10–17-year-old boys and in girls who had started their menstrual period (menstruation) at least one year before (see section 3). Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

### **Other medicines and Simvastatin Normon**

Other medicines and Simvastatin Normon. Tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines.

Taking simvastatin with any of the following drugs can increase the risk of muscle problems (some of these have already been listed in the above section “Do not take Simvastatin Normon”).

- **If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart simvastatin use. Taking simvastatin with fusidic acid may rarely lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See section 4 for more information on rhabdomyolysis.**
- Ciclosporin (often used in organ transplant patients).
- Danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus).

- Medicines with an active ingredient like itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole (used to treat fungal infections).
- Fibrates with an active ingredient like gemfibrozil and bezafibrate (used to lower cholesterol).
- Erythromycin, clarithromycin, telithromycin (used to treat bacterial infections).
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (used to treat AIDS).
- Hepatitis C antiviral agents such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C virus infection).
- Nefazodone (used to treat depression).
- Medicines with the active ingredient cobicistat.
- Amiodarone (used to treat an irregular heartbeat).
- Verapamil, diltiazem, or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions).
- Lomitapide (used to treat a serious and rare genetic cholesterol condition).
- Daptomycin (a drug used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin. Your doctor may decide that you stop taking this medicine for a while.
- Colchicine (used to treat gout).
- Ticagrelor (antiplatelet medicine).

As well as the medicines listed above, tell your doctor if you are taking medicines with any of the following active ingredients:

- Medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon or acenocumarol (anticoagulants).
- Fenofibrate (also used to lower cholesterol).
- Niacin (also used to lower cholesterol).
- Rifampicin (used to treat tuberculosis).

You should also tell any doctor who is prescribing a new medicine for you that you are taking simvastatin.

### **Simvastatin Normon with food and drink**

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

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before using this medicine.

If you get pregnant while taking this medicine, stop taking it immediately and contact your doctor.

Do not take this medicine if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

Ask your doctor or pharmacist for advice before using any medicine.

### **Driving and using machines**

Simvastatin not expected to interfere with your ability to drive or operate machinery. However, it should be taken into account that some people get dizzy after taking simvastatin.

### **Simvastatin Normon contains lactose**

This medicine contains lactose. If your doctor has told you that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

### **3. How to take Simvastatin Normon**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment, and your personal risk status.

Before starting this medicine, you should be on a diet to lower your cholesterol.

Posology:

The recommended dose is 1 tablet by mouth once a day.

Adults:

The usual starting dose is 10, 20 or, in some cases, 40 mg a day. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day. **Do not take more than 80 mg a day.**

Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have certain kidney conditions.

The 80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

#### **Use in children and adolescents**

For children and adolescents (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended daily dose is 40 mg.

Method of administration:

Take this medicine in the evening. You can take it with or without food. Keep taking it unless your doctor tells you to stop.

If your doctor has prescribed simvastatin with another medicine for lowering cholesterol containing any bile acid sequestrant, you should take simvastatin at least 2 hours before or at least 4 hours after taking the bile acid sequestrant.

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

In case of overdose or accidental intake, immediately talk to your doctor or pharmacist, or go to the nearest hospital, indicating the medicine and the amount taken.

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

Do not take a double dose to make up for a forgotten dose. Just take your normal amount of this medicine at the usual time the next day.

#### **If you stop taking Simvastatin Normon**

Talk to your doctor or pharmacist because your cholesterol may rise again.

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

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following terms are used to describe how often side effects have been reported:

- Rare (may affect up to 1 in 1,000 patients).
- Very rare (may affect up to 1 in 10,000 people).
- Not known (frequency cannot be estimated from the available data).

**If any of the below mentioned serious side effects happen, stop taking the medicine and tell your doctor immediately or go to the emergency room at your nearest hospital.**

The following **rare** serious side effects were reported:

- Muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- Hypersensitivity (allergic) reactions including:
  - Swelling of the face, tongue and throat which may cause difficulty in breathing (angioedema).
  - Severe muscle pain usually in the shoulders and hips, skin rash with weakness of limbs and neck muscles, pain or inflammation of the joints (polymyalgia rheumatica), inflammation of the blood vessels (vasculitis), unusual bruising, skin rash and swelling (dermatomyositis), hives, skin sensitivity to sunlight, fever, flushing, shortness of breath (dyspnoea) and feeling unwell, lupus-like disease picture (including skin rash, joint disorders, and effects on blood cells).
- Inflammation of the liver with the following symptoms: yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, feeling tired or weak, loss of appetite; liver failure (very rare).
- Inflammation of the pancreas often with severe abdominal pain.

The following rare serious side effects were reported:

- A severe allergic reaction that causes breathing difficulties or dizziness (anaphylactic reaction).
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions).
- Muscle rupture.
- Gynecomastia (breast enlargement in men).

The following side effects have also been reported rarely:

- Low red blood cell count (anaemia).
- Numbness or weakness of the arms and legs.
- Headache, tingling sensation, dizziness.
- Blurred vision; impaired vision.
- Digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting).
- Rash, itching, hair loss.
- Weakness.
- Trouble sleeping (very rare).
- Poor memory (very rare), memory loss, confusion.

The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):

- Erectile dysfunction.
- Depression.
- Inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever.
- Tendon problems, sometimes complicated by rupture of the tendon.

Additional possible side effects reported with some statins

- Sleep disturbances, including nightmares.
- Sexual dysfunction.
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.
- Muscle pain, tenderness, or weakness that is constant that may not go away after stopping treatment with simvastatin (frequency not known).

#### *Complementary tests*

Elevations in some laboratory blood tests of liver function (transaminases) and a muscle enzyme (creatine kinase) have been observed.

#### **Reporting of side effects**

If you get any adverse effects talk to your doctor, pharmacist, or nurse. This includes any possible adverse effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Simvastatin Normon**

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

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

##### **What Simvastatin Normon contains**

The active substance is simvastatin. Each tablet contains 20 mg of simvastatin.

The other ingredients (excipients) are: pregelatinised maize starch, microcrystalline cellulose, lactose monohydrate, butylated hydroxyanisole (E-320), magnesium stearate, ascorbic acid, citric acid, hypromellose, titanium dioxide (E-171), yellow iron oxide (E-172), red iron oxide (E-172), talc and macrogol 6000.

##### **What Simvastatin Normon looks like and contents of the pack**

Simvastatin Normon 20 mg film-coated tablets, are pinkish, round, biconvex and scored tablets. Each pack contains 28 tablets.

**Marketing Authorisation Holder and Manufacturer**

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

**The text was last reviewed in:** June 2022

## **Package leaflet: Information for the user**

### **Simvastatin Normon 40 mg film-coated tablets**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.  
If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

- 1. What Simvastatin Normon is and what it is used for**
- 2. What you need to know before you take Simvastatin Normon**
- 3. How to take Simvastatin Normon**
- 4. Possible side effects**
- 5. How to store Simvastatin Normon**
- 6. Contents of the pack and other information**

#### **1. What Simvastatin Normon is and what it is used for**

Simvastatin Normon contains the active substance simvastatin. This medicine is used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, it raises levels of “good” cholesterol (HDL cholesterol). Simvastatin Normon belongs to a class of medicines called statins.

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

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

You should stay on a cholesterol-lowering diet while taking this medicine.

This medicine is used in addition to your cholesterol lowering diet if you have:

A raised cholesterol level in your blood (primary hypercholesterolemia) or elevated fat levels in your blood (mixed hyperlipidaemia).

A hereditary illness (homozygous familial hypercholesterolemia) that increases the cholesterol level in your blood. You may also receive other treatments.

Coronary heart disease (CHD) or are at high risk of CHD (because you have diabetes, history of stroke, or other blood vessel disease). Simvastatin may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

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

## **2. What you need to know before you take Simvastatin Normon**

### **Do not take Simvastatin Normon**

- If you are allergic to simvastatin or any of the other ingredients of this medicine (listed in section 6).
- If you currently have liver problems.
- If you are pregnant or breast-feeding.
- If you are taking medicine(s) with one or more than one of the following active ingredients:
  - Itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections)
  - Erythromycin, clarithromycin or telithromycin (used to treat infections)
  - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (HIV protease inhibitors are used for HIV infections)
  - Boceprevir or telaprevir (used to treat hepatitis C virus infection)
  - Nefazodone (used to treat depression)
  - Cobicistat
  - Gemfibrozil (used to lower cholesterol)
  - Ciclosporin (used in organ transplant patients)
  - Danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- If you are taking or have taken, in the last 7 days, a medicine called fusidic acid (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and simvastatin may lead to serious muscle problems (rhabdomyolysis).

Do not take more than 40 mg simvastatin if you are taking lomitapide (used to treat a serious and rare genetic cholesterol condition).

Ask your doctor if you are not sure if your medicine is listed above.

### **Warnings and precautions**

Talk to your doctor or pharmacist before you start taking this medicine.

Talk to your doctor:

- About all your medical conditions including allergies.
- If you drink large amounts of alcohol.
- If you have ever had liver disease. Simvastatin may not be right for you.

- If you are due to have an operation. You may need to stop taking simvastatin tablets for a short time.
- If you are Asian, because a different dose may be applicable to you.

Your doctor should do a blood test before you start taking this medicine and if you have any symptoms of liver problems while you take this medicine. This is to check how well your liver is working.

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking this medicine.

While you are on this medicine, your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Tell your doctor if you have severe lung disease.

**Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.**

The risk of muscle breakdown is greater at higher doses of simvastatin, particularly the 80 mg dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- You consume large amounts of alcohol.
- You have kidney problems.
- You have thyroid problems.
- You are 65 years or older.
- You are female.
- You have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” or fibrates.
- You or a close family member have a hereditary muscle disorder.

Also talk to your doctor or pharmacist if you have constant muscle weakness. Additional tests and medicines may be necessary to diagnose and treat this problem.

Children and adolescents

Safety and effectiveness of treatment with simvastatin have been studied in 10–17-year-old boys and in girls who had started their menstrual period (menstruation) at least one year before (see section 3).

Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

#### **Other medicines and Simvastatin Normon**

Other medicines and Simvastatin Normon.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

Taking simvastatin with any of the following drugs can increase the risk of muscle problems (some of these have already been listed in the above section “Do not take Simvastatin Normon”).

- **if you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart simvastatin use. Taking simvastatin with fusidic acid may rarely lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See section 4 for more information on rhabdomyolysis.**

- Ciclosporin (often used in organ transplant patients).
- Danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus).
- Medicines with an active ingredient like itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole (used to treat fungal infections).
- Fibrates with an active ingredient like gemfibrozil and bezafibrate (used to lower cholesterol).
- Erythromycin, clarithromycin, telithromycin (used to treat bacterial infections).
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (used to treat AIDS).
- Hepatitis C antiviral agents such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C virus infection).
- Nefazodone (used to treat depression).
- Medicines with the active ingredient cobicistat.
- Amiodarone (used to treat an irregular heartbeat).
- Verapamil, diltiazem, or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions).
- Lomitapide (used to treat a serious and rare genetic cholesterol condition).
- Daptomycin (a drug used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin. Your doctor may decide that you stop taking this medicine for a while.
- Colchicine (used to treat gout).
- Ticagrelor (antiplatelet medicine).

As well as the medicines listed above, tell your doctor if you are taking medicines with any of the following active ingredients:

- Medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon or acenocumarol (anticoagulants).
- Fenofibrate (also used to lower cholesterol).
- Niacin (also used to lower cholesterol).
- Rifampicin (used to treat tuberculosis).

You should also tell any doctor who is prescribing a new medicine for you that you are taking simvastatin

### **Simvastatin Normon with food and drink**

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

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before using this medicine.

If you get pregnant while taking this medicine, stop taking it immediately and contact your doctor.

Do not take this medicine if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

Ask your doctor or pharmacist for advice before using any medicine.

### **Driving and using machines**

Simvastatin not expected to interfere with your ability to drive or operate machinery. However, it should be taken into account that some people get dizzy after taking simvastatin

### **Simvastatin Normon contains lactose**

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.

### **3. How to take Simvastatin Normon**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment, and your personal risk status.

Before starting this medicine, you should be on a diet to lower your cholesterol.

Posology:

The recommended dose is 1 tablet by mouth once a day.

Adults:

The usual starting dose is 10, 20 or, in some cases, 40 mg a day. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day. **Do not take more than 80 mg a day.**

Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have certain kidney conditions.

The 80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

### **Use in children and adolescents:**

For children and adolescents (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended daily dose is 40 mg

Method of administration:

Take this medicine in the evening. You can take it with or without food. Keep taking it unless your doctor tells you to stop.

If your doctor has prescribed simvastatin with another medicine for lowering cholesterol containing any bile acid sequestrant, you should take simvastatin at least 2 hours before or at least 4 hours after taking the bile acid sequestrant.

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

In case of overdose or accidental intake, immediately talk to your doctor or pharmacist, or go to the nearest hospital, indicating the medicine and the amount taken.

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

Do not take a double dose to make up for a forgotten dose. Just take your normal amount of this medicine at the usual time the next day.

### **If you stop taking Simvastatin Normon**

Talk to your doctor or pharmacist because your cholesterol may rise again.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following terms are used to describe how often side effects have been reported:

- Rare (may affect up to 1 in 1,000 patients).
- Very rare (may affect up to 1 in 10,000 people).
- Not known (frequency cannot be estimated from the available data).

**If any of the below mentioned serious side effects happen, stop taking the medicine and tell your doctor immediately or go to the emergency room at your nearest hospital.**

The following **rare** serious side effects were reported.

- Muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- Hypersensitivity (allergic) reactions including:
  - Swelling of the face, tongue and throat which may cause difficulty in breathing (angioedema)
  - Severe muscle pain usually in the shoulders and hips.
  - Skin rash with weakness of limbs and neck muscles.
  - Pain or inflammation of the joints (polymyalgia rheumatica).
  - Inflammation of the blood vessels (vasculitis).
  - Unusual bruising, skin rash and swelling (dermatomyositis), hives, skin sensitivity to sunlight, fever, flushing.
  - Shortness of breath (dyspnoea) and feeling unwell.
  - Lupus-like disease picture (including rash, joint disorders and effects on blood cells).
    - Inflammation of the liver with the following symptoms: yellowing of the skin and eyes, itching, dark-coloured urine, or pale-coloured stool, feeling tired or weak, loss of appetite;
    - Liver failure (very rare).
    - Inflammation of the pancreas often with severe abdominal pain.

The following rare serious side effects were reported:

- A severe allergic reaction that causes breathing difficulties or dizziness (anaphylactic reaction).
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions), muscle rupture,
- Gynecomastia (breast enlargement in men)

The following side effects have also been reported rarely:

- Low red blood cell count (anaemia).
- Numbness or weakness of the arms and legs.
- Headache, tingling sensation, dizziness.
- Blurred vision; impaired vision.
- Digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting).

- Rash, itching, hair loss.
- Weakness.
- Trouble sleeping (very rare).
- Poor memory (very rare), memory loss, confusion.

The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):

- Erectile dysfunction.
- Depression.
- Inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever.
- Tendon problems, sometimes complicated by rupture of the tendon

Additional possible side effects reported with some statins

- Sleep disturbances, including nightmares.
- Sexual dysfunction.
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.
- Muscle pain, tenderness, or weakness that is constant that may not go away after stopping treatment with simvastatin (frequency not known).

#### *Complementary tests*

Elevations in some laboratory blood tests of liver function (transaminases) and a muscle enzyme (creatinase) have been observed.

#### **Reporting of side effects**

If you get any adverse effects talk to your doctor, pharmacist, or nurse. This includes any possible adverse effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Simvastatin Normon**

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

Do not use this medicine after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

##### **What Simvastatin Normon contains**

The active substance is simvastatin. Each tablet contains 40 mg of simvastatin.

The other ingredients (excipients) are: pregelatinised maize starch, microcrystalline cellulose, lactose monohydrate, butylated hydroxyanisole (E-320), magnesium stearate, ascorbic acid, citric acid,

hypromellose, titanium dioxide (E-171), yellow iron oxide (E-172), red iron oxide (E-172), talc and macrogol 6000.

**What Simvastatin Normon looks like and contents of the pack**

Simvastatin Normon 40 mg film-coated tablets, are pinkish, round, biconvex and scored tablets. Each pack contains 28 tablets.

**Marketing Authorisation Holder and Manufacturer**

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