

Package leaflet: Information for the patient

Sinvastatina Baldacci 10 mg Film-coated tablets
Sinvastatina Baldacci 20 mg Film-coated tablets
Sinvastatina Baldacci 40 mg Film-Coated Tablets
Simvastatin

Read all of this leaflet carefully before you start taking this medicine as 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 only for you. You should not give it to others. The medicine can be harmful to them even if they show the same signs of illness.

If you experience any undesirable effects, including possible undesirable effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

What this leaflet contains:

1. What Sinvastatina Baldacci is and what it is used for
2. What you need to know before you take Sinvastatina Baldacci
3. How to take Sinvastatina Baldacci
4. Possible undesirable effects
5. How to store Sinvastatina Baldacci
6. Contents of the pack and other information

1. What Sinvastatina Baldacci is and what it is used for

Sinvastatina Baldacci contains the active substance Sinvastatina. Sinvastatina Baldacci is a medicine used to lower the values of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. Additionally, Sinvastatina Baldacci increases the values of "good" cholesterol (HDL cholesterol). Sinvastatina Baldacci is a member of a class of drugs called statins.

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

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

HDL cholesterol is often called "good" cholesterol because it helps "bad" cholesterol not build up in the arteries and protects against heart disease.

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

While you are taking this medicine, you should maintain a recommended cholesterol-lowering diet.

Sinvastatina Baldacci is indicated, in addition to the cholesterol-lowering diet, if you have:

an increased value of cholesterol in the blood (primary hypercholesterolemia) or high values of fat in the blood (mixed hyperlipidemia)
an inherited disease (homozygous familial hypercholesterolemia) responsible for increasing the value of cholesterol in the blood. You may also receive other treatments.
coronary heart disease or at risk of developing it (if you have diabetes, a history of stroke, or other blood vessel disease). Sinvastatina Baldacci can extend your life by reducing the risk of heart problems, regardless of the level of cholesterol in your blood.

Most people have no immediate symptoms of high cholesterol. Your doctor will be able to determine your cholesterol level through a simple blood test. Keep regular appointments with your doctor, so he or she can point you to the best way to control your cholesterol.

2. What you need to know before you take Sinvastatina Baldacci

Do not take Sinvastatina Baldacci:

if you are allergic (hypersensitive) to simvastatin or any of the other ingredients of this medicine (listed in section 6: Contents of the pack and other information)
if you have been diagnosed with liver disease
if you are pregnant or breastfeeding
if you are taking medicines with one or more of the following active substances:

- 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 used to treat HIV infections)
- boceprevir or telaprevir (used to treat hepatitis C virus infections)
- nefazodone (used to treat depression)
- cobicistato
- gemfibrozil (used to lower cholesterol)
- ciclosporin (used in organ transplant patients)
- danazol (a synthetic hormone used to treat endometriosis, a situation in which the lining of the uterus grows outside the uterus).

if you are taking or have taken or have been given a medicine called fusidic acid (used to treat a bacterial infection) by mouth or injection in the last 7 days. The combination of fusidic acid and Sinvastatina Baldacci can lead to serious muscle problems (rhabdomyolysis). Do not take more than 40 mg of Sinvastatina Baldacci if you are taking lomitapide (used to treat a serious and rare cholesterol-related genetic disorder).

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

Warnings and precautions

Tell your doctor:

If you have or have had myasthenia (a disease that causes generalised muscle weakness, including in some cases the muscles used during breathing) or ocular myasthenia (a disease that causes ocular muscle weakness), as statins can sometimes aggravate the disease or lead to the occurrence of myasthenia (see section 4).
about all your health problems, including allergies.

if you drink large amounts of alcoholic beverages.
if you have ever had any liver disease. Sinvastatina Baldacci may not be suitable for you.
if you are going to have a surgical operation. You may need to stop taking Sinvastatina Baldacci tablets for a short time.
if you are of Asian origin, as a different dosage may be applied to you.

Before you start treatment with Sinvastatina Baldacci, and if you experience any symptoms of liver problems while you are taking Sinvastatina Baldacci, your doctor should test your blood to check that your liver is working properly.

Your doctor may also order blood tests to check how well your liver is working after you have started treatment with Sinvastatina Baldacci.

While you are taking this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You will be at risk of diabetes if you have high blood sugar and fats, are overweight or have high blood pressure.
Tell your doctor if you have severe lung disease.

See your doctor right away if you experience muscle pain, tenderness, or weakness.
This is due to the fact that in rare situations, muscle problems can be severe, including muscle destruction (rhabdomyolysis) that results in kidney damage; and in very rare situations deaths have occurred.

There is a higher risk of muscle destruction with the higher doses of Sinvastatina Baldacci, particularly with the 80 mg dose. The risk of muscle destruction is also higher in certain patients. Tell your doctor if any of the following apply to you:

- consumes large amounts of alcohol
- have kidney problems
- have thyroid problems
- are 65 years of age or older
- are female

Have you ever had muscle problems during treatment with cholesterol-lowering medications called "statins" or fibrates
has, or some close family member has, an inherited muscle disorder.

Also tell your doctor or pharmacist if you experience constant muscle weakness. Additional tests or medications may be needed to diagnose and treat this problem.

Children and adolescents

The safety and efficacy of Sinvastatina Baldacci have been studied in boys aged 10 to 17 years and in girls who started their menstrual period (menstruation) at least one year earlier (see section 3: How to take Sinvastatina Baldacci). Sinvastatina Baldacci has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Other medicines and Sinvastatina Baldacci

Tell your doctor if you are taking, have recently taken or might take any other medicines with any of the following active substances. Taking Sinvastatina Baldacci with any of the following medicines may increase the risk of muscle problems (some of these have already been mentioned in the previous section "Do not take Sinvastatina Baldacci"):

If you need to take fusidic acid by mouth 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 taking Sinvastatina Baldacci. Taking Sinvastatina Baldacci with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). Additional information on rhabdomyolysis can be found in section 4.

ciclosporin (often used in organ transplant patients)

danazol (a synthetic hormone used to treat endometriosis, a situation in which the lining of the uterus grows outside the uterus)

medicines with an active substance such as itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole (used to treat fungal infections)

fibrates with an active substance such as gemfibrozil and bezafibrate (used to lower cholesterol)

erythromycin, clarithromycin or telithromycin (used to treat bacterial infections).

HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (used to treat AIDS)

boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C virus infections)

nefazodone (used to treat depression)

medicines with the active substance cobicystate

amiodarone (used to treat irregular heartbeat)

verapamil, diltiazem or amlodipine (used to treat high blood pressure, angina pectoris or other heart diseases)

lomitapide (used to treat a serious and rare cholesterol-related genetic condition)

colchicine (used to treat gout).

In addition to the above medicines, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell your doctor if you are taking medicines with any of the following active substances:

medicines with an active substance that prevents blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)

fenofibrate (also used to lower cholesterol)

niacin (also used to lower cholesterol)

rifampicin (used to treat tuberculosis).

You should also tell the doctor who prescribes a new medicine that you are taking Sinvastatina Baldacci.

Sinvastatina Baldacci with food and drink

Grapefruit juice contains one or more components that alter the way the body uses certain medicines, including Sinvastatina Baldacci. The consumption of grapefruit juice should be avoided.

Pregnancy and breastfeeding

Do not take Sinvastatina Baldacci if you are pregnant, plan to become pregnant or suspect you are pregnant. If you become pregnant during treatment with Sinvastatina Baldacci, stop treatment immediately and talk to your doctor. Do not take Sinvastatina Baldacci if you are breastfeeding, as it is not known whether the medicine passes into breast milk.

Consult your doctor or pharmacist before taking any medicine.

Driving and using machines

Sinvastatina Baldacci is not expected to interfere with your ability to drive or use machines. However, it should be taken into account that some people experience dizziness after taking Sinvastatina Baldacci.

Sinvastatina Baldacci contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact him or her before taking this medicine.

3. How to take Sinvastatina Baldacci

Your doctor will decide which dose is appropriate for you, according to your situation, your current treatment and your individual risk.

Take this medicine exactly as directed by your doctor. Check with your doctor or pharmacist if you are not sure.

While you are taking Sinvastatina Baldacci, you should eat a cholesterol-lowering diet.

Dosage:

The recommended dose is Sinvastatina Baldacci 20 mg or 40 mg, taken orally once a day.

Adults:

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

Your doctor may prescribe lower doses, particularly if you are taking some of the above medicines or if you have certain kidney problems.

The 80 mg dose is only recommended in adult patients with very high cholesterol levels and at high risk of heart complications, who have not reached the cholesterol target at lower doses.

Use in children and adolescents:

For children (10-17 years of age), the recommended starting dose is 10 mg per day in the evening. The maximum recommended dose is 40 mg per day.

Method of administration:

Take Sinvastatina Baldacci in the evening. You can take it with or without food. Take Sinvastatina Baldacci until your doctor tells you to stop.

If your doctor has prescribed Sinvastatina Baldacci together with another cholesterol-lowering medicine that contains a bile acid sequestrant, you should take Sinvastatina Baldacci at least 2 hours before, or 4 hours after taking the bile acid sequestrant.

If you take more Sinvastatina Baldacci than you should

Please contact your doctor or pharmacist.

If you forget to take Sinvastatina Baldacci

Do not take a double dose to make up for a forgotten dose. Take the Sinvastatina Baldacci tablets again within the scheduled time the next day.

If you stop taking Sinvastatina Baldacci

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 undesirable effects

Like all medicines, Sinvastatina Baldacci can cause undesirable effects, although these do not manifest themselves in all people.

The following terminology is used to describe the frequency with which undesirable effects have been reported:

Rare (may affect up to 1 in 1000 people)

Very rare (may affect up to 1 in 10,000 people)

Not known (frequency cannot be estimated from the available data)

The following rare undesirable effects have been reported.

If any of these serious undesirable effects occur, stop taking the medicine, consult your doctor immediately or go to the emergency department of the nearest hospital.

Muscle pain, tenderness or weakness or cramps. In rare situations, these muscle problems can be severe, including muscle destruction (rhabdomyolysis) that results in kidney damage; and in very rare situations deaths have occurred.

Hypersensitivity (allergic) reactions including:

swelling of the face, tongue, and throat, which can cause difficulty breathing

severe muscle pain, usually in the shoulders and hip

skin rash with muscle weakness of the limbs and neck

joint pain or inflammation (polymyalgia rheumatica)

inflammation of the blood vessels (vasculitis)

unusual bruising, rashes and swelling of the skin (dermatomyositis), itchy rash, skin sensitivity to the sun, fever, hot flush

difficulty breathing (dyspnoea) and general malaise

lupus-like disease (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 urine or discolored stools, feeling tired or weak, loss of appetite; liver failure (very rare)

inflammation of the pancreas, often with severe abdominal pain.

The following undesirable effects have also rarely been reported:

Low number of red blood cells (anemia)

Numbness or weakness in the arms and legs

Headache, tingling sensation, dizziness

digestive disorders (abdominal pain, constipation, intestinal gas, indigestion, diarrhoea, nausea, vomiting)

Skin rash, itching, hair loss

Weakness

Sleep disturbance (very rare)

Poor memory (very rare), memory loss, confusion

The following undesirable 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 leading to breathing problems including persistent cough and/or

Shortness of breath or fever

Tendon problems, sometimes complicated by tendon rupture.

Severe iasthenia (a disease that causes widespread muscle weakness, including, in some cases, the muscles used during breathing).

Ocular iasthenia (a disease that causes ocular muscle weakness).

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

Additional possible undesirable effects reported with some statins:

Sleep disorders, including nightmares

Sexual dysfunction

Diabetes. You're more likely to have diabetes if you have high blood sugar and fat levels, are overweight, and have high blood pressure. Your doctor will assess whether you have diabetes while you are taking this medicine.

Constant pain, tenderness or muscle weakness that may not go away after you stop taking Sinvastatina Baldacci (frequency unknown).

Laboratory Values

In blood tests, increases in some values of liver function and of a muscle enzyme (creatine kinase) were observed.

Reporting of undesirable effects

If you experience any undesirable effects, including possible undesirable effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting undesirable effects, you are helping to provide more information about the safety of this medicine.

Website: <http://www.infarmed.pt/web/infarmed/submissaoram>
(preferably)

or through the following contacts:

Direção de Gestão do Risco de Medicamentos Parque da Saúde de Lisboa, Av. Brazil 53

1749-004 Lisbon

Tel: +351 21 798 73 73

Drug Line: 800222444 (free)

Email: farmacovigilancia@infarmed.pt

5. How to store Sinvastatina Baldacci

Sinvastatina Baldacci 10 mg and 20 mg - Store below 25°C.

Sinvastatina Baldacci 40 mg - Store below 25°C.

Store in the original packaging.

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 carton after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Sinvastatina Baldacci contains

The active substance is simvastatin (10 mg, 20 mg or 40 mg)

The other ingredients are:

Tablets:

Lactose monohydrate,

Microcrystalline cellulose,

Pre-gelatinized maize starch,

Grain-hydroxianisol (E320),

Ascorbic acid

Anhydrous Colloidal silica,

Talc

Magnesium stearate.

Coating:

Hipromelose,

Hidroxiopropilmetilcelulose 606,

Hidroxiopropilmetilcelulose E15.

Povidona K-30,

Titanium dioxide (E171),

Red iron oxide (E172)

Yellow iron oxide (E172),

Triethyl citrate,

Talc.

What Sinvastatina Baldacci looks like and contents of the pack

Sinvastatina Baldacci 10 mg - Pack of 20, 30 or 60 tablets

Sinvastatina Baldacci 20 mg - Pack of 20 or 60 tablets
Sinvastatina Baldacci 40 mg - Pack of 60 tablets

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder
Baldacci Portugal, S.A.
Rua Cândido de Figueiredo, 84-B
1549-005 Lisboa
Tel: 217783031
Fax: 217785457
Email: medico@baldacci.pt

Manufacturer
Sinvastatina Baldacci 10 mg
Baldacci Portugal, S.A.
Av. Santa Iria de Azoia, Bloco B/C
2695-381 Santa Iria de Azoia

Manufacturer
Sinvastatina Baldacci 20 mg
Farmalabor – Produtos Farmacêuticos, S.A.
Zona Industrial de Condeixa-a-Nova
3150-194 Condeixa-a-Nova

Manufacturer
Sinvastatina Baldacci 40 mg
Labesfal – Laboratórios S.A.
Zona Industrial do Lagedo
3465-157 Santiago de Besteiros

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