

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

SIMCARD 10, film-coated tablet

SIMCARD 20, film-coated tablet

Simvastatin

Contains sugar (SIMCARD 10 contains 95,2 mg lactose monohydrate per tablet. SIMCARD 20 contains 190 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start using SIMCARD.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SIMCARD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET

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

1. What SIMCARD is and what it is used for

SIMCARD contains simvastatin which is a cholesterol-lowering medicine.

SIMCARD is used, in combination with a cholesterol-lowering diet, to decrease elevated serum total cholesterol and LDL-cholesterol in patients with:

- a raised cholesterol level in their blood (primary hypercholesterolaemia),
- a hereditary illness that increases the cholesterol level in your blood,
- elevated fat levels in their blood (mixed hyperlipidaemia).

SIMCARD is also used in patients with coronary heart disease and hypercholesterolaemia unresponsive to diet changes.

2. What you need to know before you use SIMCARD

Do not take SIMCARD:

- If you are allergic to simvastatin or any of the other ingredients of SIMCARD.
- If you have acute or chronic liver disease.
- If you have unexplained elevation of liver enzymes.
- If you are pregnant or breastfeeding your baby.
- 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),
 - 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),
 - erythromycin, clarithromycin, or telithromycin (used to treat infections),
 - nefazodone (used to treat depression),
 - cobicistat (used to treat HIV infection),
 - gemfibrozil (used to lower cholesterol),

- cyclosporin (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),
- lomitapide (used to lower familial cholesterol).
- If you have porphyria.

Warnings and precautions

Take special care with SIMCARD:

- If any of the following situations apply to you, you should tell your doctor before taking SIMCARD:
- If you are trying to become pregnant.
- If you consume large amounts of alcohol.
- If you have a history of liver disease. Your doctor should do a blood test before you start taking SIMCARD and if you have any symptoms of liver problems while you take SIMCARD. 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 SIMCARD.
- If you are predisposed to developing kidney failure secondary to rhabdomyolysis (a breakdown of muscle tissue that releases a damaging protein into the blood), high blood pressure, severe metabolic, endocrine and electrolyte disorders, uncontrolled seizures (epilepsy), major surgery or trauma.
- If you have severe kidney and liver problems.
- If you are due to have an operation.
- If you are using any other medicines such as immunosuppressants, fibrates (except fenofibrate), lipid lowering doses of niacin, amiodarone, amlodipine, verapamil, diltiazem or daptomycin (also see Do not take SIMCARD).
- If you are Asian.

- If you have severe lung disease.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness while on SIMCARD treatment. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

The risk of muscle breakdown is greater at higher doses of SIMCARD, 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:

- if you are older than 65 years,
- if you are female,
- if you have kidney problems,
- if you have uncontrolled hypothyroidism,
- if you have a personal or family history of muscle disorders,
- if you previously experienced muscle disorders with statin or fibrate use,
- if you consume large amounts of alcohol.

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.

Children and adolescents

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

Other medicines and SIMCARD

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please consult your doctor, pharmacist or other healthcare professional for advice if you are using any of the following products:

- fibrates with an active ingredient like gemfibrozil and bezafibrate (used to lower cholesterol),
- medicines with an active ingredient like itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (used to treat fungal infections),
- erythromycin, clarithromycin or telithromycin (used to treat bacterial infections),
- HIV protease inhibitors such as 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 (used to treat HIV infection),
- cyclosporin (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),
- niacin (a form of vitamin. If you are Asian you should not use SIMCARD with niacin),
- 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 (e.g. SIMCARD). Your doctor may decide that you stop taking SIMCARD for a while,
- ticagrelor (antiplatelet medicine),
- colchicine (anti-gout medicine),
- rifampicin (medicine used to treat tuberculosis),
- warfarin (medicine used to treat blood clots),
- digoxin (medicine used to treat various heart conditions),
- cholestyramine (medicine used to lower cholesterol),
- 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 SIMCARD. Taking SIMCARD with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis).

Taking SIMCARD with food or drink:

Avoid grapefruit juice when taking SIMCARD.

Pregnancy and breastfeeding:

You should not take SIMCARD if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking SIMCARD.

Driving and using machines:

It is not always possible to predict to what extent SIMCARD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SIMCARD affects them.

SIMCARD contains lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use SIMCARD

Do not share medicines prescribed for you with any other person.

Always take SIMCARD exactly as your doctor has instructed you. You should check with your doctor if you are unsure

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

To treat high cholesterol:

The usual adult dosage is one SIMCARD 10 tablet in the evening.

To treat coronary heart disease:

The usual adult dosage is one SIMCARD 20 tablet in the evening.

Your doctor may gradually increase the dosage.

The dosage should not exceed 80 mg of SIMCARD a day.

If your doctor has prescribed SIMCARD along with another medicine for lowering cholesterol containing any bile acid sequestrant, you should take SIMCARD at least 1 hour before or 4 hours after taking cholestyramine.

Your doctor will tell you how long your treatment with SIMCARD will last. If you have the impression that the effect of SIMCARD is too strong or too weak, talk to your doctor or pharmacist.

If you take more SIMCARD than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take SIMCARD:

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SIMCARD can have side effects. They may need medical attention.

Not all side effects reported for SIMCARD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SIMCARD, please consult your health care provider for advice.

If any of the following happens, stop using SIMCARD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SIMCARD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Asthenia (a decrease in muscle strength),
- paraesthesia (pins and needles sensations, often occurring in the arms, hands, legs or feet)
- peripheral neuropathy (weakness, numbness and pain from nerve damage, usually in the hands and feet),
- interstitial lung disease (a group of disorders that cause progressive scarring of lung tissue),
- pancreatitis (inflammation of the pancreas),
- myalgia (soreness and achiness in the muscles that can range from mild to severe),
- muscle cramps,
- myopathy (disease where muscle fibres do not function properly),
- myositis (inflammation of the muscles, symptoms include weakness, swelling and pain),
- rhabdomyolysis presenting as muscle pain with elevated creatine phosphokinase and myoglobinuria leading to renal failure,
- muscle rupture,
- tendinopathy (a condition in which the tissue connecting the muscle to the bone becomes inflamed), sometimes complicated by rupture,
- immune-mediated necrotising myopathy (IMNM),
- increases in serum transaminases (alanine aminotransferase, aspartate aminotransferase, γ -glutamyl transpeptidase),
- elevated alkaline phosphatase,
- increase in serum CK levels.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Anaemia (condition where the blood doesn't have enough healthy red blood cells),
- insomnia (problems falling and staying asleep),
- headache,
- dizziness,
- fatigue,
- memory impairment,
- blurred vision,
- visual impairment,
- constipation,
- diarrhoea,
- nausea,
- vomiting,
- flatulence,
- dyspepsia (discomfort or pain that occurs in the upper abdomen, often after eating or drinking),
- abdominal pain
- cramps,
- alopecia (sudden hair loss, usually circular bald patches),
- lichenoid drug eruptions (violaceous, scaling papules and plaques that are typically symmetrical and widespread),
- gynaecomastia (swollen male breast tissue caused by a hormone imbalance),

Frequency unknown:

- neutropenia (an abnormally low count of a type of white blood cell (neutrophils)),
- weight gain,
- depression,
- erectile dysfunction.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SIMCARD.

5. How to store SIMCARD

Polyethylene (HDPE) containers and closures:

Keep container tightly closed. Store in a dry place, below 25 °C. Protect from light.

Do not remove the blisters from the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What SIMCARD contains

The active substance is simvastatin.

The other ingredients are: ascorbic acid, butylhydroxyanisole, citric acid monohydrate, lactose monohydrate, magnesium stearate, microcrystalline cellulose pH 101, pregelatinized starch, tablet coating consisting of Opadry pink 06A540007 and Opadry beige 06A570000

consists of ferric oxide, red (E172), ferric oxide, yellow (E172), hypromellose 5 cps (E464), hypromellose 15 cps (E464), talc (E553b) and titanium dioxide (E171).

What SIMCARD looks like and contents of the pack

SIMCARD 10: Pale pink coloured, oval, convex, coated tablets with "SIM 10" embossed on one side and breakline on the other side, free from cracks, mottling and chips in the tablet surface.

SIMCARD 20: An orange coloured, oval, convex, coated tablets with "SIM 20" embossed on one side and breakline on the other side, free from cracks, mottling and chips in the tablet surface.

SIMCARD film-coated tablets are packed in white opaque polyethylene (HPDE) containers and closures (tamper evident) containing 28/30 tablets or white opaque PVC/ aluminium blister packs containing 28/30 tablets per carton.

7. Holder of Certificate of Registration

iPharma (Pty) Ltd.
124 Elevation Avenue, Randjesfontein
MIDRAND, 1683
SOUTH AFRICA
Tel: +27 (0) 11 314 2366

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The full Professional Information leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.