

APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking SIMCHOL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **SIMCHOL** 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.

S4

SIMCHOL 5 mg (Tablet)

SIMCHOL 10 mg (Tablet)

SIMCHOL 20 mg (Tablet)

SIMCHOL 40 mg (Tablet)

SIMCHOL 80 mg (Tablet)

Simvastatin

1. WHAT SIMCHOL CONTAINS

The active ingredient is simvastatin.

SIMCHOL 5 mg: Each film coated tablet contains simvastatin 5 mg.

SIMCHOL 10 mg: Each film coated tablet contains simvastatin 10 mg.

SIMCHOL 20 mg: Each film coated tablet contains simvastatin 20 mg.

SIMCHOL 40 mg: Each film coated tablet contains simvastatin 40 mg.

SIMCHOL 80 mg: Each film coated tablet contains simvastatin 80 mg.

The other ingredients of **SIMCHOL** are ascorbic acid, butyl hydroxyl anisole, cellulose microcrystalline, citric acid monohydrate, isopropyl alcohol, magnesium stearate, titanium dioxide and pregelatinised starch.

In addition, **SIMCHOL 5 mg** contains opadry yellow 20A52229 which consists of hydroxy propyl cellulose, hypromellose, iron oxide yellow (C.I. No: 77492), talc and titanium dioxide (C.I. No:

77891). **SIMCHOL 10 mg** and **20 mg** contains opadry pink 20A54239 which consists of hydroxy propyl cellulose, hypromellose, iron oxide red (C.I. No: 77491), iron oxide yellow (C.I. No: 77492), talc and titanium dioxide (C.I. No: 77891). **SIMCHOL 40 mg** and **80 mg** contains opadry pink 20A54211 which consists of hydroxy propyl cellulose, hypromellose, iron oxide red (C.I. No: 77491), talc and titanium dioxide (C.I. No: 77891).

2. WHAT SIMCHOL IS USED FOR

SIMCHOL is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, **SIMCHOL** raises levels of “good” cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking **SIMCHOL**. **SIMCHOL** is a member of the class of medicine called statins.

SIMCHOL is used along with 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 hypercholesterolaemia) 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). **SIMCHOL** may prolong your life by reducing the risk of heart disease, irregardless 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.

3. BEFORE YOU TAKE SIMCHOL

Do not take SIMCHOL:

- If you are hypersensitive (allergic) to simvastatin, other HMG-CoA reductase inhibitors, or any of the ingredients of **SIMCHOL**.
- If you have acute or chronic liver disease.
- If you are pregnant or breast-feeding.

- If you suffer from porphyria (a group of rare disorders passed down through families, in which an important part of hemoglobin, called heme, is not made properly).

Take special care with SIMCHOL:

- **SIMCHOL** should not be used by female patients of child-bearing potential.
- If you suffer from kidney or liver disease, and if you consume substantial amounts of alcohol and/or have a history of liver disease.
- If you develop unexplained muscle pain, tenderness or weakness, report this promptly to your doctor or pharmacist.

Pregnancy and Breast-feeding:

Safety of **SIMCHOL** in pregnant and breast-feeding women has not been established.

SIMCHOL is not advised in women who are pregnant or breast-feeding.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:

SIMCHOL may cause dizziness. In such a case, do not drive or operate machinery.

Important information about some of the ingredients of SIMCHOL

SIMCHOL contains lactose, which is a type of sugar. So before taking **SIMCHOL**, please consult your doctor for advice if you have an intolerance to some sugars.

Taking other medicines with SIMCHOL:

- **Cytochrome P450 isoenzyme CYP3A4 inhibitors:** **SIMCHOL** interacts with ciclosporin, itraconazole, ketoconazole, erythromycin, clarithromycin, HIV-protease inhibitors, nefazodone, danazol, amiodarone and verapamil. There may also be similar interaction with grapefruit juice.

- **Bile acid sequestrants:** **SIMCHOL** should be taken 1 hour before or 4 hours after cholestyramine.
- Please consult your doctor if you are using immunosuppressants, fibrates or niacin.
- Amiodarone (antiarrhythmic), erythromycin and clarithromycin (antibacterial) increases the plasma concentrations of **SIMCHOL**.
- Itraconazole and ketoconazole (antifungal) and HIV-protease inhibitors also increase the plasma concentrations of **SIMCHOL** and may therefore increase the effect of **SIMCHOL**.

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

4. HOW TO TAKE SIMCHOL

Always take **SIMCHOL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **SIMCHOL** is too strong or too weak, talk to your doctor or pharmacist.

You must follow a cholesterol-lowering diet before starting, and while on **SIMCHOL** therapy.

If you suffer from hypercholesterolaemia i.e. the presence of an abnormal amount of cholesterol in the cells and plasma of the blood:

Initial dose: 10 mg daily as a single dose in the evening.

If you suffer from coronary heart disease:

Initial dose: 20 mg/day as a single dose in the evening.

If you are taking cholestyramine which is also used to lower your cholesterol: you should take **SIMCHOL** 1 hour before or 4 hours after taking cholestyramine.

SIMCHOL can be taken with meals or on an empty stomach.

If you take more SIMCHOL than you should:

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

If you forget to take SIMCHOL:

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

5. POSSIBLE SIDE EFFECTS

SIMCHOL can have side effects.

*If any of the following happen, stop taking **SIMCHOL** and tell your doctor immediately or go to the casualty department at your nearest hospital:*

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- Severe itching of the skin (with raised lumps).

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

- Increased blood sugar levels
- Myalgia (pain in the muscles)
- Muscle cramps

Tell your doctor as soon as possible if you notice any of the following:

- Headache
- Pain in the feet and hands
- Cognitive impairment such as memory loss, confusion, forgetfulness and amnesia
- Myopathy (any pathology of the muscles that is not attributable to nerve dysfunction)
- Myositis (inflammation of a voluntary muscle)

- Rhabdomyolysis (the rapid disintegration of skeletal muscle tissue following injury) presenting as muscle pain.
- Hypersensitivity reactions may include the following: Arthritis (inflammation of a joint), Arthralgia (pain in a joint), urticaria (an itchy skin eruption characterised by weals with pale interiors and well-defined red margins; usually the result of an allergic response to insect bites, food or medicines), abnormal responses of your skin or eyes to the sun light, fever, flushing (Redness of the face lasting a short time),_malaise (a vague feeling of bodily discomfort and fatigue), and dyspnoea (difficulty in breathing).
- Weight gain
- Dizziness
- Fatigue (Temporary loss of strength and energy resulting from hard physical or mental work)
- Asthenia (abnormal loss of strength)
- Paraesthesia (abnormal touch sensation as tingling, tickling, itching or burning)
- Diarrhoea (frequent and watery bowel movements)
- Constipation (infrequent or difficult evacuation of faeces)
- Nausea (feeling sick)
- Vomiting
- Flatulence
- Abdominal pain and cramps
- Skin rash
- Alopecia (hair loss)

Not all side effects reported for **SIMCHOL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SIMCHOL**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF SIMCHOL

Store all medicines out of reach of children.

Store at or below 30 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF SIMCHOL

SIMCHOL 5 mg:

1. PVC/ACLAR

- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 178 mm) and 25 micron printed Aluminium foil (width 174 mm). Each Blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 214 mm) and 25 micron Printed Aluminium foil (width 208 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

2. PVC/PE/PVdC

- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 178 mm) and 25 micron Printed Aluminium foil (width 174 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 214 mm) and 25 micron Printed Aluminium foil (width 208 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

SIMCHOL 10 mg:

1. PVC/ACLAR

- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 178 mm) and 25 micron printed Aluminium foil (width 174 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.

- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 214 mm) and 25 micron Printed Aluminium foil (Width 208 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

2. PVC/PE/PVdC

- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 178 mm) and 25 micron Printed Aluminium foil (width 174 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 214 mm) and 25 micron Printed Aluminium foil (width 208 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

SIMCHOL 20 mg:

1. PVC/ACLAR

- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 178 mm) and 25 micron printed Aluminium foil (width 174 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 214 mm) and 25 micron Printed Aluminium foil (width 208 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

2. PVC/PE/PVdC

- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 178 mm) and 25 micron Printed Aluminium foil (width 174 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 214 mm) and 25 micron Printed Aluminium foil (width 208

mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

SIMCHOL 40 mg:

1. PVC/ACLAR

- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 178 mm) and 25 micron printed Aluminium foil width 174 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 214 mm) and 25 micron Printed Aluminium foil (Width 208 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

2. PVC/PE/PVdC

- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (Width 178 mm) and 25 micron Printed Aluminium foil (width 174 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 214 mm) and 25 micron Printed Aluminium foil (width 208 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

SIMCHOL 80 mg:

1. PVC/ACLAR

- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 218 mm) and 25 micron printed Aluminium foil (Width 212 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron Aclar (width 234 mm) and 25 micron Printed Aluminium foil (width 212 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

2. PVC/PE/PVdC

- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 218 mm) and 25 micron Printed Aluminium foil (width 212 mm). Each blister contains 10 tablets. Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
- Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 GSM PVdC (width 294 mm) and 25 micron Printed Aluminium foil (width 288 mm). Each blister contains 14 tablets. Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

8. IDENTIFICATION OF SIMCHOL

SIMCHOL 5 mg:

Yellow coloured, round shaped, biconvex, film coated tablets, debossed with 'A' on one side and '15' on the other side.

SIMCHOL 10 mg:

Light pink coloured, round shaped, biconvex, film coated tablets, debossed with A' on one side and '01' on the other side.

SIMCHOL 20 mg:

Light pink coloured, round shaped, biconvex, film coated tablets, debossed with 'A' on one side and '02' on the other side.

SIMCHOL 40 mg:

Pink coloured, round shaped, biconvex, film coated tablets, debossed with 'A' on one side and '03' on the other side.

SIMCHOL 80 mg:

Pink coloured, capsule shaped, biconvex, film coated tablets, debossed with 'A' on one side and '04' on the other side.

Applicant: Aurogen South Africa (Pty) Ltd

Product name: SIMCHOL 5 mg/ 10 mg/ 20 mg/ 40 mg/ 80 mg

Dosage form and strength: TABLETS 5 mg/ 10 mg/ 20 mg/ 40 mg/ 80 mg **Amended: 26.02/2021**



9. REGISTRATION NUMBER/REFERENCE NUMBER

SIMCHOL 5 mg: 41/7.5/0800

SIMCHOL 10 mg: 41/7.5/0801

SIMCHOL 20 mg: 41/7.5/0802

SIMCHOL 40 mg: 41/7.5/0803

SIMCHOL 80 mg: 41/7.5/0804

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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