APROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

PROPRIETY NAME AND DOSAGE FORM

SIMCHOL 5 mg (Tablet)

SIMCHOL 10 mg (Tablet)

SIMCHOL 20 mg (Tablet)

SIMCHOL 40 mg (Tablet)

SIMCHOL 80 mg (Tablet)

COMPOSITION

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.

Contains butyl hydroxy anisole (antioxidant), ascorbic acid, titanium dioxide, cellulose microcrystalline, citric acid monohydrate, isopropyl alcohol, lactose monohydrate, magnesium stearate and starch pregelatinised.

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).

PHARMACOLOGICAL CLASSIFICATION

A 7.5 Serum-cholesterol reducers

PHARMACOLOGICAL ACTION

Simvastatin is a cholesterol-lowering agent derived synthetically from a fermentation product of *Aspergillus terreus*. After oral ingestion, simvastatin, an inactive lactone, is hydrolysed to the corresponding beta-hydroxyacid, the active form. This is a principal metabolite and an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase, the enzyme that catalyses the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in the biosynthesis of cholesterol. As a result, simvastatin reduces total plasma cholesterol, low density lipoprotein (LDL)- and very low density lipoprotein (VLDL)-cholesterol concentrations. Apolipoprotein B is also decreased. In addition, simvastatin moderately increases high-density lipoprotein (HDL) - cholesterol and variably reduces plasma triglycerides.

Pharmacokinetics:

There is extensive first-pass extraction by the liver, with oral bioavailability of the active medicine or metabolites being less than 5 %. More than 95 % of simvastatin and its beta-hydroxy metabolite are bound to plasma proteins. Following an oral dose, peak plasma concentrations of simvastatin are seen in 1 to 2 hours. Simvastatin is excreted primarily via the liver, and less than 13 % of its metabolites are excreted in the urine.

INDICATIONS

HYPERCHOLESTEROLAEMIA

SIMCHOL is indicated, in combination with diet, to decrease elevated serum total cholesterol and LDL-cholesterol in patients with:

- Primary hypercholesterolaemia,
- Heterozygous familial hypercholesterolaemia, or
- Mixed hyperlipidaemia,

when response to diet or other non-pharmacological measures alone is not adequate.

CORONARY HEART DISEASE

SIMCHOL is indicated in patients with coronary heart disease and hypercholesterolaemia unresponsive to diet, to:

- Reduce the risk of total mortality, by reducing coronary death.
- Reduce the risk of non-fatal myocardial infarction,
- Reduce the risk of undergoing myocardial revascularisation procedures (coronary artery bypass grafting and percutaneous transluminal coronary angioplasty), and
- Slow the progression of coronary atherosclerosis.

CONTRA-INDICATIONS

Hypersensitivity to simvastatin, other HMG-CoA reductase inhibitors, or any of the ingredients of **SIMCHOL**.

Acute or chronic liver disease.

Unexplained persistent elevation of serum transaminases.

Pregnancy and lactation (see "**WARNINGS**" and "**PREGNANCY AND LACTATION**").

Porphyria: Safety has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

Use in paediatric patients is not recommended as safety and efficacy have not been established.

SIMCHOL is not effective in severe triglyceridaemia.

SIMCHOL should be used with caution in patients who:

- Consume substantial amounts of alcohol and/or who have a history of liver disease. Active liver disease or unexplained transaminase elevations are contra-indications to the use of **SIMCHOL**.
- May be predisposed to developing renal failure secondary to rhabdomyolysis such as in those with severe acute infection, hypotension, severe metabolic, endocrine or electrolyte disorders, uncontrolled seizures, major surgery or trauma. There is an increased risk of developing renal failure if rhabdomyolysis occurs.

- Have severe renal impairment.

Hepatic effects:

It is recommended that liver function tests be performed before initiation of treatment, and periodically thereafter. Patients titrated to the 80 mg dose should receive an additional test at 3 months. **SIMCHOL** should be discontinued if the rise in transaminase levels is persistent and/or increases to three times or more the upper limit of normal (ULN).

Opthalmic effects:

In the absence of any medicine therapy, an increase in the prevalence of lens opacities with time is expected as a result of aging. Current long term data from clinical trials do not indicate a causal association between **SIMCHOL** and adverse effects on the human lens.

Muscle effects:

SIMCHOL and other inhibitors of HMG-CoA reductase occasionally cause myopathy, which is manifested as muscle pain or weakness associated with grossly elevated creatine kinase (CK) (more than 10 x the upper limit of normal (ULN)). Rhabdomyolysis, with or without acute renal failure secondary to myoglobinuria, has been reported rarely.

Myopathy:

Reducing the risk of myopathy:

1. <u>General measures:</u>

   Patients starting therapy with **SIMCHOL** should be advised of the risk of myopathy and should report, promptly, unexplained muscle pain, tenderness or weakness. A creatinine kinase (CK) level above 10 times the Upper Limit of Normal (ULN) in a patient, with unexplained symptoms, indicates myopathy. **SIMCHOL** should be discontinued if myopathy is diagnosed or suspected.

   There have been reports of cognitive impairment (such as memory loss, forgetfulness, amnesia and confusion) associated with statins such as **SIMCHOL**. These were generally not serious with variable time to symptom onset (between 1 day to years) and symptom resolution (median 3 weeks).

   Increased glycosylated haemoglobin, fasting serum glucose levels and worsening of glycaemic control have been reported with statins such as **SIMCHOL**. **SIMCHOL** should be used with caution in patients with Type 2 diabetes.

2. Measures to reduce the risk of myopathy caused by medicine interactions.

   The benefits and risks of using **SIMCHOL** concomitantly with immunosuppresants, fibrates or lipid-lowering doses of niacin should be carefully considered, and the dose of **SIMCHOL** should generally not exceed 10 mg/day. Concomitant administration with ciclosporin, itraconazole, ketoconazole, erythromycin, clarithromycin and HIV-protease inhibitors is not recommended.

   In patients receiving ciclosporin, **SIMCHOL** should be temporarily discontinued if systemic azole derivative-antifungal therapy is required.

Effects on ability to drive and use machines:

SIMCHOL has no or negligible influence on the ability to drive and use machines. However, when driving vehicles or operating machines, it should be taken into account that dizziness has been reported rarely.

Important information about some of the ingredients of SIMCHOL

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

INTERACTIONS

The most serious consequence of medicine interactions with **SIMCHOL** and other statins is the development of myopathy or rhabdomyolysis. Medicines that can cause myopathy when given alone increase the risk of myopathy with all statins; these medicines include fibric acid derivatives (fibrates or gemfibrozil) and nicotinic acid. The risk of myopathy is also increased by medicines that increase the plasma concentrations of statins, by inhibiting their metabolism or by inhibiting their uptake into the liver. Since the statins have different metabolic pathways, these interactions depend on the individual medicine concerned.

Myopathy caused by medicine interactions:

Concomitant administration of medicines that inhibit cytochrome P450 isoenzyme CYP3A4 may result in high plasma levels of **SIMCHOL,** thus increasing the risk of myopathy, and is not recommended. Medicines that inhibit cytochrome P450 isoenzyme CYP3A4 include: ciclosporin,

itraconazole, ketoconazole, erythromycin, clarithromycin, HIV-protease inhibitors, nefazodone, danazol, amiodarone and verapamil. There may also be similar interactions with grapefruit juice.

The risk of myopathy is increased when other medicines that cause myopathy, such as fibrates and niacin, are given with **SIMCHOL.** A maximum dose of 10 mg **SIMCHOL** daily is recommended in patients taking ciclosporin, fibrates or lipid-lowering doses of niacin (nicotinic acid).

Digoxin: SIMCHOL may cause increases in digoxin levels.

Coumarin-derivatives (e.g. warfarin): A possible increase in the anticoagulant effect of the coumarin anticoagulants may occur. Patients taking a coumarin anticoagulant should have their INR determined before starting **SIMCHOL** therapy. The INR should be monitored frequently enough in the early stages of therapy until stabilised. Once a stable INR has been documented, INR can be monitored at the intervals usually recommended for patients on coumarin anticoagulants. Where there is a dose adjustment of **SIMCHOL**, this procedure should be repeated.

Bile acid sequestrants: SIMCHOL should be taken 1 hour before or 4 hours after cholestyramine. Concurrent use may decrease the bioavailability of **SIMCHOL.**

Antiarrhythmics: Amiodarone is an inhibitor of the cytochrome P450 isoenzyme CYP3A4 and may increase plasma concentrations of statins metabolised by this enzyme, increasing the risk of toxicity.

Antibacterials: Erythromycin and other macrolides are inhibitors of the cytochrome P450 isoenzyme CYP3A4 and may increase plasma concentrations and the risk of myopathy with some statins. Increased plasma concentrations of **SIMCHOL** have been found with erythromycin and clarithromycin but not with azithromycin.

Rifampicin, an inducer of CYP2C9 and CYP3A4, may reduce the plasma concentration of **SIMCHOL**.

Rhabdomylosis in patients receiving **SIMCHOL** with fusidic acid was reported.

Antifungals: Itraconazole and ketoconazole are inhibitors of the cytochrome P450 isoenzyme CYP3A4 and may increase plasma concentrations and the risk of myopathy with some strains. Raised plasma concentrations of **SIMCHOL**, lovastatin and atorvastatin have been reported with itraconazole, whereas the effect on pravastatin, rosuvastatin or fluvastatin appears to be minimal.

Antivirals: HIV-protease inhibitors are inhibitors of the cytochrome P450 isoenzyme CYP3A4 and may affect the metabolism of **SIMCHOL** and other statins. Studies have shown increased plasma concentrations of both **SIMCHOL** and atorvastatin with nelfinavir and with ritonavir-boosted

saquinavir whereas the plasma concentration of pravastatin was reduced with ritonavir-boosted saquinavir.

There has also been a report of rhabdomyolysis in a patient receiving **SIMCHOL** with the non-nucleoside reverse transcriptase inhibitor delavirdine.

Efavirenz is an inducer of CYP3A4 and a study in healthy subjects found that it could reduce plasma concentrations of atorvastatin and **SIMCHOL**.

Calcium-channel blockers: Rhabdomyolysis and hepatitis have been reported in patients receiving **SIMCHOL** with diltiazem.

Fruit juices: Grapefruit juice inhibits the cytochrome P450 isoenzyme CYP3A4 and studies using concentrated grapefruit juice have reported increased plasma concentrations of **SIMCHOL**, lovastatin and atorvastatin. Studies using normal strength grapefruit juice have found considerable increases in plasma concentrations of atorvastatin and **SIMCHOL**.

Immunosuppressants: Myopathy and rhabdomyolysis have been reported in patients receiving atorvastatin, lovastatin, or **SIMCHOL** with immunosuppressant regimens including ciclosporin. The mechanism of the interaction may be additive toxicity, since both statins and ciclosporin are known to cause myopathy, but effects on plasma concentrations may also be involved. Pharmacokinetic studies have shown that ciclosporin increases the plasma concentrations of atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin and **SIMCHOL**.

Lipid regulating medicines: Myopathy and myositis are recognised adverse effects of both statins and fibric acid derivatives, including fibrates and gemfibrozil, and the risk is increased if they are given together. There has also been a report of both hepatotoxicity and rhabdomyolysis in a patient given a statin and gemfibrozil together. The interaction between gemfibrozil and statins may also have a pharmacokinetic basis; studies have shown increased plasma concentrations of atorvastatin, lovastatin, rosuvastatin and **SIMCHOL** when given with gemfibrozil.

Myopathy has also been reported in patients given statins with nicotinic acid although a study of adverse effects reported to the FDA found no increase in reports for lovastatin given with nicotinic acid compared with either medicine alone.

Proton pump inhibitors: There is a report of rhabdomyolysis causing AV block in a patient receiving **SIMCHOL** when esomeprazole and clarithromycin were added to her treatment. As symptoms

started before the introduction of clarithromycin, it was thought that a possible contributory mechanism for the interaction was a reduction in the first-pass metabolism of **SIMCHOL** due to the inhibition of p-glycoprotein by esomeprazole.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

The active metabolite of **SIMCHOL** is fetotoxic and teratogenic in animals, and it should therefore not be used in female patients of child-bearing potential.

Rare reports of congenital anomalies following intrauterine exposure to HMG-CoA reductase inhibitors have been reported. However, in an analysis of approximately 200 prospectively followed pregnancies exposed during the first trimester to **SIMCHOL** or another closely related HMG-CoA reductase inhibitor, the incidence of congenital anomalies was comparable to that seen in the general population. This number of pregnancies was statistically sufficient to exclude a 2,5-fold or greater increase in congenital anomalies over the background incidence.

Although there is no evidence that the incidence of congenital anomalies in offspring of patients taking **SIMCHOL** or another closely related HMG-CoA reductase inhibitor differs from that observed in the general population, maternal treatment with **SIMCHOL** may reduce the foetal levels of mevalonate which is a precursor of cholesterol biosynthesis. Atherosclerosis is a chronic process, and ordinarily discontinuation of lipid-lowering medicinal products during pregnancy should have little impact on the long-term risk associated with primary hypercholesterolaemia. For these reasons, **SIMCHOL** must not be used in women who are pregnant, trying to become pregnant or suspect they are pregnant. Treatment with **SIMCHOL** must be suspended for the duration of pregnancy or until it has been determined that the woman is not pregnant.

It is not known whether **SIMCHOL** or its metabolites are excreted in human milk. Because many medicinal products are excreted in human milk and because of the potential for serious adverse reactions, women taking **SIMCHOL** should not breast-feed their infants.

DOSAGE AND DIRECTIONS FOR USE

The patient must follow a cholesterol-lowering diet before initiation of, and while on **SIMCHOL** therapy.

HYPERCHOLESTEROLAEMIA

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

Dosage Adjustments: If required, may be made at intervals of not less than 4 weeks, to a maximum of 80 mg daily given as a single dose in the evening.

The dose of **SIMCHOL** should be reduced if LDL-cholesterol levels fall below 1,94 mmol/L, or total plasma cholesterol levels fall below 3,6 mmol/L.

CORONARY HEART DISEASE

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

Dosage Adjustments: If required should be made as per dosage adjustments in hypercholesterolaemia.

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

DOSAGE IN RENAL INSUFFICIENCY

SIMCHOL does not undergo significant renal excretion, therefore modification of dose should not be necessary in patients with mild to moderate renal insufficiency. In patients with severe renal insufficiency (creatinine clearance less than 30 ml/min) **SIMCHOL** therapy should be closely monitored and doses above 10 mg/day should be implemented with caution.

CONCOMITANT THERAPY

SIMCHOL is effective alone or in combination with bile acid sequestrants. When both medicines are prescribed, **SIMCHOL** should be given 1 hour before or 4 hours after cholestyramine administration (see "**INTERACTIONS**").

A maximum daily dose of 10 mg **SIMCHOL** is recommended in patients taking ciclosporin, fibrates or niacin concomitantly (see "**INTERACTIONS**").

SIDE-EFFECTS

Side-effects:

Blood and lymphatic system disorders:

Rare: Anaemia, neutropenia

Metabolic and nutritional disorders:

Frequent: Increased serum glucose levels

The following side effects have been reported and the frequencies are unknown: Mass gain

Nervous system disorders:

Less frequent: Headache, peripheral neuropathy, cognitive impairment such as memory loss, confusion, forgetfulness and amnesia.

The following side effects have been reported and the frequencies are unknown: Dizziness, fatigue, asthenia and paraesthesia.

Gastrointestinal disorders:

The following side effects have been reported and the frequencies are unknown: Diarrhoea, constipation, nausea, vomiting, flatulence, dyspepsia, abdominal pain, cramps and pancreatitis.

Skin and subcutaneous tissue disorders:

The following side effects have been reported and the frequencies are unknown: Skin rash, alopecia.

Musculoskeletal, connective tissue and bone disorders:

Frequent: Myalgia, muscle cramps.

Less frequent: Myopathy, myositis, rhabdomyolysis presenting as muscle pain with elevated creatine phosphokinase and myoglobinuria leading to renal failure.

General disorders and administrative site conditions:

Less frequent: Hypersensitivity reactions may include angioedema, lupus-like syndrome, polymyalgia, rheumatic vasculitis, thrombocytopenia, increased erythrocyte sedimentation rate, eosinophilia, arthritis, arthralgia, urticaria, photosensitivity, fever, flushing, malaise and dyspnoea.

LABORATORY TEST FINDINGS

Marked and persistent increases of serum transaminases and elevated alkaline phosphatase and gamma-glutamyl transpeptidase have been reported. Liver function test abnormalities have generally been mild and transient. Increases in serum creatinine kinase (CK) levels, derived from skeletal muscle, have been reported (see "**SPECIAL PRECAUTIONS**").

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

(see "**SIDE-EFFECTS AND SPECIAL PRECAUTIONS**").

General measures should be adopted and liver function should be monitored.

Treatment is symptomatic and supportive.

IDENTIFICATION

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.

PRESENTATION

SIMCHOL 5 mg:

1. PVC/ACLAR

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

STORAGE INSTRUCTIONS

Store at or below 30 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

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

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

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