

**Simvacor 10 mg**

**Simvacor 20 mg**

**Simvacor 40 mg**

**SCHEDULING STATUS:**

S4

**PROPRIETARY NAME AND DOSAGE FORM:**

**SIMVACOR 10** mg film coated tablet

**SIMVACOR 20** mg film coated tablet

**SIMVACOR 40** mg film coated tablet

**COMPOSITION:**

Each **Simvacor 10** film coated tablet contains 10 mg simvastatin.

Each **Simvacor 20** film coated tablet contains 20 mg simvastatin.

Each **Simvacor 40** film coated tablet contains 40 mg simvastatin.

Antioxidants: Butylated Hydroxyanisole 0,02% m/m, Citric Acid Anhydrous 1,5% m/m,

Ascorbic Acid 0,06% m/m.

**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**

**SIMVACOR** 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**

**SIMVACOR** 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.

Acute or chronic liver disease.

Unexplained persistent elevations of serum transaminases.

Pregnancy and lactation (see **WARNINGS**).

Porphyria: Safety has not been established.

## **WARNINGS:**

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

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

## **INTERACTIONS:**

### Myopathy caused by medicine interactions:

Concomitant administration of medicines that inhibit cytochrome P450 isoenzyme CYP3A4 may result in high plasma levels of **SIMVACOR**, 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 and nefazodone.

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

### Digoxin

**SIMVACOR** 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 **SIMVACOR** 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. When there is a dose adjustment of **SIMVACOR**, this procedure should be repeated.

### Bile acid sequestrants:

**SIMVACOR** should be taken 1 hour before or 4 hour after cholestyramine. Concurrent use may decrease the bioavailability of **SIMVACOR**.

## **PREGNANCY AND LACTATION:**

Safety in pregnancy and lactation has not been established.

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

## **DOSAGE AND DIRECTIONS FOR USE:**

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

### HYPERCHOLESTEROLAEMIA

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

The dose of **SIMVACOR** 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, the dose should be adjusted at intervals of not less than 4 weeks, up to a maximum of 80 mg daily as a single dose in the evening.

**SIMVACOR** can be taken with meals or on an empty stomach.

### DOSAGE IN RENAL INSUFFICIENCY

**SIMVACOR** 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 **SIMVACOR** therapy should be closely monitored and doses above 10 mg/day should be implemented with caution.

### CONCOMITANT THERAPY

**SIMVACOR** is effective alone or in combination with bile acid sequestrants.

When both medicines are prescribed, **SIMVACOR** should be given 1 hour before or 4 hours after cholestyramine administration (See **INTERACTIONS**).

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

## **SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

### **Side-effects:**

#### **Gastro-intestinal:**

Constipation, diarrhoea, nausea, vomiting, flatulence, dyspepsia, abdominal pain, cramps and pancreatitis.

#### **Haematological:**

Anaemia, neutropenia.

#### **Skin and appendages:**

Skin rash, alopecia.

#### **Musculoskeletal:**

*Frequent:* Myalgia, muscle cramps.

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

#### **Neurological:**

Headache, dizziness, fatigue, aesthaenia, paraesthesia, peripheral neuropathy.

#### **Hypersensitivity reactions:**

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

#### **Other:**

Mass gain has been reported.

## **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**).

### **Special precautions:**

**SIMVACOR** should be used with caution in patients who:

- Consume substantial amounts of alcohol and/or who have a history of liver disease.
- 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:**

Liver function tests, including serum transaminase determinations are recommended prior to initiation of **SIMVACOR** therapy and periodically until one year after the last elevation in dose. **SIMVACOR** 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).

### **Myopathy**

#### **Reducing the risk of myopathy:**

##### 1. General measures

Patients starting therapy with **SIMVACOR** 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. **SIMVACOR** should be discontinued if myopathy is diagnosed or suspected.

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

The benefits and risks of using **SIMVACOR** concomitantly with immunosuppressants, fibrates or lipid-lowering doses of niacin should be carefully considered, and the dose of **SIMVACOR** should generally not exceed 10 mg/day. Concomitant administration with ciclosporin, itraconazole, ketoconazole,

erythromycin, clarithromycin, HIV-protease inhibitors and nefazodone, is not recommended.

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

#### **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:**

**SIMVACOR 10 mg:** White, round (6 mm in diameter), slightly biconvex, bevel-edged, film-coated tablet.

**SIMVACOR 20 mg:** White, round (8 mm in diameter), slightly biconvex, bevel-edged, film-coated tablet.

**SIMVACOR 40 mg:** White, round (11 mm in diameter), slightly biconvex, bevel-edged, one side scored, film-coated tablet.

#### **PRESENTATION:**

Clear, transparent, hard PVC and aluminium foil blister packs of 30 tablets each.

#### **STORAGE INSTRUCTIONS:**

Store in a cool (below 25°C), dry place. Do not remove tablets from outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

#### **REGISTRATION NUMBERS:**

**SIMVACOR 10 mg:** 35/7.5/0237

**SIMVACOR 20 mg:** 35/7.5/0238

**SIMVACOR 40 mg:** 39/7.5/0132

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

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**DATE OF PUBLICATION OF THE PACKAGE INSERT:**

14 February 2005

**Simvacor 10 mg**

**Simvacor 20 mg**

**Simvacor 40 mg**

**SKEDULERINGSSTATUS:**

S4

**EIENDOMSNAAM EN DOSEERVORMS:**

**SIMVACOR 10 mg** film-bedekte tablet

**SIMVACOR 20 mg** film-bedekte tablet

**SIMVACOR 40 mg** film-bedekte tablet

**SAMESTELLING:**

Elke **SIMVACOR 10 mg** film-bedekte tablet bevat 10 mg simvastatien.

Elke **SIMVACOR 20 mg** film-bedekte tablet bevat 20 mg simvastatien.

Elke **SIMVACOR 40 mg** film-bedekte tablet bevat 40 mg simvastatien.

Anti-oksidante: Gebutileerde Hidroksi-anisool 0,02% m/m, Sitroensuur Watervry 1,5% m/m, Askorbiensuur 0,06% m/m.

**FARMAKOLOGIESE KLASSIFISERING:**

A.7.5 Serumcholesterolreduceerders

**FARMAKOLOGIESE WERKING:**

Simvastatien is 'n cholesterol-verlagende middel wat sinteties van 'n fermentasie produk van *Aspergillus terreus* afgelei word. Na orale inname word simvastatien, 'n onaktiewe laktoon, gehidroliseer na die ooreenstemmende beta-hidroksisuur, wat die aktiewe vorm verteenwoordig. Dit is 'n hoofmetaboliet en 'n inhibeerder van 3-hidroksi-3-metielglutariel-koënsiem-A(HMG-KoA)reduktase, die ensiem wat die omsetting van HMG-KoA na mevalonaat kataliseer, 'n vroeë en tempo-beperkende stap in die biosintese van cholesterol. Gevolglik verminder simvastatien totale plasmacholesterol-, lae-densiteit-lipoproteïen(LDL)- en baie-lae-densiteit-lipoproteïen(VLDL)-cholesterolkonsentrasies. Apolipoproteïen-B is ook verlaag. Daarbenewens verhoog simvastatien hoë-densiteit-lipoproteïen(HDL)-cholesterol matig en veroorsaak wisselende verlagings van plasmatrigliseriede.

## **Farmakokinetika:**

Ekstensiewe presistemiese ekstraksie deur die lewe vind plaas, en die orale biobeskikbaarheid van die aktiewe medisyne of metaboliete is minder as 5%. Meer as 95% van simvastation en sy beta-hidroksi-metaboliet is aan plasmaproteïene gebonde. Na 'n orale dosis, word piek plasmakonsentrasies van simvastation binne 1 tot 2 uur waargeneem. Simvastation word primêr deur die lewer uitgeskei, en minder as 13% van sy metaboliete word in die urine uitgeskei.

## **INDIKASIES:**

### **HIPERCHOLESTEROLEMIE**

**SIMVACOR** is aangedui in kombinasie met dieet, om verhoogde totale serumcholesterol en LDL-cholesterol te verlaag in pasiënte met:

- Primêre hipercholesterolemie
- Heterosigotiese familiële hipercholesterolemie, of
- Gemengde hiperlipemie

wanneer die reaksie op dieet of ander nie-farmakologiese maatreëls alleen nie voldoende is nie.

### **KORONÊRE HARTSIEKTE**

**SIMVACOR** word aangedui in pasiënte met koronêre hartsiekte en hipercholesterolemie wat nie op dieet reageer nie, om:

- Die risiko van totale mortaliteit te verlaag, deur koronêre sterftes te verminder,
- Die risiko van nie-fatale miokardiale infarksie te verminder,
- Die risiko te verlaag dat 'n persoon miokardiale hervaskulariseringsprosedures (koronêre arterie omleiding-hegting en perkutane transluminale koronêre angioplastie) moet ondergaan, en
- Die progressie van koronêre aterosklerose te vertraag.

## **KONTRA-INDIKASIES:**

Hipersensitiwiteit teenoor simvastation, ander HMG-KoA-reduktase-inhibeerders, of enigeen van die bestanddele daarvan.

Akute of chroniese lewersiekte.

Onverklaarbare aanhoudende verhogings van serumtransaminases.

Swangerskap en laktasie (sien **WAARSKUWING**).

Porfirie: Veiligheid is nie vasgestel nie.

### **WAARSKUWINGS:**

Die aktiewe metaboliet van **SIMVACOR** is fetotoksies en teratogenies in rotte, en dit behoort dus nie in vroulike pasiënte met barendende potensiaal gebruik te word nie.

Gebruik in pediatriese pasiënte word nie aanbeveel, omdat veiligheid en doeltreffendheid nie vasgestel is nie.

### **INTERAKSIES:**

#### Miopatie veroorsaak deur interaksies van medisyne:

Gelyktydige toediening van medisyne wat sitochroom P450 isoënsiem CYP3A4 inhibeer, mag hoë plasmavlakke van **SIMVACOR** veroorsaak, wat dus die risiko van miopatie kan verhoog en nie aanbeveel word nie. Medisyne wat sitochroom P450 isoënsiem CYP3A4 inhibeer, sluit in: siklosporien, itrakonasool, ketokonasool, eritromisien, klaritromisien, MIV-protease-inhibeerders, en nefasodoon.

Die risiko van miopatie is verhoog wanneer ander medisyne wat miopatie veroorsaak, soos fibrate en niasien, saam met **SIMVACOR** toegedien word. 'n Maksimum dosis van 10 mg **SIMVACOR** per dag word aanbeveel in pasiënte wat siklosporien, fibrate of lipied-verlagende dosisse niasien (nikotiensuur) neem.

#### Digoksien

**SIMVACOR** mag verhogings in digoksienvlakke veroorsaak.

#### Kumarienderivate (bv. warfarien)

'n Moontlike toename in die antikoagulasie uitwerking van die kumarienantikoagulante mag voorkom. Pasiënte wat 'n kumarienantikoagulant neem, behoort hulle INR te laat bepaal voordat hulle met **SIMVACOR**-terapie begin. Die INR moet dikwels genoeg gemoniteer word in die vroeë stadiums van terapie totdat dit stabiliseer. Wanneer 'n stabiele INR aangeteken is, kan die INR gemoniteer word met tussenposes wat gewoonlik vir pasiënte op kumarien-antikoagulante aanbeveel word. Wanneer 'n dosisaanpassing van **SIMVACOR** plaasvind, moet hierdie prosedure herhaal word.

### Galsuursekwestrante

**SIMVACOR** behoort 1 uur voor, of 4 uur na cholestiramien geneem te word. Gelyktydige gebruik mag die biobeskikbaarheid van **SIMVACOR** verlaag.

### **SWANGERSKAP EN LAKTASIE:**

Veiligheid in swangerskap en laktasie is nie vasgestel nie.

Die aktiewe metabooliet van **SIMVACOR** is fetotoksies en teratogenies in rotte, en dit behoort dus nie in vroulike pasiënte met barende potensiaal gebruik te word nie.

### **DOSERING EN GEBRUIKSAANWYSINGS:**

Die pasiënt moet 'n cholesterol-verlagende dieet voor instelling van, en tydens **SIMVACOR**-terapie volg.

### HIPERCHOLESTEROLEMIE

*Volwassenes:* Aanvangsdosis: 10 mg daaglik as 'n enkele dosis in die aand.

Die dosis **SIMVACOR** moet verminder word as LDL-cholesterolvlakke onder 1,94 mmol/L daal, of as totale plasmacholesterolvlakke tot onder 3,6 mmol/L daal.

### KORONÊRE HARTSIEKTE

*Volwassenes:* Aanvangsdosis: 20 mg/dag as 'n enkele dosis in die aand.

### Dosisaanpassings:

Indien nodig behoort die dosis met tussenposes van nie minder as 4 weke aangepas te word, tot 'n maksimum van 80 mg daaglik as 'n enkele dosis in die aand.

**SIMVACOR** kan saam met maaltye of op 'n leë maag geneem word.

### DOSERING IN NIERONTOEREIKENDHEID

**SIMVACOR** ondergaan nie beduidende renale uitskeiding nie; dosisaanpassing behoort dus nie in pasiënte met ligte tot matige renale ontoereikendheid nodig te wees nie. In pasiënte met ernstige renale ontoereikendheid behoort **SIMVACOR**-terapie noukeurige gemoniteer te word en dosisse bokant 10 mg/dag met omsigtigheid gebruik te word.

### GELYKTYDIGE TERAPIE

**SIMVACOR** is effektief op sy eie of in kombinasie met galsuursekwestrante.

Wanneer albei medisyne voorgeskryf word, moet **SIMVACOR** 1 uur voor, of 4 uur na cholestiramien-toediening gegee word (Sien **INTERAKSIES**).

'n Maksimum daaglikse dosis van 10 mg **SIMVACOR** word aanbeveel in pasiënte wat siklosporien, fibrate of niasien gelyktydig neem (Sien **INTERAKSIES**).

## **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**

### **Neuwe-effekte:**

#### **Gastroïntestinaal:**

Hardlywigheid, diarree, naarheid, braking, winderigheid, dispepsie, abdominale pyn, krampe en pankreatitis.

#### **Hematologies:**

Anemie, neutropenie.

#### **Vel en aanhangsels:**

Veluitslag, alopesie.

#### **Muskuloskeletaal:**

*Frekwent:* Mialgie, spierkrampe.

*Minder frekwent:* Miopatie, miositis, rabdomiolise wat presenteer as spierpyn met verhoogde kreatienfosfokinase en mioglobulinurie wat na nierversaking lei.

#### **Neurologies:**

Hoofpyn, duiseligheid, moegheid, astenie, parestesie, perifere neuropatie.

#### **Hipersensitiwiteitsreaksies:**

*Minder frekwent:* reaksies wat angio-edeem, lupus-agtige sindroom, polymyalgia rheumatica, vaskulitis, trombositopenie, verhoogde eritrosiet sedimentasie tempo, eosinofilie, artritis, urtikarie, fotosensitiwiteit, koors, blosing, malaise en dispnee, insluit.

#### **Ander:**

Gewigstoename is aangemeld.

## LABORATORIUMTOETSBEVINDINGS

Uitgesproke en aanhoudende verhogings van serumtransaminases en verhoogde alkaliese fosfatase en gamma-glutamiel-transpeptidase is gerapporteer.

Lewerfunksietoets- abnormaliteite was gewoonlik lig en verbygaande. Verhogings in serum kreatienkinase (KK)vlakke, wat van skeletspier ontstaan, is aangemeld (**Sien SPESIALE VOORSORGMATREËLS**).

### **Spesiale Voorsorgmaatreëls:**

**SIMVACOR** moet met omsig gebruik word in pasiënte wie:

- Aansienlike hoeveelhede alkohol inneem en/of 'n geskiedenis van lewersiekte het.
- Geneig mag wees om nierversaking sekondêr tot rabdomiolise te ontwikkel, soos dié met ernstige, akute infeksie, hipotensie, ernstige metaboliese, endokriene of elektrolietversteurings, onbeheerde konvulsies, groot operasies of trauma. Daar bestaan 'n verhoogde risiko van ontwikkeling van renale versaking indien rabdomiolise voorkom.
- Ernstige renale inkorting het.

### **Hepatiëse uitwerkings:**

Lewerfunksietoetse, insluitend bepalings van serumtransaminase word aanbeveel voor instelling van **SIMVACOR**-terapie en periodiek tot een jaar na die laaste dosisverhoging.

**SIMVACOR** moet gestaak word indien die verhoging in transaminasevlakke aanhou en/of toeneem tot drie keer of meer van die Boonste Vlak van Normaal (BVN).

### **Miopatie**

#### **Verlaging van die risiko van miopatie:**

##### 1. Algemene maatreëls

Pasiënte wat terapie met **SIMVACOR** begin, moet ingelig word oor die risiko van miopatie en behoort onmiddellik onverklaarbare spierpyn, -teerheid of -swakheid aan te meld. 'n kreatienkinase(KK)vlak bokant 10 keer die Boonste Vlak van Normaal (BVN) in 'n pasiënt, met onverklaarbare simptome, dui op miopatie.

**SIMVACOR** behoort gestaak te word indien miopatie gediagnoseer of vermoed word.

2. Maatreëls om die risiko van miopatie wat deur interaksies met medisyne veroorsaak word, te verminder

Die voordele en risiko's van die gelyktydige gebruik van **SIMVACOR** saam met immuunonderdrukkende middels, fibrate of lipied-verlagende dosisse niasien moet versigtig oorweeg word, en die dosis **SIMVACOR** behoort gewoonlik nie 10 mg/dag te oorskry nie.

Gelyktydige toediening met siklosporien, itrakonasool, ketokonasool, eritromisien, klaritromisien, MIV-protease-inhibeerders, en nefasodoon, word nie aanbeveel nie.

In pasiënte wat siklosporien ontvang, behoort **SIMVACOR** tydelik gestaak te word indien sistemiese asool-afgeleide antifungale terapie benodig word.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**

(Sien **NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS**).

Algemene maatreëls moet gebruik, en lewerfunksie moet gemoniteer word.

Behandeling is simptomaties en ondersteunend.

**IDENTIFIKASIE:**

**SIMVACOR 10 mg:** Wit, ronde (6 mm in deursnee), effens bikonvekse, film-bedekte tablet met afgeplatte kante.

**SIMVACOR 20 mg:** Wit, ronde (8 mm in deursnee), effens bikonvekse, film-bedekte tablet met afgeplatte kante.

**SIMVACOR 40 mg:** Wit, ronde (11 mm in deursnee), effens bikonvekse, film-bedekte tablet met afgeplatte kante.

**AANBIEDING:**

Helder, deursigtig, hard PVC blasie en aluminiumfoelie van 30 tablette elke.

**BERGINGSAAWYSINGS:**

Bewaar op in 'n koel (benede 25°C), droë plek. Moenie die tablette uit die kartondoos verwyder tot voor gebruik nie.

**HOU BUITE BEREIK VAN KINDERS.**

**REGISTRASIENOMMERS:**

**SIMVACOR 10 mg:** 35/7.5/0237

**SIMVACOR 20 mg:** 35/7.5/0238

**SIMVACOR 40 mg:** 39/7.5/0132

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE  
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Suid Afrika

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUWILJET:**

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