**1. WHAT SIMVASTATIN GENERICON 20 MG - FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR**

Simvastatin reduces an elevated cholesterol level and belongs to the class of so-called HMG CoA reductase inhibitors.

- **Elevated blood lipid concentrations**
  To reduce elevated blood lipid concentrations (such as cholesterol and/or triglycerides).

- **Prevention of coronary heart disease**
  To prevent coronary heart disease if atherosclerosis and/or diabetes mellitus has been diagnosed with a high risk of cardiovascular disorders.

**2. BEFORE YOU TAKE SIMVASTATIN GENERICON 20 MG - FILM-COATED TABLETS**

**Do not take Simvastatin Genericon 20 mg - film-coated tablets**
- if you are allergic (hypersensitive) to Simvastatin or any of the other components of this medication
- if you are also taking certain other medications as a therapy for cardiovascular disease (e.g. calcium antagonists, particularly mibefradil)
- if you have liver problems
- if you have a history of myopathy

**Take special care with Simvastatin Genericon 20 mg - film-coated tablets**
Before you start taking Simvastatin Genericon 20 mg - film-coated tablets, your doctor will explain the possible risk of contracting myopathy [a particular (skeletal) muscle disease]. You will be advised to tell your doctor immediately if you experience any unexplained pains, tenderness or weakness in your muscles. Your doctor may order laboratory tests; it is important that you have these tests done.
Tell your doctor about any existing liver problems or if you consume large quantities of alcohol - it may be necessary to lower the dose.

Therapy with Simvastatin Genericon 20 mg - film-coated tablets should be temporarily stopped a few days prior to elective major surgery or if a major medical or surgical condition supervenes.

Please tell your attending doctor if you have been diagnosed as having a risk of rhabdomyolysis (dissolution of striomuscular muscle fibres). Your doctor may then order particular laboratory tests in the following situations before you start treatment:

- elderly patients (> 70 years old)
- renal impairment
- untreated hypothyreosis (thyroid insufficiency)
- personal or familial history of hereditary muscular disorders
- muscular symptoms during treatment with other lipid-lowering agents (statins or fibrates) in your clinical history
- alcohol abuse.

It is particularly important to tell your doctor about any other medicines (including over-the-counter medications) you are taking or have taken (see also "Drug interactions"). Caution should be exercised when prescribing fenofibrate with simvastatin because either agent can cause a muscular disorder (myopathy) when given alone.

Check with your doctor or pharmacist before taking Simvastatin Genericon 20 mg - film-coated tablets if you have severe respiratory failure.

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription.

- Many other medicines are able to affect the action of Simvastatin Genericon 20 mg - film-coated tablets. Some of these medicines are:
- Coumarin-type anticoagulants that reduce blood clotting. It is recommended that the blood clotting time of patients who are taking Simvastatin and coumarins concomitantly is checked at regular intervals. It is thus very important that you have all the tests done that have been ordered by your doctor.
- Cholesterol-lowering drugs, such as fibrates, e.g. bezafibrates and gemfibrozil (except fenofibrate) or high dosages of niacin or nicotinic acid.
- Medicines that inhibit the body's immune system, e.g. ciclosporin.
- Medicines for the oral treatment of fungal infections that contain itraconazole or ketoconazole.
- Certain antibiotics: erythromycin, clarithromycin or telithromycin.
- Drugs for the treatment of depression that contain nefazodone.
- Drugs for the treatment of HIV that inhibit a particular viral enzyme, such as aprenavir, saquinavir
- Drugs that lower the blood pressure which contain verapamil or diltiazem (calcium antagonists)
- Amiodarone (a drug used to treat an irregular heartbeat)

**Taking Simvastatin Genericon 20 mg - film-coated tablets with food and drink**
You should avoid drinking grapefruit juice while you are taking Simvastatin to prevent a possible overdose. You should also avoid drinking large quantities of alcohol whilst you are taking Simavastatin.

**Pregnancy and breast-feeding**
Simvastatin Genericon 20 mg - film-coated tablets

You should not take Simvastatin Genericon 20 mg - film-coated tablets if you are pregnant or if you are breast-feeding. Women of child-bearing potential should only take Simvastatin Genericon 20 mg - film-coated tablets if they are using suitable contraceptive measures. If you become pregnant during treatment, stop taking Simvastatin Genericon 20 mg - film-coated tablets and contact your doctor immediately. Because it is not known whether Simvastatin passes into breast milk, do not breast-feed while you are taking Simvastatin Genericon 20 mg - film-coated tablets.

Driving and using machines
Simvastatin Genericon 20 mg - film-coated tablets have no or negligible influence on your ability to drive or operate machinery. However, when driving or operating machinery, please bear in mind that there have been rare reports of dizziness after the drug was launched on the market.

Important information about some of the ingredients of Simvastatin Genericon 20 mg - film-coated tablets
One film-coated tablet of Simvastatin Genericon 20 mg contains 149 mg of lactose. Patients with a rare hereditary disease (galactose intolerance, lactase deficiency, glucose-galactose malabsorption) should not take Simvastatin Genericon 20 mg - film-coated tablets.

3. HOW TO TAKE SIMVASTATIN GENERICON 20 MG - FILM-COATED TABLETS
Always take Simvastatin Genericon 20 mg - film-coated tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take the film-coated tablets between meals with a little liquid. They can be divided at the score line.

Elevated levels of blood lipids (cholesterol)
The usual starting dose is 10 mg to 20 mg per day (in certain cases 20 mg to 40 mg per day) as a single dose taken in the evening. The recommend dosage range is between 10 and 80 mg per day. In patients with slight to moderately elevated cholesterol levels, treatment can be started with 5 mg Simvastatin. If necessary, your doctor will adjust the dose.
If you have a very high blood cholesterol level and an increased risk for cardiovascular disease, your doctor may prescribe a daily dose of 80 mg to be taken in the evening. This is the maximum daily dose.

Familial-related elevated cholesterol levels in the blood
The recommended dose for patients with familial-related elevated blood lipid levels is 40 mg Simvastatin per day (as a single dose in the evening) or 80 mg per day (divided into 3 single doses of 2 times 20 mg and one evening dose of 40 mg Simvastatin) in addition to other measures to lower blood lipid levels (such as LDL apheresis) or if these measures are unavailable.

Prevention of coronary heart disease
If an existing atherosclerosis and/or diabetes mellitus is diagnosed with a high risk of a cardiovascular disorder, with normal or elevated cholesterol levels, your doctor may prescribe Simvastatin as an adjunct to dietary measures and physical exercise to prevent coronary heart disease. The recommend dosage range is between 20 and 40 mg per day.

Combination therapy
Simvastatin is effective if administered on its own or in combination with certain drugs that lower the blood lipid levels using different mechanisms, in particular with resins that are bile acid sequestrants. However, Simvastatin should be taken at least 2 hours before or at least 4 hours after taking such resins.
For patients who take ciclosporin, gemfibrozil and other fibrates (except fenofibrate) or niacin concomitantly with simvastatin, the recommended maximum dose is 10 mg simvastatin per day.
If verapamil or amiodarone are co-administered, the maximum dose of 20 mg simvastatin per day should not be exceeded.
Patients with a moderately impaired renal function
No dose adjustment is necessary for patients with a moderately impaired renal function because very little simvastatin is excreted via the kidneys.

Patients with a seriously impaired renal function
In patients with a seriously impaired renal function, a dose greater than 10 mg per day requires particular consideration of the risks. If the doctor does decide that such a dose is necessary, it must be administered with the corresponding caution.

Elderly patients
No dosage adjustment is necessary.

Children and adolescents (under the age of 18)
There are no studies that have investigated the efficacy and the safety of simvastatin in this group of patients. Therefore, simvastatin should not be used for this age group.

You doctor will decide on how long you need to be treated.

If you take more Simvastatin Genericon 20 mg - film-coated tablets than you should
Only few cases of overdosing have been reported to date; the maximum dose taken was 3.6 g of simvastatin. None of the patients exhibited specific symptoms or after-effects. If you take an overdose, contact the nearest available doctor.

Information for the doctor
General measures should be taken and the laboratory values monitored.

If you forget to take Simvastatin Genericon 20 mg - film-coated tablets
Do not take a double dose to make up for a forgotten dose.

If you have further questions on how to take this medicine, please ask your doctor or your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Simvastatin Genericon 20 mg - film-coated tablets can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The frequencies of adverse reactions are defined as:
very common (> 1/10), common (≥ 1/100, < 1/10), uncommon (≥ 1/1000, < 1/100), rare (> 1/10000, < 1/1000), very rare (< 1/10000) including isolated reports

Blood and lymphatic system disorders:
Rare: Anaemia

Disorders of the nervous system:
Rare: Headaches, sensory disturbances (paraesthesia), dizziness, nerve disorders.

Disorders of the gastrointestinal tract:
Rare: Constipation (obstipation), abdominal pains, bloating (flatulence), disturbed digestion due to enzymatic changes (dyspepsia), diarrhoea, nausea, vomiting, inflammation of the pancreas.

Disorders of the liver and the gall-bladder:
Rare: Inflammation of the liver (hepatitis), jaundice (icterus)
Disorders of the skin and the subcutaneous tissue:
*Rare*: Rashes, itching, hair loss

Musculoskeletal and connective tissue disorders:
*Rare*: Disorders of the musculature, dissolution of striomuscular musculature (rhabdomyolysis), muscle pains, muscle cramps

General disorders and administration site conditions:
*Rare*: Asthenia

There have been rare reports of an apparent hypersensitivity event accompanied by one or more of the following symptoms: acute localised angioedema without itching lasting up to 48 hours, particularly in the region of the face, lupus-type syndrome, generalised rheumatic muscle pains, changes in the connective tissue of the skin, muscles and inner organs (dermatomyositis), inflammation of the blood vessels (vasculitis), low number of blood platelets, increased number of certain white blood cells (eosinophilic granulocytes), increased ESR, inflammation of the joints, joint pains, rash, photosensitivity, fever, facial flushing, dyspnoea and general feeling of malaise.

Investigations:
*Rare*: Increases in the liver enzyme values, alkaline phosphatase and creatine kinase in the serum.

Possible side effects are:
- Sleep disturbances, including insomnia and nightmares
- Memory loss
- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever

5. HOW TO STORE SIMVASTATIN GENERICON 20 MG - FILM-COATED TABLETS

No special storage conditions are required for this medicine.

Keep out of the reach and sight of children.

Do not use the tablets after the expiry date stated on the carton after "Use before". The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Simvastatin Genericon 20 mg - film-coated tablets contain
- The active substance is simvastatin 20 mg.
- The other excipients are:
  * **Tablet core**: Anhydrous lactose (149 mg); microcrystalline cellulose; starch, pre-gelatinised; butylated hydroxyanisole; magnesium stearate; talc.
  * **Tablet coating**: Hydroxypropyl cellulose; hypromellose; talc; titanium dioxide E 171.

What Simvastatin Genericon 20 mg - film-coated tablets look like and contents of the pack
Film-coated tablet (white, oblong, biconvex, with a score line on one side, embossed with "20" on the scored side and "SVT" on the other side)

Simvastatin Genericon 20 mg - film-coated tablets are packaged in blister packs containing 30 tablets.
Marketing Authorisation Holder and Manufacturer
Genericon Pharma Gesellschaft m.b.H, A-8054 Graz

This leaflet was last approved in September 2008.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:
Ecopharm EOOD
14, Cherni vrah Blvd., bl.3, Sofia 1421
Tel.: 02 963 15 96; 02 950 44 10
Fax: 02 963 15 61