SAFETY DATA SHEET
SIMVASTATIN TABLETS, USP

EMERGENCY OVERVIEW

Simvastatin Tablets, USP contain Simvastatin and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name : Simvastatin Tablets, USP
Formula : C_{25}H_{38}O_{5}
Chemical Name : Simvastatin is butanoic acid, 2,2 dimethyl, 1,2,3,7,8,8a hexahydro- 3,7-dimethyl-8-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)-ethyl]-1-naphthalenyl ester, [1S-[1α,3α,7β,8β(2S*,4S*)-8aβ]]
Therapeutic Category : lipid-lowering agent

Manufacturer / supplier identification

Manufacture : Hetero Labs Limited Unit III, Jeedimetla, Hyderabad
Distributor : Camber Pharmaceuticals, Inc, Piscatway, NJ 08854

Section 2. Composition / information on ingredients

Component | CAS No.
--- | ---
Principle Component | : 79902-63-9
Simvastatin | : 79902-63-9
Inactive Ingredients | :
Lactose monohydrate | : 64044515
Citric acid monohydrate | : 5949291
Butylated Hydroxyanisole | : 25013165
Microcrystalline cellulose | : 9000117
Lactose anhydrous | : 63423
Magnesium stearate : 557040
Pregelatinized starch : 9063381
Ascorbic Acid : 50817
Isopropyl Alcohol : 67-63-0
Hypermellose : 9004653
Hydroxypropylcellulose : 9004642
Titanium dioxide : 13463677
Talc : 14807966
Iron oxide Yellow : 51274001

Section 3. Health Hazards Information

Dose and Administration In patients with CHD or at high risk of CHD, simvastatin
tablets can be started simultaneously with diet. The dosage
range is 5 to 80 mg/day (see below).

The recommended usual starting dose is 20 to 40 mg once a day
in the evening.

Patients with Homozygous Familial Hypercholesterolemia:
The recommended dosage for patients with homozygous
familial hypercholesterolemia is simvastatin tablets 40 mg/day
in the evening or 80 mg/day in 3 divided doses of 20 mg, 20
mg and an evening dose of 40 mg.

Adolescents (10 to 17 years of age) with Heterozygous
Familial Hypercholesterolemia:
The recommended usual starting dose is 10 mg once a day in
the evening. The recommended dosing range is 10 to 40
mg/day.

Adverse Effects

<table>
<thead>
<tr>
<th>Body as a Whole</th>
<th>Gastrointestinal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>Constipation</td>
</tr>
<tr>
<td>Asthenia</td>
<td>Diarrhoea</td>
</tr>
<tr>
<td>Nervous System/Psychiatric</td>
<td>Dyspepsia</td>
</tr>
</tbody>
</table>
Headache    Flatulence

Respiratory

Nausea

Upper respiratory infection

Over Dose Effect  Significant lethality was observed in mice after a single oral
dose of 9 g/m². No evidence of lethality was observed in rats
or dogs treated with doses of 30 and 100 g/m², respectively.
No specific diagnostic signs were observed in rodents. At
these doses the only signs seen in dogs were emesis and
mucoid stools.

A few cases of over dosage with simvastatin tablets have
been reported; the maximum dose taken was 3.6 g. All
patients recovered without sequelae. Until further experience
is obtained.

The dialyzability of simvastatin and its metabolites in man is
not know at present.

Contraindications  Hypersensitivity to any component of this medication.

Active liver disease or unexplained persistent elevations of
serum transaminases.

Pregnancy Comments  Atherosclerosis is a chronic process and the discontinuation of
lipid-lowering drugs during pregnancy should have little
impact on the outcome of long-term therapy of primary
hypercholesterolemia.

Moreover, cholesterol and other products of the cholesterol
biosynthesis pathway are essential components for fetal
development, including synthesis of steroids and cell
membranes.

Simvastatin tablets are contraindicated during pregnancy and
in nursing mothers. If the patient becomes pregnant while
taking this drug, simvastatin tablets should be discontinued
immediately and the patient should be apprised of the
potential hazard to the fetus.

Pregnancy Category  X
Section 4. First aid measures

General
Remove from exposure. Remove contaminated Clothing.
Person developing serious hypersensitivity reaction must receive medical attention.

Overdose Treatment
No specific treatment of over dosage with simvastatin tablets can be recommended.

Section 5. Fire – fighting measures

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
<td>Not Found</td>
</tr>
<tr>
<td>Auto-Ignition Temperature</td>
<td>Not Found</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.</td>
</tr>
<tr>
<td>Fire and Explosion Hazard</td>
<td>This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.</td>
</tr>
</tbody>
</table>

Fire Fighting Procedure
As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Section 7. Exposure controls and personal protection

Respiratory Protection
Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection
Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection
Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to
touching eye and in particular handling contact lenses.

Protective Clothing

Protective clothing is not normally necessary, however it is good practice to use apron.

### Section 8. Physical and chemical properties

**Appearance**

Simvastatin tablets USP, 5 mg are yellow colored, oval shaped, film coated tablet, debossed with 'H' on one side and '16' on other side. They are supplied as follows:

- Bottles of 30 (NDC 31722-510-30)
- Bottles of 100 (NDC 31722-510-01)
- Bottles of 1000 (NDC 31722-510-10)
- Bottles of 90 (NDC 31722-510-90)

Simvastatin tablets USP, 10 mg are pink colored, oval shaped, film coated tablet, debossed with 'H' on one side and '17' on other side. They are supplied as follows:

- Bottles of 30 (NDC 31722-511-30)
- Bottles of 100 (NDC 31722-511-01)
- Bottles of 1000 (NDC 31722-511-10)
- Bottles of 90 (NDC 31722-511-90)

Simvastatin tablets USP, 20 mg are brown colored, oval shaped, film coated tablet, debossed with 'H' on one side and '18' on other side. They are supplied as follows:

- Bottles of 30 (NDC 31722-512-30)
- Bottles of 100 (NDC 31722-512-01)
- Bottles of 1000 (NDC 31722-512-10)
- Bottles of 90 (NDC 31722-512-90)

Simvastatin tablets USP, 40 mg are brick red colored, oval shaped, film coated tablet, debossed with 'H' on one side and '19' on other side. They are supplied as follows:

- Bottles of 30 (NDC 31722-513-30)
- Bottles of 100 (NDC 31722-513-01)
- Bottles of 1000 (NDC 31722-513-10)
Bottles of 90 (NDC 31722-513-90)
Simvastatin tablets USP, 80 mg are brick red capsule shaped, film coated tablet, debossed with 'H' on one side and '20' on other side. They are supplied as follows:
Bottles of 30 (NDC 31722-514-30)
Bottles of 100 (NDC 31722-514-01)
Bottles of 500 (NDC 31722-514-05)
Bottles of 90 (NDC 31722-514-90)

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility in water</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Vapour density</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Reactivity in water</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Percentage Volatile by Volume</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>No Data Available</td>
</tr>
</tbody>
</table>

Other information
Simvastatin is a white to off-white powder that is practically insoluble in water; freely soluble in chloroform, in methanol and in alcohol; sparingly soluble in propylene glycol; very slightly soluble in hexane.

**Section 9. Physical Hazards**

**Condition to avoid**
Avoid exposure to extreme heat, light and moisture.

Stable
Stable under normal ambient and anticipated storage and handling conditions

**Section 10. Toxicological information**

General
Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the
ingredient in formulations, rather than this specie formulation.

Target organ Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

other Not Applicable

### Section 11. Ecological information

No data available on Ecotoxicity

### Section 12. Disposal Considerations

**Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### Section 13. Transport Information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

### Section 14. Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

### Section 15. Other Information
The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.