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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	:	
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
Hypromellose	:	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

Body as a Whole
Abdominal pain
Asthenia

Nervous System/Psychiatric

Gastrointestinal
Constipation
Diarrhoea
Dyspepsia

	Headache	Flatulence
	Respiratory	Nausea
	Upper respiratory infection	

Over Dose Effect	Significant lethality was observed in mice after a single oral dose of 9 g/m^2. No evidence of lethality was observed in rats or dogs treated with doses of 30 and 100 g/m^2, 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

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature	Not Found	**Lower Flammable Limit**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	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.

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 (NDC31722-514-90)

Solubility in water	No Data Available	**Odor**	Odorless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
Percentage Volatile by Volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available		

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.