Material Safety data sheet

SIMVASTATIN TABLETS, USP

Strength: 5/10/20/40/80 mg. **Pack Size:** 30/60/90/500/1000/10000 Tablets per bottle **Revision No.:** 00

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-2*H*-pyran-2-yl)-ethyl]-1-naphthalenyl ester, [1*S*-[1α,3α,7β,8β(2*S**,4*S**),-8aβ]]
Therapeutic Category	lipid-lowering agent

Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Simvastatin 5 mg or 10 mg or 20 mg or 40 mg or 80 mg.	Not Found	79902-63-9
Inactive Ingredients :		
Ascorbic acid,	Not Found	50-81-7
Citric acid anhydrous,	Not Found	77-92-9
Hydroxypropyl cellulose,	Not Found	9004-64-2
Hydroxypropyl methylcellulose (hypromellose),	Not Found	9004-65-3
Lactose anhydrous,	Not Found	63-42-3
Magnesium stearate,	Not Found	557-04-0
Pregelatinized starch,	Not Found	113-15-5
Talc	Not Found	14807-96-6
Titanium dioxide	Not Found	13463-67-7

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
Headache
Respiratory
Upper respiratory infection

Gastrointestinal
Constipation
Diarrhea
Dyspepsia
Flatulence
Nausea

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 overdosage 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 known 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 contiminated Clothing. Person devloping serious hypersensitivity reaction must receive medical attention
Overdose Treatment	No specific treatment of overdosage 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 6. Storage / Spill / Disposal Measures

Storage	Store at 20° to 25°C (68° to 77°F), Dispense in a tight container.
Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

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 white, oval shaped, biconvex, beveled edge, film-coated tablets imprinted with "ZA19" in black ink on one side and plain on other side.

Simvastatin Tablets USP, 10 mg are pink, oval shaped, biconvex, beveled edge, film-coated tablets imprinted with "ZA20" in black ink on one side and plain on other side.

Simvastatin Tablets USP, 20 mg are brown, oval shaped, biconvex, beveled edge, film-coated tablets imprinted with "ZA21" in black ink on one side and plain on other side.

Simvastatin Tablets USP, 40 mg are pink, oval shaped, biconvex, beveled edge, film-coated tablets imprinted with "ZA22" in black ink on one side and plain on other side.

Simvastatin Tablets USP, 80 mg are white to off-white, capsule shaped, biconvex, film-coated tablets imprinted with "ZA23" in black ink on one side and plain on other side.

Solubility in water	No Data Available	**Odour**	Odourless
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.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities	No data available.		

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. Other information

None

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The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.