



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
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GHS Product identifier	Rosuvastatin calcium Tablets, 5 mg, 10 mg, 20mg and 40mg
Trade Name	Not applicable
Other means of identification	
Synonyms	Rosuvastatin calcium, Finished product
Recommended use	Medicinal Product.
Manufacturer	Hetero Labs Limited , Unit V, Polepally, Jadcherla Mahaboob Nagar-509 301, India.
Distributor	Camber Pharmaceuticals, Inc , Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Section 2, Hazard(s)identification	
Classified hazards	Exempt from requirements
Label elements	Exempt from requirements
Hazard statement	Exempt from requirements
Environment	
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Rosuvastatin calcium	147098-20-2
Lactose Monohydrate, USP/NF (Flowlac 100)	CAS-No.: 64044-51-5
Microcrystalline Cellulose, USP/NF (Avicel PH 102)	9004-34-6
Crospovidone, USP/NF (Kollidon CL)	616-45-5
Hydroxypropyl Cellulose, USP/NF(Klucel EXF)	9004-64-2
Sodium Bicarbonate, USP (Emprove)	144-55-8
Talc, USP (Talc Luzenac Pharma)	14807-96-6
Magnesium Stearate USP-NF (LIGAMED MF-2-V)	557-04-0
Opadry Yellow 32K520068, IHS	25322-68-3
Opadry II Pink 32K540033, IHS	
Section 4: First-Aid Measures	



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Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin Contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice Immediately. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
Section 5: Fire-Fighting Measures	
Section 5, Fire-fighting measures	
Suitable Extinguishing Media	Water, Foam, Dry chemical powder, carbon dioxide.
Unsuitable Extinguishing Media	Not available
Specific hazards arising from During fire, gases hazardous to health may be formed. the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
special fire fighting procedures	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
Section 6: Accidental Release Measures	
Section 6, Accidental release measures	
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage



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	or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
Methods and materials for containment and cleaning up	This material is classified as a water pollutant under the Clean Water Act and should be prevented from contaminating soil or from entering sewage and drainage systems which lead to waterways. Stop the flow of material, if this is without risk. Following product recovery, flush area with water for waste disposal.

Section 7: Handling and Storage

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Handling	Provide adequate ventilation. Avoid release to the environment. Avoid prolonged exposure.
Conditions for safe storage, including any incompatibilities	Store Rosuvastatin Tablets Store at 20 to 25°C (68 to 77° F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Components	Type	
	ACGIH TLV	OSHA PEL
Lactose Monohydrate, USP/NF (Flowlac 100)	AGW BGW General 1.25 mg/m ³ alveolar fraction Dust limit 10 mg/m ³ respiratory fraction	Not applicable
Microcrystalline Cellulose, USP/NF (Avicel PH 102)	10 mg/m ³ (TWA)	15 mg/m ³ (PEL) (total dust) 5 mg/m ³ (PEL) (respirable fraction of dust)
Crospovidone, USP/NF (Kollidon CL)	No occupational exposure limits known.	No occupational exposure limits known.
Hydroxypropyl Cellulose, USP/NF (Klucel EXF)	Contains no substances with occupational exposure limit values.	Contains no substances with occupational exposure limit values.
Sodium Bicarbonate, USP (Emprove)	Contains no substances with occupational exposure limit values.	Contains no substances with occupational exposure limit values.
Talc, USP (Talc Luzenac Pharma)	Not available	Not available
Magnesium Stearate USP-NF (LIGAMED MF-2-V)	Not available	Not available



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Opadry Yellow 32K520068, IHS	Not available	Not available
Opadry II Pink 32K540033, IHS	Not available	Not available
Appropriate engineering Controls	General ventilation normally adequate.	
Individual protection measures, such as personal protective equipment		
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.	
Skin protection Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.	
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.	
Hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.	
Section 9: Physical and Chemical Properties		
Section 9, Physical and chemical properties		
Physical State	Solid	
Form	Tablets	
Colour	Light Yellow- 5mg, Light pink-10mg, 20 mg and 40 mg	
Odor	Not available	
Description	Rosuvastatin calcium Tablets, 5 mg Light yellow to yellow, round, bevel edged biconvex film coated tablets debossed with 'H' on one side and 'R3' on the other side. Bottle of 90 Tablets (NDC 31722-882-90) Blister pack of 100 (10x10) Unit dose tablets	



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	<p>(NDC 31722-882-31)</p> <p>Rosuvastatin calcium Tablets, 10 mg</p> <p>Light pink to pink, round, bevel edged biconvex film coated tablets debossed with 'H' on one side and 'R4' on the other side.</p> <p>Bottle of 90 Tablets (NDC 31722-883-90)</p> <p>Blister pack of 100 (10x10) Unit dose tablets (NDC 31722-883-31)</p> <p>Rosuvastatin calcium Tablets, 20 mg</p> <p>Light pink to pink, round, bevel edged biconvex film coated tablets debossed with 'H' on one side and 'R5' on the other side.</p> <p>Bottle of 90 Tablets (NDC 31722-884-90)</p> <p>Blister pack of 100 (10x10) Unit dose tablets (NDC 31722-884-31)</p> <p>Rosuvastatin calcium Tablets, 40 mg</p> <p>Light pink to pink, oval, bevel edged biconvex film coated tablets debossed with 'H' on one side and 'R6' on the other side.</p> <p>Bottle of 30 Tablets (NDC 31722-885-30)</p> <p>Blister pack of 100 (10x10) Unit dose tablets (NDC 31722-885-31)</p>
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Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition products

Section 11: Toxicological Information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
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Skin contact	Health injuries are not known or expected under normal use.		
Eye contact	Health injuries are not known or expected under normal use.		
Ingestion	Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure.		
Acute toxicity :			
Components	LD50 oral	LD50 dermal	LD50 inhalation
Lactose Monohydrate, USP/NF (Flowlac 100)	>10 g/kg -Rat	Not available	Not available
Microcrystalline Cellulose, USP/NF (Avicel PH 102)	>5,000 mg/kg-Rat	> 2,000 mg/kg (rabbit)	> 5.05 mg/l (4 h) (rat)
Crospovidone, USP/NF (Kollidon CL)	> 2,000 mg/kg-Rat	Not available	> 5.2 mg/l -rat
Hydroxypropyl Cellulose, USP/NF (Klucel EXF)	> 10 g/kg-Rat	Not available	Not available
Sodium Bicarbonate, USP (Emprove)	4,220 mg/kg -Rat	Not available	Not available
Talc, USP (Talc Luzenac Pharma)	Not available	Not available	Not available
Magnesium Stearate USP-NF (LIGAMED MF-2-V)	Not available	Not available	Not available
Opadry Yellow 32K520068, IHS	23854 mg/kg	Not available	Not available
Opadry II Pink 32K540033, IHS		Not available	Not available
Skin corrosion/irritation	Health injuries are not known or expected under normal use		
Respiratory or skin sensitization	No studies have been conducted		
Germ cell mutagenicity	Health injuries are not known or expected under normal use		
Carcinogenicity	Rosuvastatin, the active substance in this product, produced carcinogenic effects in a lifetime study in mice. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.		
Reproductive toxicity	Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.		



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Effects on Fertility:	Other measures of fertility
Specific target organ toxicity - single exposure (GHS)	no data available
Specific target organ toxicity - repeated exposure (GHS)	May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	no data available

Section 12: Ecological Information

Toxicity : Contains a substance which causes risk of hazardous effects to the environment.

Components	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Daphnia Magna(Water flea)
Lactose Monohydrate, USP/NF (Flowlac 100)	Not available	Not available	Not available	Not available
Microcrystalline Cellulose, USP/NF (Avicel PH 102)	Not available	Not available	Not available	48-hour LC ₅₀ > 100%, saturated solution, NOEC = 100% (daphnia)
Crospovidone, USP/NF (Kollidon CL)	Not available	LC ₅₀ (96 h) > 10,000 mg/l,	Not available	Not available
Hydroxypropyl Cellulose, USP/NF (Klucel EXF)	Not available	> 100 mg/l Exposure time: 96 h	Not available	Not available
Sodium Bicarbonate, USP (Emprove)	Not available	7,550 mg/l; 96 h	Not available	2,350 mg/l; 48 h
Talc, USP (Talc Luzenac Pharma)	Not available	Not available	Not available	Not available
Magnesium Stearate USP-NF (LIGAMED MF-2-V)	Not available	Not available	Not available	Not available
Opadry Yellow 32K520068, IHS	Not available	Not available	Not available	Not available
Opadry II Pink 32K540033, IHS	Not available	Not available	Not available	Not available

Section 13: Disposal Considerations

Waste treatment methods

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water Courses or onto the ground. Dispose in accordance with all applicable regulations.



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Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues I unused	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner Avoid discharge into water courses or onto the ground. Products.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14: Transport Information

DOT

UN-Number
Proper shipping name
Hazard class
Reportable quantity
Description
Emergency response guide
Number

Not applicable

IATA

UN-Number
Proper shipping name
Hazard class
Description

Not applicable

IMDG

UN-Number
Proper shipping name
Hazard class
Reportable quantity
Description
Emergency response guide
Number

Not applicable

Section 15: Regulatory Information

U.S State regulations

California Proposition 65: This product does not content any proposition 65 chemicals

Section 16: Other Information

Section 16, Other information

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Version : 00

Further information

Revision date: New issue

Revision note: New issue

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