



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	Silodosin capsules, 4 mg and 8 mg.	
Trade Name	Not Applicable	
Other means of identification	Silodosin, Finished Product	
Synonyms		
Recommended use	Pharmaceutical product for the treatment of BPH.	
Manufacturer	Hetero Labs Limited Unit V Sy. No.: 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla (Mandal), Mahabubnagar (District), Telangana 509301, India (IND)	
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ, 08854.	
Section 2: Hazard(s) Identification		
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Classification according to Regulation (EC) No. 1272/2008 [CLP]		
Not classified		
Classification according to Directive 67/548/EEC or 1999/45/EC		
Carc.Cat.3; R40		
Adverse physicochemical, human health and environmental effects		
No additional information available		
Section 3: Composition/Information on Ingredients		
Chemical Name	Common Name and Synonym	CAS
Silodosin	2, 3-Dihydro-1-(3-hydroxy-propyl)-5-[(2R)-2-[[2-[2-(2,2,2-trifluoroethoxy) phenoxy] ethyl]amino]-propyl]-1H-indole-7-carboxamide	[160970-54-7]
Composition comments	Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.	
Section 4: First-Aid Measures		
Inhalation	Remove to fresh air.	
Skin Contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.	



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Eye Contact	Rinse immediately with plenty of water and seek medical advice.
Ingestion	Consult a physician if necessary.
Section 5: Fire-Fighting Measures	
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Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media	None known
Specific hazards arising from the chemical	Fire may produce irritating, corrosive and/or toxic gases.
Explosion data	
Sensitivity to Mechanical Impact	Not impact sensitive.
Sensitivity to Static Discharge	Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Protective equipment and precautions for firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Section 6: Accidental Release Measures	
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Personal precautions	Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	Do not allow into any sewer, on the ground or into any body of water.
Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Avoid creating dust.
Section 7: Handling and Storage	
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Advice on safe handling	Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.
Storage Conditions	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light and moisture.
Incompatible materials	None known based on information supplied.
Section 8: Exposure Controls/Personal Protection	
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Control parameters	
No additional information available	
Appropriate engineering controls	<p>The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used.</p> <p>Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.</p>
Individual protection measures, such as personal protective equipment	
Eye/ Face protection	No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.
Skin and body protection	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).
Respiratory protection	Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.
Section 9: Physical and Chemical Properties	
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Physical Form	<p>Silodosin Capsules 4 mg</p> <p>White cap / White body size '3' hard gelatin capsule imprinted with 'H' on cap and 'S1' on body, filled with white to off white powder.</p> <p>White Colored Bottles of 30 Capsules (NDC 31722-635-30)</p> <p>Amber Colored Bottles of 30 Capsules (NDC 31722-635-31)</p> <p>White Colored Bottles of 90 Capsules (NDC 31722-635-90)</p> <p>Amber Colored Bottles of 90 Capsules (NDC 31722-635-91)</p> <p>Silodosin Capsules 8 mg</p> <p>White cap / White body size '1' hard gelatin capsule imprinted with</p>



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	'H' on cap and 'S2' on body, filled with white to off white powder. White Colored Bottles of 30 Capsules (NDC 31722-636-30) Amber Colored Bottles of 30 Capsules (NDC 31722-636-31) White Colored Bottles of 90 Capsules (NDC 31722-636-90) Amber Colored Bottles of 90 Capsules (NDC 31722-636-91)
Section 10: Stability and Reactivity	
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Reactivity	Not defined As Reactive substance
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Aerosol formation.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.
Section 11: Toxicological Information	
Acute toxicity	Not classified
Skin corrosion/irritation	Not classified
Serious eye damage/irritation	Not classified
Respiratory or skin sensitisation	Not classified
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified
Reproductive toxicity	Not classified
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Not classified
Aspiration hazard	Not classified
Section 12: Ecological Information	
Ecology - general	Sparingly soluble in methanol
Ecology - air	Not dangerous for the ozone layer (1999/45/EC).
Section 13: Disposal Considerations	
Waste treatment methods	
Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Do not reuse container. Dispose of contents/containers in accordance with local regulations.
Section 14: Transport Information	
DOT	
Not regulated.	



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TDG
Not regulated.
ICAO(air)
Not regulated
IATA
Not regulated.
IMDG
Not regulated.
ADR
Not regulated.
ADN
Not regulated.
Section 15: Regulatory Information
This Section Contains Information relevant to compliance with other Federal and/or state laws.
This Section Contains Information relevant to compliance with other Federal and/or state laws
Issue Date: 28-02-2020
Version: 00
Further information
Revision date: New issue
Revision note: New issue
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