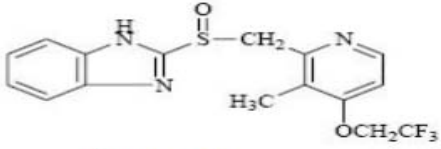




HETERO LABS LIMITED

"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	
Section 1, Identification	
GHS Product identifier	Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg
Trade Name	Not Applicable
Chemical name	2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl] sulfinyl] benzimidazole  Lansoprazole
Recommended use/Therapeutic Category	Antacid
Restriction on Use/Contraindications	Lansoprazole is contraindicated in patients with known severe hypersensitivity to any component of the formulation of lansoprazole delayed-release capsules.
Manufacturer	Hetero Labs Limited, Unit-III Plot No. 22-110, Part-II, IDA, Jeedimetla, Hyderabad 500055, Telangana, India (IND).
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ, 08854.
Section 2: Hazard(s) Information	
Dose and Administration	Lansoprazole is available as a capsule in 15 mg and 30 mg strengths. Lansoprazole should be taken before eating. You should swallow lansoprazole delayed-release capsules whole. Do not crush or chew lansoprazole delayed-release capsules. If you have trouble swallowing a whole capsule, you can open the capsule and take the contents with certain foods or juices. See the "Instructions for Use" at the end of this Medication Guide for instructions on how to take lansoprazole delayed-release capsules with certain foods and juices.
Adverse Effects	Most commonly reported adverse reactions (\geq 1%): diarrhea, abdominal pain, nausea and constipation.
Over Dose Effect	Lansoprazole is not removed from the circulation by hemodialysis. In one reported overdose, a patient consumed 600 mg of lansoprazole with no adverse reaction.
Medical Conditions	Tell your doctor if you: have been told that you have low magnesium levels in your blood, have liver problems, have any other medical conditions,



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	<p>are pregnant or plan to become pregnant. It is not known if lansoprazole delayed-release capsules will harm your unborn baby, are breastfeeding or plan to breastfeed. It is not known if lansoprazole passes into your breast milk. You and your doctor should decide if you will take lansoprazole delayed-release capsules or breastfeed. You should not do both. Talk to your doctor about the best way to feed your baby if you take lansoprazole delayed-release capsules.</p> <p>Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Lansoprazole delayed release capsules may affect how other medicines work, and other medicines may affect how lansoprazole delayed-release capsules work.</p> <p>Especially tell your doctor if you take: atazanavir (Reyataz[®]), digoxin (Lanoxin[®]), a product that contains iron, ketoconazole (Nizoral[®]), warfarin (Coumadin[®], Jantoven[®]), tacrolimus (Prograf[®]), theophylline (Theo-24[®], Elixophyllin[®], Theochron[®], Theolair[®]), an antibiotic that contains ampicillin or clarithromycin, methotrexate</p> <p>Ask your doctor or pharmacist for a list of these medicines if you are not sure. Know the medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.</p>			
<p>Contraindications</p>	<p>Lansoprazole is contraindicated in patients with known severe hypersensitivity to any component of the formulation of lansoprazole delayed-release capsules.</p>			
<p>Pregnancy Comments</p>	<p>There are no adequate or well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.</p>			
<p>Pregnancy Category</p>	<p>B</p>			
<p>Section 3: Composition/Information on Ingredients</p>				
<p>Principle Component</p>	<p>Lansoprazole CAS No.: 103577-45-3</p>			
<p>Ingredient</p>	<p>CAS Number</p>	<p>EU EINECS/ELINCS List</p>	<p>GHS Classification</p>	<p>%</p>
<p>Hard gelatin capsules</p>	<p>Mixture</p>	<p>Not Listed</p>	<p>Not Listed</p>	<p>*</p>
<p>Additional Information</p>	<p>* Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.</p>			



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	In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.
Section 4: First-Aid Measures	
General	<p>Inhalation</p> <p>Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.</p> <p>Contact with skin.</p> <p>Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.</p> <p>Contact with eyes Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.</p> <p>Ingestion</p> <p>If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.</p> <p>Remove and wash/dispose of contaminated clothing promptly.</p>
Overdose Treatment	Lansoprazole is not removed from the circulation by hemodialysis. In one reported overdose, a patient consumed 600 mg of lansoprazole with no adverse reaction.
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 at high temperature.
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: Accidental Release Measures	
Section 6, Accidental release measures	
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.
Section 7: Handling and Storage	



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Section 7, Handling and storage	
Storage	Store at 20° to 25°C (68° to 77°F). Protect from moisture.
Incompatibilities	Reacting with oxidizing substance.
Section 8: Exposure Controls/Personal Protection	
Section 8, Exposure controls/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.
Engineering Control	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Section 9: Physical and Chemical Properties	
Section 9, Physical and chemical properties	
Physical State	Capsules
Solubility	Freely soluble in dimethylformamide, insoluble in hot and cold water.
Odor	Odorless
Appearance	<p>Lansoprazole Delayed Release Capsules, 15 mg Pink/Green colored size '3' hard gelatin capsules imprinted with 'H' on cap and '166' on body filled with white to off white pellets. Bottle of 30 capsules NDC 31722-570-30 Bottle of 100 capsules NDC 31722-570-01 Bottle of 500 capsules NDC 31722-570-05 Bottle of 1000 capsules NDC 31722-570-10</p> <p>Lansoprazole Delayed Release Capsules, 30 mg Pink/Black colored size '1' Hard gelatin capsules imprinted with 'H' on cap and '167' on body filled with white to off white pellets. Bottle of 30 capsules NDC 31722-571-30 Bottle of 100 capsules NDC 31722-571-01 Bottle of 500 capsules NDC 31722-571-05 Bottle of 1000 capsules NDC 31722-571-10</p>
Boiling point: Not available	Melting Point: 152° C to 162° C



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Evaporation rate: Not Available	Vapour density: Not Available
Reactivity in water: Not Available	Vapour pressure: Not Available
Percentage Volatile by volume: Not Available	Specific gravity: Not Available
Section 10: Stability and Reactivity	
Condition to avoid: Avoid exposure to extreme heat, light and moisture.	Stable: Product is stable
Incompatibilities: Reacting with oxidizing substance.	Hazardous Reaction: No data available
Section 11: Toxicological Information	
General Information	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 capsule.
Other	Oral lansoprazole doses up to 5000 mg/kg in rats [approximately 1300 times the 30 mg human dose based on body surface area (BSA)] and in mice (about 675.7 times the 30 mg human dose based on BSA) did not produce deaths or any clinical signs.
Section 12: Ecological Information	
Do not allow product to enter drinking water supplies, waste water or soil.	
Section 13: Disposal Considerations	
Dispose the waste in accordance with all applicable Federal, State and local laws.	
Section 14: Transport Information	
The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).	
Section 15: Regulatory Information	
Generic Medicine. Approved by USFDA	
Section 16: Other Information, including date of preparation or last revision	
<u>Text of CLP/GHS Classification abbreviations mentioned in Section 3</u>	
None	
Issue Date: 20-05-2020	
Version: 00	
Revision note: New	
The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.	
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