



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

Material	Esomeprazole Magnesium Delayed-Release Capsules, 20 mg and 40 mg
Manufacturer	Unit III, Plot No. 22-110, Part-II, IDA, Jeedimetla, Hyderabad, Telangana 500055, India (IND)
Distributor	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification

Classification	Suspected of causing cancer May cause damage to organs through prolonged or repeated exposure.
Environment	Specific target organ toxicity (repeated exposure) Category 2 No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	CAS	Quantity
Esomeprazole Magnesium Dihydrate	217087-10-0	20 mg/capsule, 40 mg/capsule

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation	Remove the victim into fresh air-Respiratory problems: consult a doctor/medical service.
Skin Contact	Remove any contaminated clothing. Wash exposed area thoroughly with soap and water. If irritation occurs or persists, seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.



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NOTES TO HEALTH PROFESSIONALS

Notes to Physician

Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc..

Treatment Of Overdosage

As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Not available
Extinguishing Media	Suitable extinguishing media: Use carbon dioxide, dry chemical.
Special hazards arising from the substance or mixture	Explosion hazard: Not expected for the product, although the packaging is combustible Reactivity: Reacts slowly with air-Upon combustion CO and CO ₂ are formed-And formation of metallic fumes-Reacts with (some)-metals.
Advice for firefighters	Precautionary measures fire: Fight fire from a safe distance. Wear full protective clothing. Use water spray to keep exposed containers and equipment cool. Toxic, corrosive of flammable thermal decomposition products are expected when the product is exposed to fire. Self-contained breathing apparatus and full protective equipment is recommended for firefighters.
Other information	Decontaminate protective clothing and equipment before reuse.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	General measures: Keep upwind-Mark the danger area-Consider evacuation-Seal off low-lying area-Close doors and windows of adjacent premiss.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	For containment: Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions. Methods for cleaning up: Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly. Other information: Wash clothing and equipment after handling.

Section 7: Handling and Storage

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Handling

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. Dispense in a tight container.



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Storage

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Keep esomeprazole magnesium delayed-release capsules, USP container tightly closed.

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form

Esomeprazole Magnesium Delayed-Release Capsules, 20 mg

Purple colored size '3' hard gelatin capsule imprinted with 'H' on cap and '71' on body filled with off white to pale yellow colored pellets.

Bottle of 30 Capsules (NDC 31722-572-30)

Bottle of 90 Capsules (NDC 31722-572-90)

Bottle of 1000 Capsules (NDC 31722-572-10)

Esomeprazole Magnesium Delayed-Release Capsules, 40 mg

Purple colored size

'2' hard gelatin capsule imprinted with 'H' on cap and '72' on body filled with off white to pale yellow colored pellets.

Bottle of 30 Capsules (NDC 31722-573-30)

Bottle of 90 Capsules (NDC 31722-573-90)

Bottle of 1000 Capsules (NDC 31722-573-10)

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenesis

The carcinogenic potential of esomeprazole magnesium delayed-release capsules were assessed using studies of omeprazole of which esomeprazole is an enantiomer. In two 24-month oral carcinogenicity studies in rats, omeprazole at daily doses of 1.7, 3.4, 13.8, 44, and 140.8 mg/kg/day (about 0.4 to 34 times the human dose of 40 mg/day expressed on a body surface area basis) produced gastric ECL cell carcinoids in a dose-related manner in both male and female rats; the incidence of this effect was markedly higher in female rats, which had higher blood levels of omeprazole. Gastric carcinoids seldom occur in the untreated rat. In addition, ECL cell hyperplasia was present in all



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treated groups of both sexes. In one of these studies, female rats were treated with 13.8 mg omeprazole/kg/day (about 3.4 times the human dose of 40 mg/day on a body surface area basis) for 1 year, then followed for an additional year without the drug. No carcinoids were seen in these rats. An increased incidence of treatment-related ECL cell hyperplasia was observed at the end of 1 year (94% treated vs. 10% controls). By the second year the difference between treated and control rats was much smaller (46% vs. 26%) but still showed more hyperplasia in the treated group. Gastric adenocarcinoma was seen in one rat (2%). No similar tumor was seen in male or female rats treated for 2 years. For this strain of rat no similar tumor has been noted historically, but a finding involving only one tumor is difficult to interpret. A 78-week mouse carcinogenicity study of omeprazole did not show increased tumor occurrence, but the study was not conclusive.

Mutagenesis

Esomeprazole was negative in the Ames mutation test, in the in vivo rat bone marrow cell chromosome aberration test, and the in vivo mouse micronucleus test. Esomeprazole, however, was positive in the in vitro human lymphocyte chromosome aberration test. Omeprazole was positive in the in vitro human lymphocyte chromosome aberration test, the in vivo mouse bone marrow cell chromosome aberration test, and the in vivo mouse micronucleus test.

Impairment of Fertility

The potential effects of esomeprazole on fertility and reproductive performance were assessed using omeprazole studies. Omeprazole at oral doses up to 138 mg/kg/day in rats (about 34 times the human dose of 40 mg/day on a body surface area basis) was found to have no effect on reproductive performance of parental animals.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Advice On Disposal And Packaging: Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A



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IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16, 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.