



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	Indomethacin Extended-Release Capsules USP, 75mg
Manufacturer	Hetero Labs Limited Unit III 22-110, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc., Piscatway, NJ 08854

Section 2: Hazard(s) Identification

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Potential Acute Health Effects	Very hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation. Severe over-exposure can result in death.
Potential Chronic Health Effects	CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Mutagenic for bacteria and/or yeast. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	Indomethacin
CAS	53-86-1

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	If swallowed, do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Serious Inhalation	Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not



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Skin Contact	breathing, perform mouth-to-mouth resuscitation. Seek medical attention.
Eye Contact	Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.
Eye Contact	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures	
Fire and Explosion Hazards	May be combustible at high temperature.
Extinguishing Media	SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures	
Small Spill	Use appropriate tools to put the spilled solid in a convenient waste disposal container.
Large Spill	Poisonous solid. Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Eliminate all ignition sources. Call for assistance on disposal.

Section 7: Handling and Storage

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HANDLING	
General Requirements	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.
STORAGE	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

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None required for normal handling. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

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Physical Form

Indomethacin Extended-Release Capsules USP, 75mg

Indomethacin Extended-release capsules are size '2' hard gelatin capsules, with dark yellow cap imprinted with 'H' and clear transparent body imprinted with '105' containing cream spherical pellets.

Bottles of 30 capsules (NDC 31722-565-30)

Bottles of 60 capsules (NDC 31722-565-60)

Bottles of 100 capsules (NDC 31722-565-01)

Bottles of 500 capsules (NDC 31722-565-05)

Bottles of 1000 capsules (NDC 31722-565-10)

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

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Carcinogenesis, Mutagenesis, Impairment of Fertility

In an 81-week chronic oral toxicity study in the rat at doses up to 1 mg/kg/day, indomethacin had no tumorigenic effect.

Indomethacin produced no neoplastic or hyperplastic changes related to treatment in carcinogenic studies in the rat (dosing period 73 to 110 weeks) and the mouse (dosing period 62 to 88 weeks) at doses up to 1.5 mg/kg/day.

Indomethacin did not have any mutagenic effect in in vitro bacterial tests (Ames test and E.

coli with or without metabolic activation) and a series of in vivo tests including the host mediated assay, sex-linked recessive lethals in *Drosophila*, and the micronucleus test in mice.

Indomethacin at dosage levels up to 0.5 mg/kg/day had no effect on fertility in mice in a two generation reproduction study or a two litter reproduction study in rats.

Section 12: Ecological Information

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Ecotoxicity	Not available.
BOD5 and COD	Not available.
Products of Biodegradation	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
Toxicity of the Products of Biodegradation	The products of degradation are less toxic than the product itself.
Special Remarks on the Products of Biodegradation	Not available.

Section 13: Disposal Considerations

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Waste Disposal

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

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The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

Section 15: Regulatory Information

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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.