



# 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

<b>Section 1: Identification</b>	
<b>Section 1, Identification</b>	
<b>Material</b>	<b>Levocetirizine Dihydrochloride Tablets, 5 mg</b>
<b>Manufacturer</b>	<b>Hetero labs limited</b> , Unit III, 22-110, IDA Jeedimetla Hyderabad -500 055, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc</b> , Piscatway, NJ 08854
<b>Section 2: Hazard(s) Identification</b>	
<b>Section 2, Hazard(s) identification</b>	
<b>Emergency Overview</b>	Levocetirizine, the active enantiomer of cetirizine, is an anti-histamine; its principal effects are mediated via selective inhibition of H1 receptors antagonist with indications for allergic rhinitis and for chronic idiopathic urticaria.
<b>Target Organs</b>	Respiratory system, central nervous system.
<b>Signs and symptoms of overexposure</b>	Symptoms of overexposure may include drowsiness.
<b>Potential Health Effects</b>	Based on clinical trials, effects of exposure may include somnolence, fatigue, asthenia, dry mouth, pharyngitis, and nasopharyngitis.
<b>Ingestion</b>	Based on clinical trials, effects of exposure may include somnolence, fatigue, asthenia, dry mouth, pharyngitis, and nasopharyngitis.
<b>Inhalation</b>	Effects of inhaling aerosolized solution have not been determined (may be similar to ingestion effects).
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Section 3, Composition/information on ingredients</b>	
<b>Ingredients</b>	<b>CAS</b>
Levocetirizine Dihydrochloride	130018-87-0
<b>Section 4: First-Aid Measures</b>	
<b>Section 4, First-aid measures</b>	
<b>Ingestion</b>	In case of acute overdose by ingestion, seek immediate medical attention.
<b>Inhalation</b>	If liquid is inhaled, remove to fresh air. Seek immediate medical attention.



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<b>Skin Contact</b>	If liquid comes in contact with skin and clothing, remove contaminated clothing and wash thoroughly with running water for at least 15 minutes. Use soap if available. Seek medical attention if irritation develops.
<b>Eye Contact</b>	In case of contact with liquid, flush eyes with water for at least 15 minutes. Seek medical attention if irritation develops.

<b>OVERDOSAGE</b>	<p>Overdosage has been reported with levocetirizine dihydrochloride.</p> <p>Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children. There is no known specific antidote to levocetirizine dihydrochloride. Should overdose occur, symptomatic or supportive treatment is recommended. Levocetirizine dihydrochloride is not effectively removed by dialysis, and dialysis will be ineffective unless a dialyzable agent has been concomitantly ingested.</p> <p>The acute maximal non-lethal oral dose of levocetirizine was 240 mg/kg in mice (approximately 190 times the maximum recommended daily oral dose in adults, approximately 230 times the maximum recommended daily oral dose in children 6 to 11 years of age on a mg/m<sup>2</sup> basis). In rats the maximal non-lethal oral dose was 240 mg/kg (approximately 390 times the maximum recommended daily oral dose in adults, approximately 460 times the maximum recommended daily oral dose in children 6 to 11 years of age on a mg/m<sup>2</sup> basis).</p> <p><i>Pediatric use information in pediatric patients (age 6 months to 5 years) is approved for UCB Inc.'s levocetirizine dihydrochloride drug product labeling. However, due to UCB Inc.'s marketing exclusivity rights; this drug product is not labeled for such use in those pediatric patients.</i></p>
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## Section 5: Fire-Fighting Measures

<b>Section 5, Fire-fighting measures</b>	
<b>General Hazards</b>	In case of fire and/or explosion do not breathe fumes. CO, CO <sub>2</sub> , hydrogen chloride and oxides of nitrogen and may be generated in a fire.
<b>Fire Fighting Extinguishing Media</b>	In case of fire use water spray, foam or dry chemical.
<b>Fire Fighting Instructions</b>	In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.
<b>Hazardous Combustion Products</b>	CO, CO <sub>2</sub> , hydrogen chloride and oxides of nitrogen and may be generated in a fire.



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## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

<b>Large Spill</b>	Contain spill. Absorb on suitable medium and deposit in container for disposal. Mop area with soap and water.
<b>Small Spill</b>	Absorb on paper towels. Deposit in suitable container for disposal. Broken glass requires additional caution.

## Section 7: Handling and Storage

### Section 7, Handling and storage

<b>Handling</b>	No special control measures required for the normal handling of this product.
<b>Storage</b>	Store Levocetirizine dihydrochloride 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

Avoid eye contact with liquid. Wear safety glasses with side shields or goggles where risk of eye exposure exists. Avoid skin contact with liquid. Impervious gloves should be worn.

## Section 9: Physical and Chemical Properties

### Section 9, Physical and chemical properties

<b>Physical Form</b>	Levocetirizine Dihydrochloride Tablets, 5 mg white film coated, scored, round shaped, standard concave tablets debossed with '161' on one side and 'H' on other side Bottles of 30 Tablets (NDC 31722-551-30) Bottles of 90 Tablets (NDC 31722-551-90) Bottles of 180 Tablets (NDC 31722-551-18) Bottles of 500 Tablets (NDC 31722-551-05) Bottles of 1000 Tablets (NDC 31722-551-10)
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## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

<b>Carcinogenesis, Mutagenesis, Impairment of Fertility</b>	No carcinogenicity studies have been performed with levocetirizine. However, evaluation of cetirizine carcinogenicity studies are relevant for determination of the carcinogenic potential of levocetirizine. In a 2-year carcinogenicity study, in rats, cetirizine was not carcinogenic at dietary doses up to 20 mg/kg (approximately 15 times the maximum recommended daily oral dose in adults, approximately 10 times the maximum
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recommended daily oral dose in children 6 to 11 years of age on a mg/m<sup>2</sup> basis). In a 2-year carcinogenicity study in mice, cetirizine caused an increased incidence of benign hepatic tumors in males at a dietary dose of 16 mg/kg (approximately 6 times the maximum recommended daily oral dose in adults, approximately 4 times the maximum recommended daily oral dose in children 6 to 11 years of age, on a mg/m<sup>2</sup> basis). No increased incidence of benign tumors was observed at a dietary dose of 4 mg/kg (approximately 2 times the maximum recommended daily oral dose in adults, equivalent to the maximum recommended daily oral dose in children 6 to 11 years of age on a mg/m<sup>2</sup> basis). The clinical significance of these findings during long-term use of levocetirizine dihydrochloride is not known.

Levocetirizine was not mutagenic in the Ames test, and not clastogenic in the human lymphocyte assay, the mouse lymphoma assay, and in vivo micronucleus test in mice.

In a fertility and general reproductive performance study in mice, cetirizine did not impair fertility at an oral dose of 64 mg/kg (approximately 25 times the recommended daily oral dose in adults on a mg/m<sup>2</sup> basis).

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## Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

## 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

### **IMDG - Not Regulated**

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



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IMDG Flash Point	:	N/A
IMDG Label	:	N/A
<b><u>DOT - Not Regulated</u></b>		
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
<b>Section 15: Regulatory Information</b>		
This Section Contains Information relevant to compliance with other Federal and/or state laws.		
<b>Section 16: Other Information</b>		
<b>Section 16, Other information</b>		
<p>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.</p> <p>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 MSDS.</p>		