



# 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

<b>Material</b>	<b>Nebivolol Tablets</b>
<b>Recommended use</b>	Beta blocker for hypertension
<b>Manufacturer</b>	<b>Hetero Labs Limited Unit III</b> 22-110, Industrial Development Area Jeedimetla, Hyderabad - 500 055
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854

### Section 2: Hazard(s) Identification

#### **Classification:**

#### **OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

#### **Precautionary statements**

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- P308 + P313 - IF exposed or concerned: Get medical advice/attention
- P405 - Store locked up
- P501 - Dispose of contents/ container to an approved waste disposal plant
- P280 - Wear protective gloves/protective clothing/eye protection/face protection

### Section 3: Composition/Information on Ingredients

<b>Ingredients</b>	Nebivolol
<b>CAS</b>	[152520-56-4] R-67555

### Section 4: First-Aid Measures

<b>Ingestion</b>	Consult a physician if necessary.
<b>Inhalation</b>	Remove to fresh air
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Eye Contact</b>	Rinse immediately with plenty of water and seek medical advice.



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## Section 5: Fire-Fighting Measures

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable Extinguishing Media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Fire may produce irritating, corrosive and/or toxic gases
<b>Explosion data</b>	
<b>Sensitivity to Mechanical Impact</b>	Not impact sensitive.
<b>Sensitivity to Static Discharge</b>	Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
<b>Protective equipment and precautions for firefighters</b>	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

<b>Personal precautions</b>	Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
<b>Environmental Precautions</b>	Take steps to avoid release into the environment, if safe to do so.
<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

## Section 7: Handling and Storage

<b>Storage</b>	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.
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## Section 8: Exposure Controls/Personal Protection

<b>Engineering Controls</b>	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. Ventilation rates should be matched to conditions. If applicable, use process enclosures,
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## Personal protection equipment Eye/face protection

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.

## Skin and body 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.

## Respiratory 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 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

### Physical Form

Tablet

### Description

Nebivolol tablets, 2.5 mg are light blue, triangular biconvex tablets debossed with 'J' on one side and '8' on other side.

Bottle of 30 tablets NDC 31722-585-30

Bottle of 100 tablets NDC 31722-585-01

Blister card of 10 Unit dose tablets (PVC/PVdC) NDC 31722-585-31

Blister pack of 120 (12 x 10) Unit dose tablets (PVC/PVdC) NDC 31722-585-32

Blister card of 10 Unit dose tablets (Alu-Alu) NDC 31722-585-33

Blister pack of 150 (15 x 10) Unit dose tablets (Alu-Alu) NDC 31722-585-34

Nebivolol tablets, 5 mg are light orange, triangular biconvex tablets debossed with 'J' on one side and '9' on other side.

Bottle of 30 tablets NDC 31722-586-30

Bottle of 90 tablets NDC 31722-586-90

Bottle of 100 tablets NDC 31722-586-01

Blister card of 10 Unit dose tablets (PVC/PVdC) NDC 31722-586-31

Blister pack of 100 (10 x 10) Unit dose tablets (PVC/PVdC) NDC 31722-586-32

Blister card of 7 Unit dose NDC 31722-586-33



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tablets (Alu-Alu)

Blister pack of 126 (18 x 7) NDC 31722-586-34

Unit dose tablets (Alu-Alu)

Nebivolol tablets, 10 mg are light pink, triangular shaped biconvex tablets debossed with 'J' on one side and '10' on other side.

Bottle of 30 tablets NDC 31722-587-30

Bottle of 90 tablets NDC 31722-587-90

Bottle of 100 tablets NDC 31722-587-01

Blister card of 10 Unit dose NDC 31722-587-31

tablets (PVC/PVdC)

Blister pack of 100 (10 x 10) NDC 31722-587-32

Unit dose tablets (PVC/PVdC)

Blister card of 7 Unit dose NDC 31722-587-33

tablets (Alu-Alu)

Blister pack of 126 (18 x 7) NDC 31722-587-34

Unit dose tablets (Alu-Alu)

Nebivolol tablets, 20 mg are light blue, triangular biconvex tablets debossed with 'J' on one side and '11' on other side.

Bottle of 30 tablets NDC 31722-588-30

Bottle of 90 tablets NDC 31722-588-90

Bottle of 100 tablets NDC 31722-588-01

Blister card of 10 Unit dose NDC 31722-588-31

tablets (PVC/PVdC)

Blister pack of 100 (10 x 10) NDC 31722-588-32

Unit dose tablets (PVC/PVdC)

Blister card of 7 Unit dose NDC 31722-588-33

tablets (Alu-Alu)

Blister pack of 126 (18 x 7) NDC 31722-588-34

Unit dose tablets (Alu-Alu)

## Section 10: Stability and Reactivity

<b>Reactivity</b>		Not defined As Reactive substance
<b>Stability</b>		Stable under normal conditions
<b>Possibility of Reactions</b>	<b>Hazardous</b>	None under normal processing.



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<b>Conditions to Avoid</b>	Aerosol formation.
<b>Incompatibility- Materials to Avoid</b>	None known based on information supplied.
<b>Hazardous products</b>	<b>Decomposition</b> None known based on information supplied.

## Section 11: Toxicological Information

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

Not mutagenic in the standard battery of tests

## Section 12: Ecological Information

<b>Toxicity</b>	Avoid release into the environment.
<b>Persistence and Degradability</b>	No data available.
<b>Bioaccumulative Potential</b>	No data available.
<b>Mobility in Soil</b>	No data available.
<b>Results of PBT and vPvB assessment:</b>	No data available.
<b>Other adverse effects</b>	No data available.

## Section 13: Disposal Considerations

<b>Waste treatment methods</b>	
<b>Disposal of wastes</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
<b>Contaminated packaging</b>	Do not reuse container. Dispose of contents/containers in accordance with local regulations.

## Section 14: Transport Information

DOT	Not regulated
TDG	Not regulated
ICAO (air)	Not regulated
IATA	Not regulated
IMDG	Not regulated
ADR	Not regulated
ADN	Not regulated

## Section 15: Regulatory Information

### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

### SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No



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## Section 16: Other Information

**Issue Date : 23-08-2021**

**Version : 00**

**Further information**

**Revision date: New issue**

**Revision note: New issue**

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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