



## SAFETY DATA SHEET

Section 1: Identification	
<b>Material</b>	Posaconazole Delayed-Release Tablets 100 mg
<b>Recommended use</b>	Pharmaceutical use
<b>Manufacturer</b>	Hetero Labs Limited, 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.
<b>Health</b>	<p>Posaconazole is contraindicated in persons with known hypersensitivity to posaconazole or other azole antifungal agents.</p> <p>Posaconazole is contraindicated with sirolimus. Concomitant administration of posaconazole with sirolimus increases the sirolimus blood concentrations by approximately 9-fold and can result in sirolimus toxicity.</p> <p>Posaconazole is contraindicated with CYP3A4 substrates that prolong the QT interval. Concomitant administration of posaconazole with the CYP3A4 substrates, pimozide and quinidine may result in increased plasma concentrations of these drugs, leading to QTc prolongation and cases of torsades de pointes.</p> <p>Coadministration with the HMG-CoA reductase inhibitors that are primarily metabolized through CYP3A4 (e.g., atorvastatin, lovastatin, and simvastatin) is contraindicated since increased plasma concentration of these drugs can lead to rhabdomyolysis</p> <p>Posaconazole may increase the plasma concentrations of ergot alkaloids (ergotamine and dihydroergotamine) which may lead to ergotism.</p>
Section 3: Composition/Information on Ingredients	
<b>Ingredients</b>	Posaconazole
<b>CAS</b>	171228-49-2
Section 4: First-Aid Measures	
<b>Ingestion</b>	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Inhalation</b>	Remove to fresh air, If not breathing, give artificial respiration. Get medical attention.
<b>Skin Contact</b>	Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists



<b>Eye Contact</b>	Immediately flush eyes with water for at least 1.5 minutes. If irritation occurs or persists, get medical attention.
<b>Section 5: Fire-Fighting Measures</b>	
<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion
<b>Extinguishing Media</b>	Water spray, carbon dioxide, dry chemical powder or appropriate foam
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
<b>Section 6: Accidental Release Measures</b>	
<b>Personal Precautions</b>	Wear suitable protective clothing, gloves and eye/face protection
<b>Environmental Precautions</b>	Avoid release to the environment.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal
<b>Section 7: Handling and Storage</b>	
<b>Handling:</b>	Minimize dust generation and accumulation, If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Skin, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin.
<b>Storage:</b>	Store at 20 to 25° C (68 to 77° F), excursions permitted to 15 to 30°C(59 to 86° F) [see USP Controlled Room Temperature].
<b>Section 8: Exposure Controls/Personal Protection</b>	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling	
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical Form</b>	Delayed Release Tablets
<b>Description</b>	Posaconazole delayed-release tablets are available as light orange, oblong shape, film-coated tablets debossed with 'H' on one side and 'P11' on the other side containing 100 mg of posaconazole.



Bottles with child-resistant closures of 60 delayed-release tablets (NDC 31722-677-60).

### Section 10: Stability and Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport

### Section 11: Toxicological Information

No drug-related neoplasms were recorded in rats or mice treated with posaconazole for 2 years at doses higher than the clinical dose. In a 2-year carcinogenicity study, rats were given posaconazole orally at doses up to 20 mg/kg (females), or 30 mg/kg (males). These doses are equivalent to 3.9- or 3.5-times the exposure achieved with a 400-mg BID oral suspension regimen, respectively, based on steady-state AUC in healthy volunteers administered a high-fat meal (400-mg BID oral suspension regimen). In the mouse study, mice were treated at oral doses up to 60 mg/kg/day or 4.8-times the exposure achieved with a 400-mg BID oral suspension regimen.

Posaconazole was not genotoxic or clastogenic when evaluated in bacterial mutagenicity (Ames), a chromosome aberration study in human peripheral blood lymphocytes, a Chinese hamster ovary cell mutagenicity study, and a mouse bone marrow micronucleus study.

Posaconazole had no effect on fertility of male rats at a dose up to 180 mg/kg (1.7 x the 400-mg BID oral suspension regimen based on steady-state plasma concentrations in healthy volunteers) or female rats at a dose up to 45 mg/kg (2.2 x the 400-mg BID oral suspension regimen).

### 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

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

**Issue Date: 19-01-2023**

**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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