



# 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>Section 1, Identification</b>	
<b>GHS Product identifier</b>	Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg
<b>Trade Name</b>	Not Applicable
<b>Other means of identification</b> <b>Synonyms</b>	Pregabalin Capsules, Finished Product
<b>Recommended use</b>	Pharmaceutical product for the treatment of Management of neuropathic pain associated with diabetic peripheral neuropathy.
<b>Manufacturer</b>	Hetero Labs Limited, Unit-III Plot No. 22-110, Part-II, IDA, Jeedimetla, Hyderabad 500055, Telangana, India (IND).
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ, 08854.
Section 2: Hazard(s) Identification	
<b>Section 2, Hazard(s)identification</b>	
<b>Classification of the Substance or Mixture</b>	
<b>GHS - Classification</b>	Reproductive Toxicity: Category 2
<b>Label Elements</b>	
<b>Signal Word</b>	Warning
<b>Hazard Statements</b>	H361d - Suspected of damaging the unborn child
<b>Precautionary Statements</b>	P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P308 + P313 - IF exposed or concerned: Get medical attention/advice P405 - Store locked up P501 - Dispose of contents/container in accordance with all local and national regulations
<b>Other Hazards</b>	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
<b>Note</b>	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.



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## Section 3: Composition/Information on Ingredients

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Hard gelatin capsules	Mixture	Not Listed	Not Listed	*
<b>Additional Information</b>	* Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.			
For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16				

## Section 4: First-Aid Measures

Description of First Aid Measures	
<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Most Important Symptoms and Effects, Both Acute and Delayed	
<b>Symptoms and Effects of Exposure</b>	For information on potential signs and symptoms of exposure, See Section 2-Hazards Identification and/or Section 11-Toxicological Information.
<b>Medical Conditions Aggravated by Exposure</b>	None known
Indication of the Immediate Medical Attention and Special Treatment Needed	
<b>Notes to Physician</b>	None

## Section 5: Fire-Fighting Measures

<b>Extinguishing Media</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Special Hazards Arising from the Substance or Mixture</b> <b>Hazardous Combustion Products</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire / Explosion Hazards</b>	Not applicable
<b>Advice for Fire-Fighters</b>	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## Section 6: Accidental Release Measures

Section 6, Accidental release measures	
<b>Personal precautions, protective equipment and emergency procedures</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Environmental Precautions</b>	Place waste in an appropriately labeled, sealed



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	container for disposal. Care should be taken to avoid environmental release.
<b>Methods and Material for Containment and Cleaning Up</b>	
<b>Measures for Cleaning / Collecting</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
<b>Section 7: Handling and Storage</b>	
<b>Section 7, Handling and storage</b>	
<b>Precautions for safe handling</b>	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use appropriate ventilation. Avoid generating airborne dust. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Conditions for safe storage, including any incompatibilities</b>	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Section 8, Exposure controls/personal protection</b>	
<b>Control Parameters</b>	
Refer to available public information for specific member state Occupational Exposure Limits	
<b>Exposure Controls Engineering Controls</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Personal Protective Equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.



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<b>Hands</b>	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent).
<b>Eyes</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent).
<b>Skin</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent).
<b>Respiratory protection</b>	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

## Section 9: Physical and Chemical Properties

### Section 9, Physical and chemical properties

<b>Physical State</b>	<b>Capsules</b>
<b>Colour</b>	<b>Various</b>
<b>Odor</b>	<b>Not Available</b>
<b>Description</b>	<b>Pregabalin Capsules, 25 mg</b> White cap / white body size '4' hard gelatin capsules imprinted with '138' on cap and 'J' on body with black ink, filled with white to off white powder. Bottle of 60 capsules NDC 68554-3110-0 Bottle of 90 capsules NDC 68554-3110-1 Bottle of 500 capsules NDC 68554-3110-2 Blister Pack of 100 (10x10) Unit-dose capsules (PVC-Alu) NDC 68554-3110-4 Blister Pack of 70 (10x7) Unit-dose capsules (Alu-Alu) NDC 68554-3110-6  <b>Pregabalin Capsules, 50 mg</b> White cap / white body size '4' hard gelatin capsules imprinted with '139' on cap and 'J' on body with black ink, filled with white to off white powder.



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Bottle of 60 capsules NDC 68554-3111-0

Bottle of 90 capsules NDC 68554-3111-1

Bottle of 500 capsules NDC 68554-3111-2

Blister Pack of 100 (10x10) Unit-dose capsules

(PVC-Alu) NDC 68554-3111-4

Blister Pack of 70 (10x7) Unit-dose capsules

(Alu-Alu) NDC 68554-3111-6

## **Pregabalin Capsules, 75 mg**

Light peach opaque cap / white opaque body size '4' hard gelatin capsules imprinted with '140' on cap and 'J' on body with black ink, filled with white to off white powder.

Bottle of 60 capsules NDC 68554-3112-0

Bottle of 90 capsules NDC 68554-3112-1

Bottle of 500 capsules NDC 68554-3112-2

Blister Pack of 100 (10x10) Unit-dose capsules

(PVC-Alu) NDC 68554-3112-4

## **Pregabalin Capsules, 100 mg**

Light peach opaque cap / light peach opaque body size '3' hard gelatin capsules imprinted with '141' on cap and 'J' on body with black ink, filled with white to off white powder.

Bottle of 60 capsules NDC 68554-3113-0

Bottle of 90 capsules NDC 68554-3113-1

Bottle of 500 capsules NDC 68554-3113-2

Blister Pack of 100 (10x10) Unit-dose capsules

(PVC-Alu) NDC 68554-3113-4

## **Pregabalin Capsules, 150 mg**

White cap / white body size '2' hard gelatin capsules imprinted with '142' on cap and 'J' on body with black ink, filled with white to off white powder.

Bottle of 60 capsules NDC 68554-3114-0

Bottle of 90 capsules NDC 68554-3114-1

Bottle of 500 capsules NDC 68554-3114-2

Blister Pack of 100 (10x10) Unit-dose capsules

(PVC-Alu) NDC 68554-3114-4



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## **Pregabalin Capsules, 200 mg**

Light peach opaque cap / light peach opaque body size '1' hard gelatin capsules imprinted with '143' on cap and 'J' on body with black ink, filled with white to off white powder.

Bottle of 60 capsules NDC 68554-3115-0

Bottle of 90 capsules NDC 68554-3115-1

Bottle of 500 capsules NDC 68554-3115-2

Blister Pack of 100 (10x10) Unit-dose capsules  
(PVC-Alu) NDC 68554-3115-4

## **Pregabalin Capsules, 225 mg**

Light peach opaque cap / white opaque body size '1' hard gelatin capsules imprinted with '144' on cap and 'J' on body with black ink, filled with white to off white powder..

Bottle of 60 capsules NDC 68554-3116-0

Bottle of 90 capsules NDC 68554-3116-1

Bottle of 500 capsules NDC 68554-3116-2

Blister Pack of 100 (10x10) Unit-dose capsules  
(PVC-Alu) NDC 68554-3116-4

## **Pregabalin Capsules, 300 mg**

Light peach opaque cap / white opaque body size '0' hard gelatin capsules imprinted with '145' on cap and 'J' on body with black ink, filled with white to off white powder.

Bottle of 60 capsules NDC 68554-3117-0

Bottle of 90 capsules NDC 68554-3117-1

Bottle of 500 capsules NDC 68554-3117-2

Blister Pack of 100 (10x10) Unit-dose capsules  
(PVC-Alu) NDC 68554-3117-4

Blister Pack of 70 (10x7) Unit-dose capsules  
(Alu-Alu) NDC 68554-3117-6



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## Section 10: Stability and Reactivity

Section 10, Stability and reactivity	
Reactivity	No data available
Chemical stability	Stable under normal conditions of use
Possibility of hazardous reactions	
Oxidizing Properties	No data available
Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	No data available

## Section 11: Toxicological Information

Information on toxicological effects	
General Information	The information included in this section describes the potential hazards of the individual ingredients.
Long Term	Animal studies indicate that this material may cause adverse effects on the fetus.
Known Clinical Effects	Adverse effects most commonly reported in clinical use include dizziness, blurred vision, weight gain, sleepiness (somnolence), inability to concentrate, swelling, dry mouth. Hypersensitivity reactions may also occur in susceptible individuals. Other less common effects include suicidal behavior.

### Acute Toxicity (Species, Route, End Point, Dose)

Species	Route	End Point	Dose
<b>Talc (non-asbestiform)</b>			
Rat	Oral	LD50	> 1600 mg/kg
<b>Pregabalin</b>			
Rat	IV	LD50	> 300 mg/kg
Mouse	Oral	LD50	> 5000 mg/kg
Rat	Oral	LD50	> 5000 mg/kg

Acute Toxicity Comments	A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.
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### Irritation / Sensitization: (Study Type, Species, Severity)

Study Type	Species	Severity
<b>Pregabalin</b>		
Skin Sensitization - LLNA	Rat	Negative
Skin Sensitization - Beuhler	Guinea Pig	Negative





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## Repeated Dose Toxicity

### Pregabalin

Duration	Species	Route	Dose	End Point	Target Organ
<b>Pregabalin</b>					
13 Week(s)	Rat	Oral	50 mg/kg/day	NOAEL	Central nervous system, Male reproductive system
4 Week(s)	Rat	Oral	500 mg/kg/day	LOAEL	Central nervous system, Male reproductive system
4 Week(s)	Monkey	Oral	100 mg/kg/day	NOAEL	Central Nervous System
52 Week(s)	Rat	Oral	50 mg/kg/day	LOAEL	Blood forming organs

## Reproduction & Developmental Toxicity

Study Type	Species	Route	Dose	End Point	Effect (s)
<b>Pregabalin</b>					
Peri /Postnatal Development	Rat	Oral	100 mg/kg/day	NOAEL	Developmental toxicity, Fertility
Fertility & Early Embryonic Development-Males	Rat	Oral	250 mg/kg/day	NOAEL	No effects at maximum dose
Fertility & Embryonic Development-Females	Rat	Oral	1250 mg/kg/day	NOAEL	Negative
Embryo / Fetal Development	Rat	Oral	500 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Oral	500 mg/kg/day	NOAEL	Not Teratogenic

## Genetic Toxicity

Study Type	Cell Type/Organism	Result
<b>Pregabalin</b>		
Bacterial Mutagenicity (Ames)	Bacteria	Negative
In Vivo Unscheduled DNA Synthesis	Rat	Negative
In Vivo Micronucleus	Mouse	Negative
In Vitro Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative

## Carcinogenicity

Duration	Species	Route	Dose	End Point	Effect (s)
<b>Pregabalin</b>					
104 Week(s)	Mouse	Oral	1000 mg/kg/day	NOAEL	Not carcinogenic
104 Week(s)	Rat	Oral	450 mg/kg/day	NOAEL	Not carcinogenic
104 Week(s)	Mouse	Oral	200 mg/kg/day	NOAEL	Malignant tumors





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<b>Carcinogen Status</b>	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
<b>Talc (non-asbestiform)</b>	
<b>IARC</b>	Group 3 (Not Classifiable)

## Section 12: Ecological Information

<b>Environmental Overview</b>		The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.			
<b>Toxicity</b>					
<b>Aquatic Toxicity</b>					
	<b>Species</b>	<b>Method</b>	<b>End Point</b>	<b>Duration</b>	<b>Result</b>
<b>Pregabalin</b>					
	Daphnia magna (Water Flea)	-	EC50	48 Hours	> 1000 mg/L
	Oncorhynchus mykiss (Rainbow Trout)	OECD	LC50	96 Hours	> 1000 mg/L
	Green algae	OECD	EbC50	72 Hours	> 300 mg/L
	Green Algae	OECD	ErC50	72 Hours	> 300 mg/L
<b>Aquatic Toxicity Comments</b>		A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.			
<b>Bacterial Inhibition</b>					
	<b>Inoculum</b>	<b>Method</b>	<b>End Point</b>	<b>Result</b>	
<b>Pregabalin</b>					
	Aspergillus niger (Fungus)	OECD	MIC	> 1000 mg/L	
	Trichoderma viride (Fungus)	OECD	MIC	> 1000 mg/L	
	Clostridium perfringens (Bacterium)	OECD	MIC	> 997 mg/L	
	Bacillus subtilis (Bacterium)	OECD	MIC	> 1000 mg/L	
	Nostoc sp. (Freshwater Cyanobacteria)	OECD	MIC	> 1000 mg/L	
<b>Persistence and degradability</b>			No data available		
<b>Bio-accumulative potential</b>					
<b>Partition coefficient</b>					
	<b>Method</b>	<b>pH</b>	<b>Endpoint</b>	<b>Value</b>	
<b>Pregabalin</b>					
	Predicted	7.4	Log D	-1.35	
<b>Mobility in Soil</b>			No data available		

## Section 13: Disposal Considerations

<b>Waste Treatment Methods</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This
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may include destructive techniques for waste and wastewater.

## Section 14: Transport Information

The following refers to all modes of transportation unless specified below:  
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## Section 15: Regulatory Information

### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

WHMIS hazard class: Class D, Division 2, Subdivision A

#### Hard gelatin capsules

CERCLA/SARA 313 Emission reporting : Not Listed

California Proposition 65 : Not Listed

EU EINECS/ELINCS List: Not Listed

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule V

## Section 16: Other Information, including date of preparation or last revision

### Text of CLP/GHS Classification abbreviations mentioned in Section 3

H361d - Suspected of damaging the unborn child

Issue Date: 18-10-2019

Version: 00

#### Revision note: New

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.

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.