



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	
GHS Product identifier	Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg
Trade Name	Not Applicable
Other means of identification Synonyms	Pregabalin Capsules, Finished Product
Recommended use	Pharmaceutical product for the treatment of Management of neuropathic pain associated with diabetic peripheral neuropathy.
Manufacturer	Hetero Labs Limited, Unit-III Plot No. 22-110, Part-II, IDA, Jeedimetla, Hyderabad 500055, Telangana, India (IND).
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ, 08854.
Section 2: Hazard(s) Identification	
Section 2, Hazard(s)identification	
Classification of the Substance or Mixture	
GHS - Classification	Reproductive Toxicity: Category 2
Label Elements	
Signal Word	Warning
Hazard Statements	H361d - Suspected of damaging the unborn child
Precautionary Statements	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
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
Note	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.



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

Section 3: Composition/ Information on Ingredients

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Hard gelatin capsules	Mixture	Not Listed	Not Listed	*
Additional Information	* 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	
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	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.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Most Important Symptoms and Effects, Both Acute and Delayed	
Symptoms and Effects of Exposure	For information on potential signs and symptoms of exposure, See Section 2-Hazards Identification and/or Section 11-Toxicological Information.
Medical Conditions Aggravated by Exposure	None known
Indication of the Immediate Medical Attention and Special Treatment Needed	
Notes to Physician	None

Section 5: Fire-Fighting Measures

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

Section 6: Accidental Release Measures

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



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

	container for disposal. Care should be taken to avoid environmental release.
Methods and Material for Containment and Cleaning Up	
Measures for Cleaning / Collecting	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.
Additional Consideration for Large Spills	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Section 7: Handling and Storage	
Section 7, Handling and storage	
Precautions for safe handling	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.
Conditions for safe storage, including any incompatibilities	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	
Control Parameters	
Refer to available public information for specific member state Occupational Exposure Limits	
Exposure Controls Engineering Controls	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.
Personal Protective Equipment	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.



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

Hands	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).
Eyes	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).
Skin	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).
Respiratory protection	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

Physical State	Capsules
Colour	Various
Odor	Not Available
Description	Pregabalin Capsules, 25 mg 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 31722-610-60 Bottle of 90 capsules NDC 31722-610-90 Bottle of 500 capsules NDC 31722-610-05 Blister Pack of 100 (10x10) Unit-dose capsules (PVC-Alu) NDC 31722-610-31 Blister Pack of 70 (10x7) Unit-dose capsules (Alu-Alu) NDC 31722-610-32 Pregabalin Capsules, 50 mg 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.



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>

Bottle of 60 capsules NDC 31722-611-60
Bottle of 90 capsules NDC 31722-611-90
Bottle of 500 capsules NDC 31722-611-05
Blister Pack of 100 (10x10) Unit-dose capsules
(PVC-Alu) NDC 31722-611-31
Blister Pack of 70 (10x7) Unit-dose capsules
(Alu-Alu) NDC 31722-611-32

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 31722-612-60
Bottle of 90 capsules NDC 31722-612-90
Bottle of 500 capsules NDC 31722-612-05
Blister Pack of 100 (10x10) Unit-dose capsules
(PVC-Alu) NDC 31722-612-31

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 31722-613-60
Bottle of 90 capsules NDC 31722-613-90
Bottle of 500 capsules NDC 31722-613-05
Blister Pack of 100 (10x10) Unit-dose capsules
(PVC-Alu) NDC 31722-613-31

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 31722-614-60
Bottle of 90 capsules NDC 31722-614-90
Bottle of 500 capsules NDC 31722-614-05
Blister Pack of 100 (10x10) Unit-dose capsules
(PVC-Alu) NDC 31722-614-31



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>

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 31722-615-60

Bottle of 90 capsules NDC 31722-615-90

Bottle of 500 capsules NDC 31722-615-05

Blister Pack of 100 (10x10) Unit-dose capsules
(PVC-Alu) NDC 31722-615-31

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 31722-616-60

Bottle of 90 capsules NDC 31722-616-90

Bottle of 500 capsules NDC 31722-616-05

Blister Pack of 100 (10x10) Unit-dose capsules
(PVC-Alu) NDC 31722-616-31

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 31722-617-60

Bottle of 90 capsules NDC 31722-617-90

Bottle of 500 capsules NDC 31722-617-05

Blister Pack of 100 (10x10) Unit-dose capsules
(PVC-Alu) NDC 31722-617-31

Blister Pack of 70 (10x7) Unit-dose capsules
(Alu-Alu) NDC 31722-617-32



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

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
Talc (non-asbestiform)			
Rat	Oral	LD50	> 1600 mg/kg
Pregabalin			
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.

Irritation / Sensitization: (Study Type, Species, Severity)

Study Type	Species	Severity
Pregabalin		
Skin Sensitization - LLNA	Rat	Negative
Skin Sensitization - Beuhler	Guinea Pig	Negative



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

Repeated Dose Toxicity

Pregabalin

Duration	Species	Route	Dose	End Point	Target Organ
Pregabalin					
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)
Pregabalin					
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
Pregabalin		
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)
Pregabalin					
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



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

Carcinogen Status		None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.		
Talc (non-asbestiform)				
IARC		Group 3 (Not Classifiable)		
Section 12: Ecological Information				
Environmental Overview		The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.		
Toxicity				
Aquatic Toxicity				
Species	Method	End Point	Duration	Result
Pregabalin				
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
Aquatic Toxicity Comments	A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.			
Bacterial Inhibition				
Inoculum	Method	End Point	Result	
Pregabalin				
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	
Persistence and degradability		No data available		
Bio-accumulative potential				
Partition coefficient				
Method	pH	Endpoint	Value	
Pregabalin				
Predicted	7.4	Log D	-1.35	
Mobility in Soil		No data available		
Section 13: Disposal Considerations				
Waste Treatment Methods		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		



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

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: 12-11-2020

Version: 01

Revision note:

NDC codes corrected.

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.