# SAFETY DATA SHEET

| Section 1: Identification | |
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| **Material**<br>**Recommended use** | Gabapentin Capsules USP 100 mg, 300 mg and 400 mg<br>Pharmaceutical product used as anticonvulsant. |
| **Manufacturer** | Hetero Labs Limited,<br>Plot No. 28P1 to 36P1 and 37 to 54,<br>Vemagal Industries Area, Hobli Vemagal Kolar - 563102,<br>Karnataka, India. |
| **Distributor** | **Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854 |
| **Section 2: Hazard(s) Identification** | |
| **Classified hazards** | Not classified as hazardous |
| **Label elements**<br>**Signal Word:**<br>**Hazard Statements:** | <br>Not classified<br>Not classified in accordance with international standards for workplace safety. |
| **Other Hazards** | An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8). |
| **Section 3: Composition/Information on Ingredients** | |
| **Ingredients** | **CAS** |
| Gabapentin | 60142-96-3 |
| Mannitol | 69-65-8 |
| Pregelatinised Starch | 9005-25-8 |
| Talc | 14807-96-6 |
| EHG capsule | NA |
| **Section 4: First-Aid Measures** | |
| **Inhalation** | Remove to fresh air and keep patient at rest. Seek medical attention immediately. |
| **Skin contact** | Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. |

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| **Eye contact** | Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. |
| **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. |
| **Most important symptoms and effects, both acute and delayed Symptoms** | For information on potential signs and symptoms of exposure, See Section 2 - Hazards |
| **Indication of any immediate medical attention and special treatment needed** | None |
| **Section 5: Fire-Fighting Measures** | |
| **Extinguishing media** | Extinguish fires with $CO_2$, extinguishing powder, foam, or water. |
| **Special Hazards Arising from the Substance or Mixture** | |
| **Hazardous Combustion Products:** | Formation of toxic gases is possible during heating or fire. |
| **Fire / Explosion Hazards:** | Fine particles (such as dust and mists) may fuel fires/ explosions. |
| **Advice for Fire-Fighters** | During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. |
| **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 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. Cleanup operations should only be undertaken by trained personnel. |

| Section 7: Handling and Storage | |
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| **Precautions for Safe Handling** | 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 (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** | |
| **Storage Conditions:** | Store as directed by product packaging. |
| **Specific end use(s):** | Pharmaceutical drug product |
| **Section 8: Exposure Controls/Personal Protection** | |
| **Control Parameters** | Refer to available public information for specific member state Occupational Exposure Limits. |
| **Exposure Controls**<br>**Engineering Controls:** | General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. 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. |
| **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.) |

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| **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

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| **Physical Form** | Capsule |
| **Description** | 100 mg capsules:<br>Hard Gelatin Capsule Shell Size "3" White Opaque cap and White Opaque body printed with "A" on Cap and "469" on body in black ink filled with White to Off-white powder; supplied in Bottles of 500: NDC 31722-148-05<br><br>300 mg capsules:<br>Hard Gelatin Capsule Shell Size "1" Yellow Opaque cap and Yellow Opaque body printed with "A" on Cap and "470" on body in black ink filled with White to Off-white powder; supplied in Bottles of 500: NDC 31722-149-05<br><br>400 mg capsules:<br>Hard Gelatin Capsule Shell Size "0" Orange Opaque cap and Orange Opaque body printed with "A" on Cap and "471" on body in black ink filled with White to Off-white powder; supplied in Bottles of 500: NDC 31722-150-05<br><br>Store gabapentin capsules at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. |

| Section 10: Stability and Reactivity | |
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| **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. |
| **Short Term:** | Dust may cause irritation (based on components) . The active ingredient is not acutely toxic. |
| **Known Clinical Effects:** | Adverse effects associated with therapeutic use include dizziness, tiredness, swelling, and nausea. |
| **Acute Toxicity: (Species, Route, End Point, Dose)** | |
| **Gabapentin**<br>Mouse Oral LD50 > 5000 mg/kg<br>Rat Oral LD50 > 5000mg/kg<br>Rat IV LD50 > 2000mg/kg<br>Mouse IV LD50 1000-2000mg/kg<br>Rat Subcutaneous LD50 > 4000mg/kg<br>**Talc (non-asbestiform)**<br>Rat Oral LD50 > 1600 mg/kg<br>**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)** | |
| **Gabapentin**<br>Eye Irritation Rabbit Non-irritating | |

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Gabapentin**

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| 52 Week(s) | Rat | Oral 250 mg/kg/day | NOAEL | Liver, Kidney |
| 52 Week(s) | Monkey | Oral 250 mg/kg/day | NOAEL | None identified |
| 13 Week(s) | Mouse | Oral 1000 mg/kg/day | NOAEL | No effects at maximum dose |

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Gabapentin**

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| Reproductive & Fertility | Rat | Oral 500 mg/kg/day | NOAEL | Negative |
| Embryo / Fetal Development | Mouse | Oral 3000 mg/kg/day | NOAEL | No effects at maximum dose |
| Embryo / Fetal Development | Rat | Oral 300 mg/kg/day | NOAEL | Developmental toxicity, Not Teratogenic |
| Embryo / Fetal Development | Rabbit | Oral 1500 mg/kg/day | NOAEL | Not Teratogenic, Maternal Toxicity |
| Peri-/Postnatal Development | Rat | Oral 500 mg/kg/day | NOAEL | Negative |

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Gabapentin**

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| Bacterial Mutagenicity (Ames) | Salmonella , E. coli | Negative |
| *In Vitro* Chromosome Aberration | Hamster Lung Cells | Negative |
| *In Vivo* Unscheduled DNA Synthesis | Rat Hepatocyte | Negative |
| *In Vivo* Chromosome Aberration | Hamster Bone Marrow | Negative |

**Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Gabapentin**

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| 2 Year(s) | Mouse | Oral, in feed 2000 mg/kg/day | NOEL | Not carcinogenic |
| 2 Year(s) | Male Rat | Oral, in feed 1000 mg/kg/day | NOEL | Malignant tumors, Pancreas |

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

**Talc (non-asbestiform)**

IARC: Group 3 (Not Classifiable)

## Section 12: Ecological Information

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| **Environmental Overview:** | The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. |
| **Toxicity:** | No data available |
| **Persistence and Degradability:** | No data available |
| **Mobility in Soil:** | No data available |

## Section 13: Disposal Considerations

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| **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 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**

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| **Gabapentin** | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 |
| EU EINECS/ELINCS List | 262-076-3 |
| **Hard gelatin capsules** | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |
| **Starch** | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 232-679-6 |
| **Talc (non-asbestiform)** | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 238-877-9 |

## Section 16: Other Information

**Issue Date : 12-06-2024**

**Version : 00**

**Further information**

**Revision date: New issue**

**Revision note: New issue**

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