

## SAFETY DATA SHEET

### Gabapentin Capsules, USP

#### 1. IDENTIFICATION

**Manufacturer:**

InvaGen Pharmaceuticals Inc.  
7, Oser Avenue  
Hauppauge, NY 11788

**Emergency Phone:**

1-631-231-3233

**Common Name:** Gabapentin Capsules

**Chemical Family:** Cyclohexane-acetic acid derivative

**Synonym(s):** Not Applicable

**Chemical Name:** 2-[1-(amino methyl) cyclohexyl] acetic acid

**Trade Name(s):** Gabapentin Capsules, USP 100 mg, 300 mg and 400 mg.

**Therapeutic Category:** Used to relieve pain, especially neuropathic pain,  
Anticonvulsant.

**Molecular formula:** C<sub>9</sub>H<sub>17</sub>NO<sub>2</sub> **Molecular Weight:** 171.24

#### 2. HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

#### EMERGENCY OVERVIEW

**Caution Statement:** Each Gabapentin Capsules intended for oral administration contains Gabapentin, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

**Routes of Entry:** Oral

**Effects of Overexposure:** Filled Capsules are intended for human consumption under guidance of a physician. Intact Capsules are not considered hazardous under normal handling procedures.

**Medical conditions Aggravated by Long Term Exposure:** Active alcoholism, Diabetes, Impaired kidney function.

**Carcinogenicity:** Gabapentin - Not listed by IARC, NTP and OSHA.

### 3.COMPOSITION / INFORMATION ON INGREDIENTS

<u><b>Ingredient</b></u>	<u><b>CAS #</b></u>	<u><b>Concentration %</b></u>		
		<b>100 mg</b>	<b>300 mg</b>	<b>400 mg</b>
Gabapentin, USP	60142-96-3	≈80 %	≈80 %	≈80 %
Excipients	NA	≈20 %	≈20 %	≈20 %

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

\* All Concentrations are percent by weight.

### 4. FIRST AID MEASURES

**Inhalation:** Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

**Skin Contact:** Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

**Eye Contact:** Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

#### **Notes to the Physician:**

The precise mechanisms by which gabapentin produces its analgesic and antiepileptic actions are unknown.

Gabapentin exhibits antiseizure activity in mice and rats in both the maximal electroshock and pentylenetetrazole seizure models and other preclinical models (e.g., strains with genetic epilepsy, etc.). The relevance of these models to human epilepsy is not known.

#### **Overdose Treatment:**

A lethal dose of gabapentin was not identified in mice and rats receiving single oral doses as high as 8000 mg/kg. Signs of acute toxicity in animals included ataxia, labored breathing, ptosis, sedation, hypoactivity, or excitation.

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Acute oral overdoses of gabapentin up to 49 grams have been reported. In these cases, double vision, slurred speech, drowsiness, lethargy and diarrhea, were observed. All patients recovered with supportive care.

Gabapentin can be removed by hemodialysis. Although hemodialysis has not been performed in the few overdose cases reported, it may be indicated by the patient's clinical state or in patients with significant renal impairment.

## **5.FIRE-FIGHTING MEASURES**

**Extinguishing Media:** Water spray, CO<sub>2</sub>, dry chemical or alcohol resistant foam.

**Unusual Fire & Explosion Hazards:** Emits toxic fumes under fire conditions.

**Special Fire Fighting Procedures:** Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

**Protective Measures:** Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

## **6.ACCIDENTAL RELEASE MEASURES**

**Personal precautions:** Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

**Environmental precautions:** Do not release in to the environment.

**Spill Cleanup methods:** Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

## **7.HANDLING AND STORAGE**

**Handling:** Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

**Storage:** Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

## **8.EXPOSURE CONTROLS / PERSONAL PROTECTION**

Filled Capsules are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

**Protective Measures:** Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

**Respiratory Protection:** Use a NIOSH approved respirator or an alternate approved dust mask should be used.

**Hand Protection:** Chemical resistant gloves.

**Eye Protection:** Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and Body Protection:** Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene Measures:** Wash skin thoroughly with soap and water.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Physical Properties:

**Physical State:** Solid

**Form:** Capsules

### Appearance:

<b>100 mg Capsules</b>	Hard Gelatin Capsules Size “3” with White Opaque Cap and White Opaque body imprinted with <b>100 mg</b> and <b>IG321</b> filled with white to Off-white powder.
<b>200 mg Capsules</b>	Hard Gelatin Capsules Size “1” with Yellow Opaque Cap and Yellow Opaque body imprinted with <b>300 mg</b> and <b>IG322</b> filled with white to Off-white powder.
<b>300 mg Capsules</b>	Hard Gelatin Capsules Size “0” Orange Opaque Cap and Orange Opaque body imprinted with <b>400 mg</b> and <b>IG323</b> filled with white to Off-white powder.

## 10. STABILITY AND REACTIVITY

**Possibility of hazardous reactions:** Stable under ordinary conditions of use and storage.

**Conditions to avoid:** Excessive heat & Moisture.

**Incompatible materials:** Strong oxidizers, Strong Bases and Strong Acids.

**Hazardous Decomposition products:** Thermal decomposition or combustion may liberate irritating gases or vapors.

## **11. TOXICOLOGICAL INFORMATION**

**General information:** The information presented below pertains to the individual ingredients (Gabapentin, USP), and not to the mixture(s) or final formulations.

**Inhalation:** No data available.

**Ingestion:** No data available.

**Skin Corrosion/ irritation:** No data available.

**Serious eye damage/eye irritation:** No data available.

**Respiratory sensitizer/Skin sensitizer:** No data available.

### **Carcinogenesis:**

Gabapentin was administered orally to mice and rats in 2-year carcinogenicity studies. No evidence of drug-related carcinogenicity was observed in mice treated at doses up to 2000 mg/kg/day. At 2000 mg/kg, the plasma gabapentin exposure (AUC) in mice is approximately 2 times that in humans at the MRHD of 3600 mg/day. In rats, increases in the incidence of pancreatic acinar cell adenoma and carcinoma were found in male rats receiving the highest dose (2000 mg/kg), but not at doses of 250 or 1000 mg/kg/day. At 1000 mg/kg, the plasma gabapentin exposure (AUC) in rats is approximately 5 times that in humans at the MRHD.

### **Mutagenesis:**

Gabapentin did not demonstrate mutagenic or genotoxic potential in three in vitro and four in vivo assays. It was negative in the Ames test and the in vitro HGPRT forward mutation assay in Chinese hamster lung cells; it did not produce significant increases in chromosomal aberrations in the in vitro Chinese hamster lung cell assay; it was negative in the in vivo chromosomal aberration assay and in the in vivo micronucleus test in Chinese hamster bone marrow; it was negative in the in vivo mouse micronucleus assay; and it did not induce unscheduled DNA synthesis in hepatocytes from rats given gabapentin.

### **Impairment of Fertility:**

No adverse effects on fertility or reproduction were observed in rats at doses up to 2000 mg/kg. At 2000 mg/kg, the plasma gabapentin exposure (AUC) in rats is approximately 8 times that in humans at the MRHD.

**Other information:**

The adverse reactions have been identified during post marketing use of gabapentin is Fever, jaundice, blood glucose fluctuation, elevated creatine kinase, elevated liver function tests, hyponatremia, movement disorder, rhabdomyolysis, breast enlargement, angioedema, erythema multiforme, Stevens-Johnson syndrome.

Adverse reactions following the abrupt discontinuation of gabapentin have also been reported. The most frequently reported reactions were anxiety, insomnia, nausea, pain, and sweating.

**12.ECOLOGICAL INFORMATION**

**General information:** The information presented below pertains to the individual ingredients (Gabapentin, USP), and not to the mixture(s) or final formulations.

**Ecotoxicity Effects:**

**Acute toxicity to Fish:** No data available.

**Acute toxicity to Aquatic Invertebrates:** No data available.

**Toxicity to Aquatic Plants:** No data available.

**Bioaccumulation:** No data available.

**Mobility:** No data available.

**13.DISPOSAL CONSIDERATIONS**

**Waste Disposal:** Dispose of waste must be in accordance with all applicable Federal, State and local laws.

**Measures for Avoidance and Recovery:** Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

**14.TRANSPORT INFORMATION**

**DOT:** Not Regulated

**IMDG:** Not regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

**15.REGULATORY INFORMATION**

Stated regulatory information chosen primarily for possible usage of InvaGen Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**CERLA Hazardous Substance List (40 CFR 302.4):** None

**TSCA :** None

**SARA Title III**

**Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):** None

**Section 313 Toxic Release Inventory (40 CFR 372):** None

<b>16.OTHER INFORMATION</b>
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**SDS Sections Revised:**

Revision 01: Sections 1 to 16 contain revisions to comply with 29 CFR 1910.1200(g) and Appendix D.

**GLOSSARY:**

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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