

SAFETY DATA SHEET

Carbamazepine Tablets, USP 100 mg and 200 mg

Section 1 Identification of the Substance / Preparation and Company Undertaking

Product Name: Carbamazepine Tablets, USP 100 mg and 200 mg

Product Information: Carbamazepine Tablets, USP

Therapeutic Category: Anticonvulsant, Analgesic, For Symptomatic Relief of Trigeminal Neuralgia

Company Name: Nivagen Pharmaceuticals, Inc.

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Section 2 Hazards Identification

Classification of the substance or mixture : Carcinogenicity - category 2
Toxic to reproduction (fertility or the unborn child) - Category 1B
Specific target organ toxicity (repeated exposure) - Category 2

GHS label elements

Hazard pictograms



Signal word : Danger

Hazard statements : H360 - May damage fertility or the unborn child.
H351 - Suspected of causing cancer.
H373 - May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

General : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.
Use personal protective equipment as required. Do not breathe dust.

Response : Get medical attention if you feel unwell. If exposed or concerned: Get medical attention.

Storage : Store locked up.

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise : None known.

SAFETY DATA SHEET**Carbamazepine Tablets, USP 100 mg and 200 mg**

classified

Section 3 Composition / Information on Ingredients**Active Pharmaceutical Ingredient:** Carbamazepine (CAS No.:298-46-4)**Chemical Family:** Tricyclic iminostilbene derivative**Chemical Name:** 5*H*-dibenz[*b,f*]azepine-5-carboxamide**Product Code:** Not applicable**Hazardous Ingredients / Components:** Not Applicable**Other Components:**

Inactive Ingredients	CAS No.
Pregelatinized maize starch	9005258
croscarmellose sodium	74811657
colloidal silicon dioxide	7631-86-9
magnesium stearate	557040
FD & C red 40	25956176

Section 4 First-aid Measures

Eye contact: Flush with copious quantities of water. If irritation persists, obtain medical advice.

Skin Contact: Flush with copious amounts of water. Seek medical attention if irritation persist.

Inhalation: Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.

Ingestion: Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.

Section 5 Fire-fighting measures

Special Properties Related to Fire Hazard: This product is assumed to be combustible. Emits toxic fumes under fire conditions

Specific hazard arising from the chemical: During fire, gases hazardous to health may be

SAFETY DATA SHEET**Carbamazepine Tablets, USP 100 mg and 200 mg**

formed.

Suitable extinguishing media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Special protective equipment for firefighters: Special firefighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6 Accidental Release Measures

Methods and materials for containment and cleaning up: Cordon off spill area as needed. Assess hazard levels (contact Safety Department if required). Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols.

Protective equipment and personal precautions: Personnel involved in clean up should wear appropriate personal protective equipment (refer to section 8) to avoid exposure.

Section 7 Handling and Storage

Precautions for safe handling: Handle in an environment with adequate ventilation. In case of insufficient ventilation, wear suitable respiratory protection. Avoid inhalation, skin and eye contact. Wash hands thoroughly after handling.

Precautions to Be Taken in Storing: Container should be tightly closed and light resistant.

Storage: 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not store Carbamazepine Tablets above 30°C (86°F). Protect from moisture.

Section 8 Exposure Controls / Personal Protection

Engineering Controls: Airborne exposure to this material should be mitigated using engineering controls such as mechanical ventilation, dilution and process enclosure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Local exhaust ventilation (e.g. fume hoods or other vented enclosures) is recommended, particularly for crushing, grinding or other activities prone to generating dust or aerosols.

SAFETY DATA SHEET

Carbamazepine Tablets, USP 100 mg and 200 mg

Personal protection equipment:

- **Skin:** Covering uniform.
- **Respiratory:** Where respiratory protection has been deemed necessary use an approved air purifying respirator with appropriate cartridges. Contact your local safety professional for specific requirements. Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding, breakage, generation of aerosols or for spill cleaning, an approved respirator may be required. Contact your local safety professional for specific requirements.
- **Hand:** Nitrile or other chemically compatible gloves.
- **Eye:** Safety glasses
- **Other Protective Clothing:** Wear appropriate PPE according to dust level.

Occupational exposure limits: Not available

Section 9 Physical and chemical properties
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Carbamazepine Tablets, USP 100 mg

Pink Colored, round flat beveled edge, uncoated single scored tablet debossed with 'CAR' on one side and '100' on the scored side and other side plain, free from physical defects.

Carbamazepine Tablets, USP 200 mg

Pink colored, capsule-shaped biconvex, uncoated tablet, debossed 'CAR' on one side and '200' on the partially scored side, free from physical defects.

Odour	Odorless
pH	Not available
Melting Point	Not available
Boiling Point	Not available
Volatility	Not available
Flash Point	Not available
Evaporation Rate	Not available
Flammability	Emits toxic fumes under fire condition

SAFETY DATA SHEET

Carbamazepine Tablets, USP 100 mg and 200 mg

Explosive Limits	Not available
Vapor Density (vs. Air=1)	Not available
Specific Gravity (Water=1)	Not available
Solubility in Water	Insoluble
Octanol /Water Partition Coefficient	Not available
Auto-ignition Point	Not available
Decomposition Temperature	Not available
Viscosity	Not available
Other Information:	Carbamazepine USP is a white to off-white powder, practically insoluble in water and soluble in alcohol and in acetone
Molecular formula (API):	C ₁₅ H ₁₂ N ₂ O
Molecular weight (API):	236.27 g/mol

Section 10 Stability and Reactivity

Reactivity: Not available

Chemical Stability: This material is considering stable from a safety point of view.

Possibility of hazardous reactions: Not available

Hazardous decomposition products: When heated to decomposition material emits toxic fumes.

Incompatible materials: Not Available

Conditions to avoid: Protect from moisture

Section 11 Toxicology Information:

Toxicological Data: Carbamazepine: LD50: 1957 mg/kg (oral-rat), LD50: 529 mg/kg (oral-mouse), LD50: 2680 mg/kg (dermal-rabbit), LC50: >2160 mg/m³ (inhalation-rat), Irritancy data: rabbit/eye: mild; rabbit/skin: non-irritant.

Delayed and immediate effects and also chronic effects from short and long term exposure:

Carcinogenicity: Not listed as a carcinogenic by NTP, IARC, OSHA. A dose-related increase in hepatocellular tumors and benign interstitial cell adenomas in the testes were reported in studies of Sprague Dawley female and male rats, respectively, administered carbamazepine for 2 years.

SAFETY DATA SHEET

Carbamazepine Tablets, USP 100 mg and 200 mg

Teratogenicity/Reproductive Toxicity: Pregnancy category: D. Craniofacial defects, fingernail hypoplasia, and developmental delays were found in a series of 35 patients whose mothers took only carbamazepine. Human and animal studies indicate that carbamazepine and its epoxide metabolite are found and excreted in breast milk and may affect the nursing child.

Mutagenicity: No mutagenic activity was noted with carbamazepine in bacterial and mammalian mutagenicity studies.

Symptoms related to the physical, chemical and toxicological characteristics: Adverse effects may include: hypersensitivity reactions, dystonic reactions, rashes, exacerbation and development of cardiac dysrhythmias, cytopenias, transaminitis, pancreatitis, and the manifestations of mild toxicity with chronic therapy.

Section 12 Ecological Information

Ecotoxicity: Carbamazepine: EC50 (Daphnia): 92 mg/l 24 hours, LC50 (Zebra danio (Danio rerio)): 43 mg/l 96 hours

Persistence and degradability: Not available

Bioaccumulative potential: Not available

Mobility in soil: Not available

Other adverse effects: Not available

Section 13 Disposal considerations

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14 Transport Information

Regulatory Information	UN Number	Proper Shipping Name	Class	Packing	Additional Information
TGD/U.S.			Not regulated		
ICAO/IATA			Not regulated		
IMDG Class			Not regulated		



SAFETY DATA SHEET

Carbamazepine Tablets, USP 100 mg and 200 mg

Section 15 Regulatory Information

Generic Medicine. Approved by USFDA

The ANDA Number is 207798 (**ANDA Holder:** Umedica Laboratories Private Ltd)

Section 16 Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

Nivagen Pharmaceuticals, Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.

Nivagen Pharmaceuticals, Inc. reserves the right to revise this SDS.

Date of Issue: 05/01/2020

Supersedes: N/A