

SAFETY DATA SHEET

Lomustine Capsules USP, 10 mg, 40 mg, and 100 mg
Version: 01

Issue Date: 10/29/2025

1. PRODUCT AND COMPANY IDENTIFICATION

A. Product Information

- **Product Name:** Lomustine Capsules USP, 10 mg, 40 mg, and 100 mg
- **Version:** 01; 10/29/2025
- **Active Substance:** Lomustine
- **Intended Uses:** This material is a finished drug product for patient use. It is used in the treatment of cancer

B. Company Identification

- **Address:** Carnegie Pharmaceuticals LLC
600 Delran Pkwy, Delran, New Jersey, 08075, USA
Emergency: +1 (732) 783-7011 or 1-800-FDA-1088 or call 911
Information: +1 (732) 783-7011

2. HAZARDS IDENTIFICATION

- **Classification:** Acute Toxicity - Oral - Category 4
Germ Cell Mutagenicity - Category 1B
Carcinogenicity - Category 1B
Toxic To Reproduction - Reproductive Toxicity - Category 1B
Toxic To Reproduction - Developmental Toxicity - Category 1B
Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1

- **Symbol:**



- **Signal Word:** Danger
- **Hazard Statements:** Harmful if swallowed.
May cause genetic defects.
May cause cancer.
May damage fertility (male reproductive toxicity, female reproductive toxicity).
May damage the unborn child (developmental toxicity).
Causes damage to organs (bone marrow, lungs, kidney, male reproductive organs, liver) through prolonged or repeated exposure.
- **Precautionary Statements:** Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS- No.
Lomustine	13010-47-4

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Mannitol	69-65-8
Magnesium Stearate	557-04-0
Gelatin	9000-70-8

4. FIRST AID MEASURES

- **Eye contact:** Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.
- **Skin contact:** Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
- **Inhalation:** Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.
- **Ingestion:** IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.
- **Notes to Physician:** This product has been reported to interact with the following medications: certain vaccines, cytotoxic and cytostatic medicines. Refer to Section 11.
- **Medical Surveillance:** The need for a pre-placement physical examination and history for employees with potential exposure to this compound is to be evaluated by a physician that is thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. Baseline testing would include: a complete blood count with differential, a blood test for kidney function, a blood test for liver function, a urine analysis. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. It is recommended that the content be similar to the pre-placement exam.

Employees who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

5. FIRE-FIGHTING MEASURES

- **Flammable Properties:** Not Available
- **Extinguishing Media Suitable extinguishing media:** Dry chemical, Water spray, Foam
Unsuitable extinguishing media: Do NOT use water jet.
- **Protection of Specific hazards:** Toxic Irritant Mutagen Developmental toxicant
Firefighters Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.
Hazardous Combustion Products: carbon oxides (CO_x), nitrogen oxides (NO_x), gaseous hydrogen chloride (HCl).
Further Information: HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes.
- **Other information:** Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES

- **Personal precautions:** Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill

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(quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.

- **Environmental precautions:** Prevent release to drains and waterways. Prevent release to the environment
- **Containment Methods:** Wet down any dust to prevent generation of aerosols, if appropriate. Cover with suitable material. Cleanup Methods Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

7. HANDLING AND STORAGE

- **Handling Precautions:** Highly potent material. Avoid exposure - obtain special instructions before use. Avoid formation of dust and aerosols. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
- **Storage Conditions:** Store at room temperature. Protect against light. Keep away from heat, sparks and flames. Store locked up.
- **Container Requirements:** Store in the original primary packaging as provided. Keep tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

• Component Exposure Limit(s)

	Company Guideline	ACGIH	OSHA	NIOSH
Lomustine				
Titanium Dioxide		10 mg/m ³ TWA		5,000 mg/m ³ IDLH
Magnesium Stearate		10 mg/m ³ 8 hourTW		
Yellow Iron Oxide				

- **Exposure Control Band:** Lomustine- 5sc -- Material is assigned to Exposure Control Band 5, Special Case (range < 0.1 µg/m³).
- **Exposure Guidelines Summary:** Lomustine- A specific exposure guideline has not yet been established. Materials require particular care and handling.
- **Recommended Industrial Hygiene Monitoring Methods:** A specific exposure sampling method is not available. General - The health hazard risk of handling this material is dependent on many factors, including physical form, % API in material being handled, duration and frequency of process task, and effectiveness of controls. If it is necessary to handle this compound outside of engineering controls, an exposure risk assessment should be conducted and procedures documented by a qualified EHS professional. Engineering Controls and Ventilation: FOR MANUFACTURING PROCESSES (BULK): Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities from 0-5 grams work in a designated laboratory or containment facility using a fume hood, biological safety cabinet (Class II, Type B1, or B2) ; glove box; and, approved vented enclosure. HEPA filtered exhaust with Bag-In/Bag-Out capacity preferred for hoods, BSCs and glove boxes. Quantities exceeding 5 grams should be handled in a containment facility using appropriate containment isolation technology with isolator/glove box systems, glove bags, double/split butterfly valves,

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remote operations, direct process connections and systems, or automated systems. For manufacturing and pilot plant operations, the containment level should be to keep exposures as low as reasonable achievable. Barrier/containment technology with isolator/glove bags, remote operations, direct process connections and systems, or automated systems should be used. Isolated work areas are required with rooms to provide thorough secondary containment. FOR CLINICAL SETTING USE (DRUG PRODUCT): When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed.

- **Respiratory Protection:** Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges (EN 140/EN 136) when exposures are up to 10 times the exposure control guideline. Wear a loose fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) (EN 12941) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters (EN 136) when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR (EN 12942) when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR (EN 12941) or full facepiece supplied air respirator (EN 139) operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.
- **Eye protection:** Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected
- **Hand protection:** Wear double gloves (EN 420, EN 374). Wear gloves at all times when handling containers, including when unpacking, inspecting or transporting within a facility. Disposable chemotherapy gloves made from nitrile, neoprene, polyurethane and natural latex have been shown to have low permeability to many chemotherapy agents. Persons who are allergic to natural rubber latex should select gloves made from one of the other materials. Check gloves frequently to ensure that there are no small cuts or holes. Change gloves frequently, and remove immediately after overt contamination. Use care when removing and disposing of gloves in order to minimize exposure. If material is handled in solution, the solvent should also be considered when selecting protective clothing material.
- **Skin and body protection:** FOR MANUFACTURING PROCESSES (BULK): For quantities, up to 5 grams: wear disposable labcoat or coverall of low permeability (EN 1149-1); disposable wrist gauntlets/sleeves unless working in glove box. For quantities > 5 grams: wear full disposable coverall of low permeability (EN 1149-1); shoe covers; disposable wrist gauntlets/sleeves unless working in glove box. For manufacturing operations, gloves and booties should be taped to protective clothing to prevent gaps in PPE and air supplied full-body suits (EN 1073) may be required as associated with advanced respiratory protection. FOR CLINICAL SETTING USE (DRUG PRODUCT): When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed
- **Hygiene:** Wash hands and face before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**

Physical State	Solid
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Color	White White/ Green White/ Green Green
Form	Capsule

• **Other Information**

Molecular Weight	Not Applicable
Molecular Formula	Not Applicable
Bulk Density	Not Applicable
Evaporation rate	Not Applicable
Hydrolysis/Photolysis	Not Applicable
Hygroscopicity	Not Applicable
Log Octanol/Water Partition Coefficient [log Kow]	Not Applicable
Surface Tension	Not Applicable
Odor	Not Applicable
Odor Threshold	Not Applicable
pH	Not Applicable
pKa	Not Applicable
Particle Size	Not Applicable
Solubility, Water	Not Applicable
Specific Gravity/ Relative density	Not Applicable
Viscosity	Not Applicable

• **Thermal/Stability properties**

Autoignition temperature	Not Applicable
Boiling Point	Not Applicable
Thermal decomposition	Not Applicable
Explosive Limits, LEL	Not Applicable

• **Explosive limits, UEL**

Explosiveness	Not Applicable
Flammability	Not Applicable
Flash Point	Not Applicable
Melting Point	Not Applicable
Oxidizing Potential	Not Applicable

• **Vapor Properties**

Vapor Density	Not Applicable
Vapor Pressure	Not Applicable
Saturated Vapor Concentration	Not Applicable

10. STABILITY AND REACTIVITY

A. Stability

- **Chemical Stability:** Stable under normal conditions. It is an alkylating agent.
- Conditions to avoid: Excessive Heat
- Incompatible Products: Not Available

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- **Hazardous Decomposition Products:** Hazardous decomposition products formed under fire conditions may include: carbon oxides (COx), nitrogen oxides (NOx), gaseous hydrogen chloride (HCl).
 - **Hazardous Reactions:** None Known.
- B. Sensitivity to static discharge/Dust exp.**
- **Summary Statements:** Although material has not been specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. Provide appropriate bonding and grounding protection to control static charge. Powder handling equipment such as dust collectors, dryers, and mills may require additional protective measures (e.g. explosion venting, inerting, etc.).

11. TOXICOLOGICAL INFORMATION

Routes of Entry: Ingestion, inhalation, Eye contact, Skin contact

Route of Entry		Lomustine	Titanium Dioxide
Eye Irritation		Mildly and/or transiently irritating to eyes	Mildly and/or transiently irritating to eyes
Skin Irritation		Mildly and/or transiently irritating to eyes	Mildly and/or transiently irritating to eyes
Respiratory Irritation		May cause irritation of respiratory tract	Irritating to respiratory tract
Sensitization		See Human Experience	Not a dermal sensitizer
Acute Toxicity Study	Acute Oral	LD50 (rat, males and females): 72 mg/kg LD50 (mouse, females): 38 mg/kg	LD50 (rat): > 10,000 mg/kg
	Acute Dermal		LD50 (rat): > 10,000 mg/kg
	Acute inhalation		LC50 (rat): > 2.29 mg/l/4 H
	Acute toxicity (other routes of administration)	LD50 (rat, intraperitoneal): 50 mg/kg LD50 (mouse, intraperitoneal): 53 mg/kg	
Repeated Dose Toxicity		See "Human Experience". See Section 11 Target Organs and Symptoms for a description of effects.	Several studies were conducted. See "Human Experience"
Genetic Toxicity		Mutagenicity Assessment This material was positive in a battery of in vivo and in vitro genotoxicity assays.	Mutagenicity Assessment This material was negative in a battery of in vivo and in vitro genotoxicity assays.
Carcinogenicity		This material was a carcinogen in animal studies. Some secondary cancers developed in persons with other cancers who were treated with this drug, either alone or in	Tumors were observed at high dose in animal studies by inhalation and intratracheal administration. Tumors were not observed by other routes

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	combination with other anticancer drugs. It is not known whether these were a result of the treatment with this drug, with one of the other drugs, or a result of progression of the underlying disease. This material is probably carcinogenic to humans NTP: Listed IARC: 2A	ACGIH: A4 IARC: 2B
Reproductive Toxicity	Compound may cause injury to male reproductive organs	
Developmental Toxicity	Several developmental studies were conducted. Birth defects were observed in animal studies.	
Human experience	General effects therapeutic use low exposure - acute effects include: nausea, vomiting, diarrhea, loss of appetite, inflammation of the stomach, burning, pain, redness and swelling of skin, bruising, bleeding, hair loss, infection, fever, chills, sore throat, jaundice, shortness of breath, cough, swelling, ataxia, lethargy, confusion, eye effects, changes in skin pigment, blood vessel changes, increased liver enzymes. low exposure - delayed effect include: bone marrow suppression, decreased white blood cell count, decreased red blood cell count, lung toxicity, pulmonary fibrosis. low exposure - long term exposure effects include: cancer.	Incident report(s) worker exposure low exposure - acute effects include: cough, breathing difficulties, rhinitis, Irritating to respiratory tract
Target Organs	Bone marrow, lungs, kidney, male reproductive organs, liver	Lungs
Symptoms	See "Human Experience"	
Pharmacokinetics/ Toxicokinetics	Absorption: Not available Distribution: Not available Metabolism: Not available Elimination: Half-life = 12 Hour(s) (Human)	
Other Toxicity Information	Not available	Not available

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12. ECOLOGICAL INFORMATION

- **Ecotoxicological Information (Aquatic):** Acute Toxicity to Aquatic Invertebrates (Titanium Dioxide): EC50 (Daphnia magna (Water flea), 48 H): > 100 mg/L.
- **Ecotoxicological Information (Terrestrial):** Not available
- **Chemical Fate Information:** Not available

13. DISPOSAL CONSIDERATIONS

- **Advice On Disposal And Packaging:** Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.
- **Other Information:** Disposal by incineration is recommended.

14. TRANSPORT INFORMATION

This material is not a dangerous good for the purpose of transportation in all modes.

15. OTHER REGULATORY INFORMATION

Prescription Drug Status: Rx Only

16. OTHER INFORMATION

No other information is available.

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