Carmustine

for Injection, USP

100 mg per vial

with 3 mL Diluent | 70860-223-61

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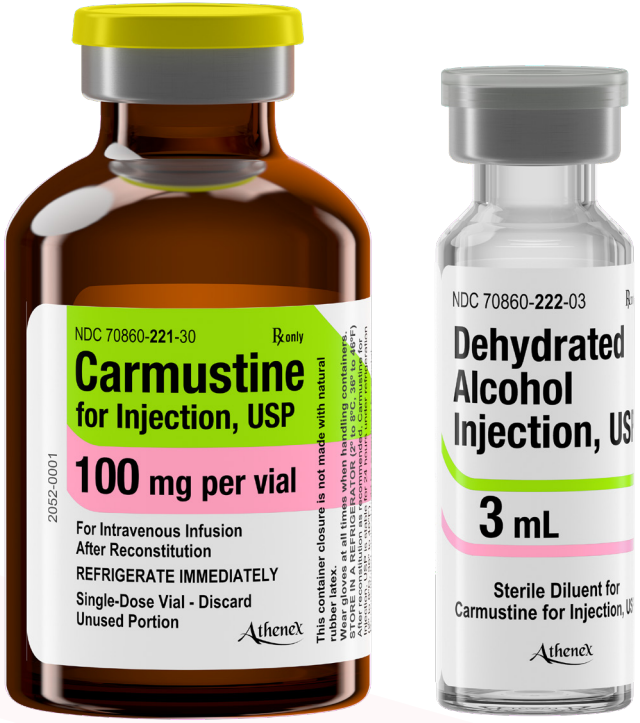
- **BIG, BOLD AND BRIGHT —**
  TO HELP YOU SEE IT, SAY IT AND PICK IT RIGHT
- **DIFFERENTIATION IN EVERY LABEL,**
  DESIGNED TO HELP REDUCE MEDICATION ERRORS



PLEASE SEE IMPORTANT SAFETY INFORMATION ATTACHED, INCLUDING BOXED WARNING.

VISIT WWW.ATHENEXPHARMA.COM/PRODUCTS/CARMUSTINE-FOR-INJECTION-USP FOR FULL PRESCRIBING INFORMATION.

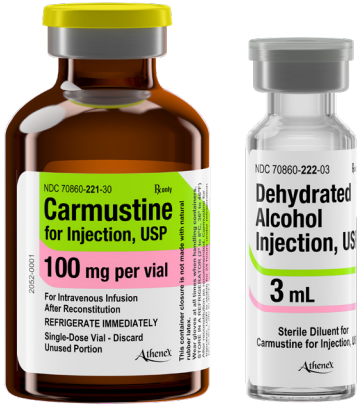
THE NEXT GENERATION OF PHARMACY INNOVATION

Carmustine

for Injection, USP

100 mg	NDC 70860-223-61 100 mg per vial	3 mL	3 mL Diluent
DESCRIPTION	Single-dose vial	DESCRIPTION	Diluent vial
CONCENTRATION	100 mg per vial	FILL VOLUME	3 mL
CLOSURE	20 mm	CLOSURE	13 mm
UNIT OF SALE	1 Kit		
BAR CODED	Yes	BAR CODED	Yes
STORAGE	Refrigerated	STORAGE	Refrigerated

• NOT MADE WITH NATURAL RUBBER LATEX • AP-RATED •



AccuraSEE™ PACKAGING & LABELING

CHOOSE AccuraSEE™ FOR YOUR PHARMACY

Our proprietary, differentiated and highly-visible label designs can assist pharmacists in accurate medication selection.

With a unique label design for every Athenex product, we're offering your pharmacy added AccuraSEE. The idea is simple: "So what you see is **exactly** what you get."

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CARMUSTINE for Injection, USP

INDICATIONS AND USAGE

Carmustine for Injection is a nitrosourea indicated as palliative therapy as a single agent or in established combination therapy with other approved chemotherapeutic agents in the following:

- Brain tumors- glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, and metastatic brain tumors
- Multiple myeloma- in combination with prednisone
- Relapsed or refractory Hodgkin's lymphoma in combination with other approved drugs
- Relapsed or refractory Non-Hodgkin's lymphomas in combination with other approved drugs

WARNING: MYELOSUPPRESSION and PULMONARY TOXICITY

- Suppression of marrow function, notably thrombocytopenia and leukopenia is the most common and severe of the toxic effects of carmustine for injection. Monitor blood counts.
- Pulmonary toxicity from carmustine for injection appears to be dose related. Patients receiving greater than 1400 mg/m 2 cumulative dose are at significantly higher risk than those receiving less.

CONTRAINDICATIONS

- Carmustine for Injection is contraindicated in patients with previous hypersensitivity to carmustine for injection or its components.

WARNINGS and PRECAUTIONS

- Myelosuppression- Bone marrow toxicity is a dose-limiting, common and severe toxic effect of carmustine for injection occurring 4 to 6 weeks after drug administration (thrombocytopenia occurs at about 4 weeks post-administration persisting for 1 to 2 weeks; leukopenia occurs at 5 to 6 weeks after a dose of carmustine for injection persisting for 1 to 2 weeks; thrombocytopenia is generally more severe than leukopenia; anemia is less frequent and less severe compared to thrombocytopenia and/or leukopenia). Complete blood count should therefore be monitored weekly for at least six weeks after a dose. Repeat doses of carmustine for injection should not be given more frequently than every six weeks. The bone marrow toxicity of carmustine for injection is cumulative and therefore the dosage adjustment must be considered on the basis of nadir blood counts from prior dose. Greater myelotoxicity (e.g., leukopenia and neutropenia) has been reported when carmustine was combined with cimetidine.
- Pulmonary Toxicity- Cases of fatal pulmonary toxicity with carmustine for injection have been reported. Pulmonary toxicity characterized by pulmonary infiltrates and/or fibrosis has been reported to occur from 9 days to 43 months after treatment with carmustine for injection and related nitrosoureas. Pulmonary toxicity from carmustine for injection is dose-related. Patients receiving greater than 1400 mg/m 2 cumulative dose are at significantly higher risk than those receiving less. However, there have been reports of pulmonary fibrosis in patients receiving lower total doses. Interstitial fibrosis (with lower doses) occurred rarely. Additionally, delayed onset pulmonary fibrosis occurring up to 17 years after treatment has been reported in patients who received carmustine for injection (in cumulative doses ranging from 770 to 1800 mg/m 2 combined with cranial radiotherapy for intracranial tumors) in childhood and early adolescence. Other risk factors include past history of lung disease and duration of treatment. Baseline pulmonary function studies should be conducted along with frequent pulmonary function tests during treatment. Patients with a baseline below 70% of the predicted forced vital capacity (FVC) or carbon monoxide diffusing capacity (DLCO) are particularly at risk.
- Administration Reactions- Injection site reactions may occur during the administration of carmustine for injection. Rapid intravenous infusion of carmustine for injection may produce intensive flushing of the skin and suffusion of the conjunctiva within 2 hours, lasting about 4 hours. It is also associated with burning at the site of injection although true thrombosis is rare. Given the possibility of extravasation, close monitoring of the infusion site for possible infiltration during drug administration is recommended. A specific treatment for extravasation reactions is unknown at this time.
- Carcinogenicity- Long-term use of nitrosoureas, such as carmustine for injection, has been reported to be associated with the development of secondary malignancies. Carmustine was carcinogenic when administered to laboratory animals. Nitrosourea therapy, such as carmustine for injection, has carcinogenic potential in humans. Patients treated with carmustine for injection should be monitored long-term for development of second malignancies.
- Ocular Toxicity- Carmustine for Injection has been administered through an intraarterial intracarotid route; this procedure is investigational and has been associated with ocular toxicity. Safety and effectiveness of the intra arterial route have not been established.
- Embryo-Fetal Toxicity- Carmustine was embryotoxic in rats and rabbits and teratogenic in rats when given in doses lower than the maximum cumulative human dose based on body surface area. There are no adequate and well- controlled studies in pregnant women. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use highly effective contraception during and after treatment with carmustine for injection for at least 6 months after therapy. Advise males of reproductive potential to use effective contraception during and after treatment with carmustine for injection for at least 3 months after therapy.

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To order, call 1-855-273-0154 or visit www.Athenexpharma.com

ADVERSE REACTIONS

- The following serious adverse reactions have been described in the Warnings and Precautions section above: myelosuppression, pulmonary toxicity, administration reactions, carcinogenicity, and ocular toxicity.
- The most common adverse reactions are nausea, vomiting, renal toxicity, pneumonitis, pulmonary toxicity, and myelosuppression.
- Other adverse reactions include:
  - Cardiac Disorders- Tachycardia and chest pain
  - Eye Disorders- Conjunctival edema, conjunctival hemorrhage, blurred vision and loss of depth perception
  - Gastrointestinal Toxicity- Nausea, vomiting, anorexia, and diarrhea
  - Hepatotoxicity- Increased transaminase, alkaline phosphatase, and bilirubin levels
  - Infections and Infestations- Opportunistic infection (including fatal outcome)
    - Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)- Acute leukemia, bone marrow dysplasias
  - Nephrotoxicity- Progressive azotemia, decrease in kidney size, renal failure
  - Nervous System Disorders- Headaches, encephalopathy, and seizures
  - Pulmonary Toxicity- Pneumonitis, interstitial lung disease
  - Reproductive System and Breast Disorders- Gynecomastia
  - Skin and Subcutaneous Tissue Disorders- Burning sensation, hyperpigmentation, swelling, pain, erythema, skin necrosis, alopecia, allergic reaction
  - Vascular Disorders- Veno-occlusive disease

OVERDOSAGE

The main result of overdose is myeloablation. No proven antidotes have been established for carmustine for injection overdosage.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for CARMUSTINE for Injection, USP.

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