

## CLINICAL UPDATE

<b>Brand Name</b>	carmustine
<b>Generic Name</b>	carmustine
<b>Drug Manufacturer</b>	Accord Healthcare Inc.

### Clinical Update

#### TYPE OF CLINICAL UPDATE

New Strengths

#### FDA APPROVAL DATE

May 16, 2022

#### LAUNCH DATE

July 26, 2022

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Type 2 - New Active Ingredient; NDA 215000

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION(S) FOR USE

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.

#### MECHANISMS OF ACTION

The mechanism of action of carmustine is not fully understood. While carmustine alkylates DNA and RNA, it is not cross-resistant with other alkylators. As with other nitrosoureas, it may also inhibit several key enzymatic processes by carbamylation of amino acids in proteins. The metabolites may contribute to antitumor activity and toxicities of carmustine.

#### DOSAGE FORM(S) AND STRENGTH(S)

- 50 mg of carmustine lyophilized powder for injection in a single-dose vial for reconstitution and a vial containing 3 mL sterile diluent (Dehydrated Alcohol Injection)

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## CLINICAL UPDATE

- 300 mg of carmustine lyophilized powder for injection in a single-dose vial for reconstitution and a vial containing 9 mL sterile diluent (Dehydrated Alcohol Injection).

### DOSE & ADMINISTRATION

Recommended Dosage: As a single agent, 150 mg/m<sup>2</sup> to 200 mg/m<sup>2</sup> carmustine for Injection intravenously every 6 weeks as a single dose or divided into daily injections such as 75 mg/m<sup>2</sup> to 100 mg/m<sup>2</sup> on 2 successive days.

### EFFICACY

N/A