NOVADOZ
AN MSN COMPANY

CARMUSTINE INJECTION USP 100 mg vial

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Carmustine for injection is a nitrosourea used as palliative therapy as single agent or in combination with other chemotherapeutic agents for: 1. Brain tumors (glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, metastatic brain tumors) 2. Multiple myeloma (in combination with prednisone) 3. Relapsed/refractory Hodgkin's lymphoma (in combination with other drugs) 4. Relapsed/refractory Non-Hodgkin's lymphoma (in combination with other drugs).
2	Dosage	What is the recommended dosage?	Recommended dosage of Carmustine for injection: • **Single agent**: 150-200 mg/m² IV every 6 weeks (single dose) or 75-100 mg/m² IV on 2 successive days. • Adjust dose for combination therapy or in patients with reduced bone marrow reserve.
3	Administration	How do I take it?	Administer reconstituted solution only as a slow intravenous infusion over at least 2 hours.
4	Reconstitution	Instructions for reconstitution?	According to the package insert, vials should not be removed from the Combi Kit Guard during reconstitution. Please follow the instructions mentioned in the package insert
5	Administration	Use in Pediatric Population	Safety and effectiveness in children have not been established.
6	Administration	Use in Geriatric Population	In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dose range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Carmustine for injection and its metabolites are known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and renal function should be monitored.

7	Mechanism	Mechanism of Action	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 carbamoylation of amino acids in proteins. The metabolites may contribute to antitumor activity and toxicities of carmustine.
8	Warning	Black Box Warning	1. ***Myelosuppression:*** Carmustine for injection causes suppression of marrow function (including thrombocytopenia and leukopenia), which may contribute to bleeding and overwhelming infections. Monitor blood counts weekly for at least 6 weeks after each dose. Adjust dosage based on nadir blood counts from the prior dose. Do not administer a repeat course of carmustine for injection until blood counts recover. 2. ***Pulmonary Toxicity:*** Carmustine for injection causes dose-related pulmonary toxicity. Patients receiving greater than 1,400 mg/m² cumulative dose are at significantly higher risk than those receiving less. Delayed pulmonary toxicity can occur years after treatment, and can result in death, particularly in patients treated in childhood.
9	Lactation	Use in Lactation	There is no information regarding the presence of carmustine in human milk, the effects on the breastfed infant, or the effects on milk production. Because many drugs are excreted in human milk and because of the potential for serious adverse events (e.g., carcinogenicity and myelosuppression) in nursing infants, nursing should be discontinued while taking carmustine for injection.
10	Pregnancy	Use in Pregnancy	Advise pregnant women and females of reproductive potential that carmustine for injection exposure during pregnancy can result in fetal harm. Advise female patients to contact their healthcare provider with a known or suspected pregnancy. Advise women of reproductive potential to avoid becoming pregnant. Advise females of reproductive potential to use effective contraception during treatment.
11	Interaction	Is there any interaction with drugs?	**Effects of Other Drugs on Carmustine for Injection** **Cimetidine:** Greater myelosuppression (e.g., leukopenia and neutropenia) has been reported when oral cimetidine has been coadministered with carmustine. Consider alternative drugs to cimetidine. **Phenobarbital:** Phenobarbital induces the metabolism of carmustine and may compromise antitumor activity of carmustine for injection. Consider alternative drugs to phenobarbital. **Effects of Carmustine for Injection on Other Drugs** **Phenytoin:** Carmustine for injection when coadministered with phenytoin may reduce phenytoin serum concentrations. Consider alternative drugs to phenytoin.

12	Storage	What are the storage conditions?	Store the unopened vial of the dry drug in a refrigerator (2° to 8°C, 36° to 46°F). Store the diluent vials in a refrigerator (2° to 8°C, 36° to 46°F). The recommended storage of unopened carmustine for injection vials provides a stable product for up to 2 years.
13	Dispensing	How to Dispense?	As prescribed by the Physician
14	Contraindication	What are the contraindications of (medication).	Carmustine for injection is contraindicated in patients with previous hypersensitivity to carmustine for injection or its components.
Pharmaceutical Particulars			
15	Pharmaceutical Form	How is it supplied?	Carmustine for injection,USP. Each package includes a vial containing 100 mg carmustine, USP and a vial contains 3 mL sterile diluent (Dehydrated Alcohol Injection, USP) vial. NDC 72205-198-01
16	Ingredients	Active and Inactive Ingredients	**Active**: Carmustine **Inactive**: Alcohol
Allergens			
17	Ingredients	Is it Vegetarian?	Yes
18	Ingredients	Does it contain Gluten?	No
19	Ingredients	Does it contain Dairy Products?	No
20	Ingredients	Does it contain Casein	No
21	Ingredients	Does it contain Whey?	No
22	Ingredients	Does it contain corn?	No
23	Ingredients	Does it contain rye?	No
24	Ingredients	Does it contain sugar?	No
25	Ingredients	Does it contain Oats?	No
26	Ingredients	Does it contain wheat?	No
27	Ingredients	Does it contain spelt?	No
28	Ingredients	Does it contain barley?	No
29	Ingredients	Does it contain rennet?	No
30	Ingredients	Does it contain starch?	No
31	Ingredients	Does it contain Iodine?	No
32	Ingredients	Does it contain latex?	No
33	Ingredients	Does it contain alcohol?	Yes; API contains solvents within the limits as per ICH

34	Ingredients	Does it contain dyes?	No
35	Ingredients	Does it contain flavor?	No
36	Ingredients	Does it contain Lactose?	No
37	Ingredients	Does it contain Nuts?	No
38	Ingredients	Does it contain Preservatives?	No
39	Ingredients	Does it contain Soy products?	No
40	Ingredients	Does it contain peanut?	No
41	Ingredients	Does it contain nickel?	No
42	Ingredients	Does it contain Latex?	No; Free from latex
Miscellaneous			
43	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.
44	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
45	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company.
46	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
47	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.
48	Miscellaneous	Manufacturer and Distributor	Manufactured by: MSN Laboratories Private Limited, Unit – II, Formulations Division, Nandigama.