Bortezomib for injection single dose 3.5mg vial

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Bortezomib for injection is a proteasome inhibitor indicated for: • Treatment of adult patients with multiple myeloma • Treatment of adult patients with mantle cell lymphoma.
2	Dosage	What is the recommended dosage?	**DOSAGE AND ADMINISTRATION** For subcutaneous or intravenous use only. Each route of administration has a different reconstituted concentration. Exercise caution when calculating the volume to be administered The recommended starting dose of bortezomib for injection is 1.3 mg/m administered either as a 3 to 5 second bolus intravenous injection or subcutaneous injection. Retreatment for Multiple Myeloma: May retreat starting at the last tolerated dose. Hepatic Impairment: Use a lower starting dose for patients with moderate or severe hepatic impairment. Dose must be individualized to prevent overdose.
3	Administration	Administration precautions	• Caution should be used in calculating the dose to the drug quantity contained in one vial (3.5 mg) may exceed the usual dose required. • Caution should be used in calculating the dose to prevent overdose • When administered subcutaneously, sites for each injection (thigh or abdomen) should be rotated. New injections should be given at least one inch from an old site and never into areas where the site is tender, bruised, erythematous, or indurated. • If local injection site reactions occur following bortezomib for injection administration subcutaneously, a less concentrated bortezomib for injection solution (1 mg/mL instead of 2.5 mg/mL) may be administered subcutaneously. Alternatively, consider use of the intravenous route of administration • Bortezomib for injection is a hazardous drug. Follow applicable special handling and disposal procedures

	Administration	Reconstitution for intravenous and subcutaneous	• Use proper aseptic technique. • Reconstitute only with 0.9% sodium chloride. The reconstituted product should be a clear and colorless solution. • Different volumes of 0.9% sodium chloride are used to reconstitute the product for the different routes of administration. • The reconstituted concentration of bortezomib for subcutaneous administration (2.5 mg/mL) is greater than the reconstituted concentration of bortezomib for intravenous administration (1 mg/mL). **For complete information, please refer to prescribing information**
4	Administration	Use in Pediatric Population	No new safety concerns were observed when bortezomib was added to a chemotherapy backbone regimen as compared with a historical control group in which the backbone regimen was given without bortezomib. The BSA-normalized clearance of bortezomib in pediatric patients was similar to that observed in adults.
5	Administration	Use in Geriatric Population	No overall differences in safety or effectiveness were observed between patients ≥age 65 and younger patients receiving bortezomib; but greater sensitivity of some older individuals cannot be ruled out.
6	Mechanism	Mechanism of Action	Bortezomib is a reversible inhibitor of the chymotrypsin-like activity of the 26S proteasome in mammalian cells. The 26S proteasome is a large protein complex that degrades ubiquitinated proteins. The ubiquitin-proteasome pathway plays an essential role in regulating the intracellular concentration of specific proteins, thereby maintaining homeostasis within cells. Inhibition of the 26S proteasome prevents this targeted proteolysis, which can affect multiple signaling cascades within the cell. This disruption of normal homeostatic mechanisms can lead to cell death. Experiments have demonstrated that bortezomib is cytotoxic to a variety of cancer cell types in vitro. Bortezomib causes a delay in tumor growth in vivo in nonclinical tumor models, including multiple myeloma.
7	Warning	Warnings and precautions	• Peripheral Neuropathy: Manage with dose modification or discontinuation. Patients with preexisting severe neuropathy should be treated with bortezomib only after careful risk-benefit assessment. • Hypotension: Use caution when treating patients taking antihypertensives, with a history of syncope, or with dehydration. • Cardiac Toxicity: Worsening of and development of cardiac failure has occurred. Closely monitor patients with existing heart disease or risk factors for heart disease. • Pulmonary Toxicity: Acute respiratory syndromes have occurred. Monitor closely for new or worsening symptoms and consider interrupting bortezomib therapy. • Posterior Reversible Encephalopathy Syndrome: Consider MRI imaging for onset of visual or

			neurological symptoms; discontinue bortezomib if suspected • Gastrointestinal Toxicity: Nausea, diarrhea, constipation, and vomiting may require use of antiemetic and antidiarrheal medications or fluid replacement. • Thrombocytopenia or Neutropenia: Monitor complete blood counts regularly throughout treatment. • Tumor Lysis Syndrome: Closely monitor patients with high tumor burden. • Hepatic Toxicity: Monitor hepatic enzymes during treatment. Interrupt bortezomib therapy to assess reversibility. • Thrombotic Microangiopathy: Monitor for signs and symptoms. Discontinue bortezomib if suspected. • Embryo-Fetal Toxicity: Bortezomib can cause fetal harm. Advise females of reproductive potential and males with female partners of reproductive potential of the potential risk to a fetus and to use effective contraception.
8	Lactation	Use in Lactation	There are no data on the presence of bortezomib or its metabolites in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. Because many drugs are excreted in human milk and because the potential for serious adverse reactions in breastfed child from bortezomib is unknown, advise nursing women not to breastfeed during treatment with bortezomib and for two months after treatment.
9	Pregnancy	Use in Pregnancy	Based on its mechanism of action [see Clinical Pharmacology and findings in animals, bortezomib can cause fetal harm when administered to a pregnant woman. There are no studies with the use of bortezomib in pregnant women to inform drug associated risks. Bortezomib caused embryo-fetal lethality in rabbits at doses lower than the clinical dose. Advise pregnant women of the potential risk to the fetus. Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively
10	Storage	What are the storage conditions?	Unopened vials may be stored at controlled room temperature 25ºC (77ºF); excursions permitted from 15ºC to 30ºC (59ºF to 86ºF) [see USP Controlled Room Temperature]. Retain in original package to protect from light.
11	Dispensing	How to Dispense?	As prescribed by physician.
12	Contraindication	What are the contraindications of (medication)?	Bortezomib is contraindicated in patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol. Reactions have included anaphylactic reactions Bortezomib is contraindicated for intrathecal administration. Fatal events have occurred with intrathecal administration of bortezomib.

Pharmaceutical Particulars			
13	Pharmaceutical Form	How Supplied	Bortezomib for Injection is supplied as individually cartooned 10 mL vials containing 3.5 mg of bortezomib as a white to off-white cake or powder. NDC 72205-183-01 3.5 mg single-dose vial
14	Ingredients	Active and Inactive	**Active ingredient:** Bortezomib. **Inactive ingredients:** Mannitol
Allergens			
13	Ingredients	Does it contain Gluten?	Mannitol excipient Used as bulking agent in the FP contains gluten limit lower than 20 mg/kg
14	Ingredients	Does it contain alcohol?	API contains solvents within the limits as per ICH
15	Ingredients	Does it contain dyes?	No
16	Ingredients	Does it contain Lactose?	No
17	Ingredients	Does it contain Nuts?	No
18	Ingredients	Does it contain Wheat?	Mannitol PRDS attached as reference
19	Ingredients	Does it contain Preservatives?	No
20	Ingredients	Does it contain Soy products?	No
21	Ingredients	Does it contain Rye?	Find the attached mannitol PRDS
22	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
23	Ingredients	Does it contain Corn?	Find the attached mannitol PRDS
Miscellaneous			
22	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.
23	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
24	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
25	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my	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

		prescription with Novadoz formulation?	
26	Miscellaneous	May I know where is this product manufactured?	**Manufactured by**: MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by**: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714