DECITABINE 50 MG INJECTION

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Decitabine for injection is a nucleoside metabolic inhibitor indicated for treatment of adult patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anaemia with ringed side oblasts, refractory anaemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.
2	Dosage	What is the recommended dosage?	• **Three Day Regimen** Administer decitabine for injection at a dose of 15 mg/m^2 by continuous intravenous infusion over 3 hours repeated every 8 hours for 3 days. Repeat cycle every 6 weeks upon hematologic recovery for a minimum of 4 cycles. • **Five Day Regimen** Administer decitabine for injection at a dose of 20 mg/m^2 by continuous intravenous infusion over 1 hour daily for 5 days. Repeat cycle every 4 weeks upon hematologic recovery for a minimum of 4 cycles.
4	Administration	Use in Paediatric Population	The safety and effectiveness of decitabine in pediatric patients have not been established.
5	Administration	Use in Geriatric Population	No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
6	Side Effects	What are the most common side effects?	Most common adverse reactions (>50%) are neutropenia, thrombocytopenia, anemia, and pyrexia.
7	Mechanism	Mechanism of Action	Decitabine is believed to exert its antineoplastic effects after phosphorylation and direct incorporation into DNA and inhibition of DNA methyltransferase, causing hypomethylation of DNA and cellular differentiation or apoptosis. Decitabine inhibits DNA methylation in vitro, which is achieved at concentrations that do not cause major suppression of DNA synthesis. Decitabine-induced hypomethylation in neoplastic cells may restore normal function to genes that are critical for the control of cellular differentiation and proliferation. In rapidly dividing cells, the cytotoxicity of decitabine may also be attributed to the formation of covalent adducts between DNA methyltransferase and decitabine incorporated into DNA. Non-proliferating cells are relatively insensitive to decitabine.
8	Warning	Black Box Warning	No black box warning
9	Lactation	Use in Lactation	Breastfeeding is not advised. Advise patients to avoid breastfeeding while receiving decitabine and for 1 week after the last dose.

10	Pregnancy	Use in Pregnancy	It is advised that women of childbearing potential to avoid pregnancy and to use effective contraception while receiving decitabine and for 6 months after last dose. It is advised that men with female partners of childbearing potential to use effective contraception while receiving treatment with decitabine, and for 3 months following the last dose
11	Storage	What are the storage conditions?	Store vials at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F).
12	Dispensing	How to Dispense?	Decitabine for Injection 50 mg is white to almost white Lyophilized cake or powder in 20 mL Type-I clear glass vial with 20 mm igloo grey rubber stopper and sealed with 20 mm aluminum seal having blue color polypropylene disc. NDC 69539-115-01, 50 mg single-dose vial individually packaged in a carton.
13	Contraindication	What are the contraindications of (medication).	None.
Pharmaceutical Particulars			
14	Pharmaceutical Form	How Supplied	Decitabine for Injection 50 mg is white to almost white Lyophilized cake or powder in 20 mL Type-I clear glass vial with 20 mm igloo grey rubber stopper and sealed with 20 mm aluminum seal having blue color polypropylene disc. NDC 69539-115-01, 50 mg single-dose vial individually packaged in a carton.
15	Ingredients	Active and Inactive	Decitabine for Injection is a sterile white to almost white lyophilized cake or powder supplied in a clear colourless glass vial. Each 20 mL, single dose, glass vial contains 50 mg decitabine, 68 mg monobasic potassium phosphate (potassium dihydrogen phosphate) and 11.6 mg sodium hydroxide.
Allergens			
16	Ingredients	Does it contain Gluten?	No
17	Ingredients	Does it contain alcohol?	No
18	Ingredients	Does it contain dyes?	No
19	Ingredients	Does it contain Lactose?	No
20	Ingredients	Does it contain Nuts?	No
21	Ingredients	Does it contain Preservatives?	No
22	Ingredients	Does it contain Soy products?	Yes (Rubber stopper is used as a primary packing material, which contains trace of epoxidized soybean oil)
23	Ingredients	Does it contain peanut?	No
24	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
Miscellaneous			
25	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
26	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
27	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
28	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
29	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. You can also visit our website: http://novadozpharma.com/contact-us/
35	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.