

DEXRAZOXANE INJECTION USP- 250 mg & 500 mg vial

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Dexrazoxane injection is used to protect the heart from damage caused by doxorubicin in women with advanced breast cancer who have already received high doses. It should not be started at the same time as doxorubicin.
2	Dosage	What is the recommended dosage?	✓ Administer dexrazoxane for injection by intravenous infusion over 15 minutes. ✓ The recommended dosage ratio of dexrazoxane for injection to doxorubicin is 10:1 (e.g., 500 mg/m dexrazoxane for injection to 50 mg/m doxorubicin). ✓ Do not administer doxorubicin before dexrazoxane for injection. ✓ Reduce dose by 50% for patients with creatinine clearance <40 mL/min.
3	Administration	How do I take it?	• Reconstitute vial contents and dilute before use. (2.3) • Administer dexrazoxane for injection by intravenous infusion over 15 minutes. • DO NOT ADMINISTER VIA AN INTRAVENOUS PUSH.
4	Reconstitution	Instructions for reconstitution?	Add sterile water to the vial (25 mL for 250 mg or 50 mL for 500 mg) to make 10 mg/mL solution, then dilute further with Lactated Ringer's to 1.3–3 mg/mL for IV infusion. Use quickly (within 30 min at room temp or store in fridge for a short time) and discard any unused solution.
5	Administration	Use in Pediatric Population	Safety and effectiveness in children have not been established.
6	Administration	Use in Geriatric Population	• Studies in people ≥ 65 are limited, but no major differences were seen. • In elderly patients, start with a lower dose and use caution due to possible liver, kidney, heart issues, and other medicines.
7	Mechanism	Mechanism of Action	Dexrazoxane helps protect cells (especially the heart), but the exact way it works is not fully known. It enters cells and blocks harmful iron-related free radicals, which can damage the heart during anthracycline (like doxorubicin) treatment

8	Warning	Warnings and precaution	• Myelosuppression: Dexrazoxane may increase the myelosuppressive effects of chemotherapeutic agents. Perform regular hematological monitoring. • Embryo-Fetal Toxicity: Dexrazoxane can cause fetal harm. Advise patients of the potential risk to the fetus and recommend the use of effective contraception during treatment.
9	Lactation	Use in Lactation	Advise women not to breastfeed during treatment with dexrazoxane and for 2 weeks after the last dose
10	Pregnancy	Use in Pregnancy	• Advise pregnant women and females of reproductive potential of the potential risk to a fetus. • The background risk of major birth defects and miscarriage for the indicated population is unknown.
11	Interaction	Is there any interaction with drugs?	No drug interactions have been identified
12	Storage	What are the storage conditions?	Store the medicine at room temperature (about 25°C), with small temperature changes allowed. Handle and dispose of it carefully according to safety guidelines, and always discard any unused solution.
13	Dispensing	How to Dispense?	As prescribed by the Physician
14	Contraindication	What are the contraindications of (medication).	Do not use dexrazoxane with non-anthracycline chemotherapy regimens.
Pharmaceutical Particulars			
15	Pharmaceutical Form	How is it supplied?	• Form: Sterile powder (off-white to pale yellow) in single-dose vials (needs mixing before use) • Strengths: • 250 mg – single-dose vial (blue flip-top) NDC Code 72205-247-01 • 500 mg – single-dose vial (blue flip-top) , NDC Code 72205-248-01 • Pack: Each comes in a carton with one vial
16	Ingredients	Active and Inactive Ingredients	Active: Dexrazoxane Inactive: Hydrochloric acid
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
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	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to

		particular medicine, no longer fills my prescription with Novadoz formulation?	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.