Thiotepa Injection 15 mg/ml and 100 mg/ml

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Thiotepa for injection is an alkylating drug indicated: • For treatment of adenocarcinoma of the breast or ovary. • For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities. • For treatment of superficial papillary carcinoma of the urinary bladder.
2	Dosage	What is the recommended dosage and administration?	• The recommended dose of thiotepa for injection for treatment of adenocarcinoma of the breast or ovary is 0.3 to 0.4 mg/kg intravenously. • The recommended dose of thiotepa for injection for treatment of malignant effusions is 0.6 to 0.8 mg/kg intracavitary. • The recommended dose of thiotepa for injection for treatment of superficial papillary carcinoma of the urinary bladder is 60 mg in 30 to 60 mL of Sodium Chloride Injection into the bladder by catheter.
3	Administration	Use in Pediatric Population	Safety and effectiveness of thiotepa in neonates have not been established. *Pediatric use information is approved for Adienne SA's TEPADINA (thiotepa) for Injection. However, due to Adienne SA's marketing exclusivity rights, the drug product is not labeled with that information.*
4	Administration	Use in Geriatric Population	In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreasing hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.
5	Mechanism	Mechanism of Action	Thiotepa is a cytotoxic agent of the polyfunctional type, related chemically and pharmacologically to the nitrogen mustard. The radiomimetic action of thiotepa is believed to occur through the release of ethyleneimine radicals which, like irradiation, disrupt the bonds of DNA. One of the principle bond disruptions is initiated by alkylation of guanine at the N-7 position, which severs the linkage between the purine base and the sugar and liberates alkylated guanines.
6	Warning	Black Box Warning	**SEVERE MYELOSUPPRESSION, CARCINOGENICITY** • May cause severe marrow suppression or ablation with resulting infection or bleeding. Monitor hematologic laboratory parameters

			• Potentially carcinogenic in humans *(See full prescribing information for complete boxed warning)*.
7	Lactation	Use in Lactation	Breastfeeding is not recommended. There is no information regarding the presence of thiotepa in human milk, the effects on the breastfed infant, or the effects on milk production.
8	Pregnancy	Use in Pregnancy	Thiotepa can cause fetal harm when administered to a pregnant woman. Females of reproductive potential were advised to avoid pregnancy due to the potential risk to fetus. Females of reproductive potential were advised to use highly effective contraception during and after treatment with thiotepa for at least 6 months after therapy. Males of reproductive potential were advised to use effective contraception during and after treatment with thiotepa for at least 1 year after therapy.
9	Storage	What are the storage conditions?	Thiotepa for injection, USP vials must be stored and transported refrigerated at 2°C to 8°C (36° to 46°F). Do not freeze. After dilution, use within 24 hours when stored in a refrigerator. Thiotepa for injection, USP is a cytotoxic drug. Follow applicable special handling and disposal procedures.
10	Contraindication	What are the contraindications of (medication).	• Hypersensitivity to the active substance. • Concomitant use with live or attenuated vaccines.
11	Drug Interactions	Any Drug Interactions?	Avoid coadministration of strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, ritonavir) and strong CYP3A4 inducers (e.g., rifampin, phenytoin) with thiotepa due to the potential effects on efficacy and toxicity. Thiotepa may increase the exposure of drugs that are substrates of CYP2B6 in patients.
Pharmaceutical Particulars			
12	Pharmaceutical Form	How is it supplied?	Thiotepa for injection, USP is supplied as Unit carton with one single-dose Type I clear glass vial with a bromobutyl stopper. Thiotepa for injection, USP 15 mg: One vial contains 15 mg thiotepa (NDC 72205-045-01). Thiotepa for injection, USP 100 mg: One vial contains 100 mg thiotepa (NDC 72205-046-01).
13	Ingredients	Active and Inactive	Active ingredient: Thiotepa
Allergens			
14	Ingredients	Does it contain Gluten?	No
15	Ingredients	Does it contain alcohol?	Yes
16	Ingredients	Does it contain dyes?	No
17	Ingredients	Does it contain Lactose?	No
18	Ingredients	Does it contain Nuts?	No
19	Ingredients	Does it contain Preservatives?	No
20	Ingredients	Does it contain Soy	No

		products?	
21	Ingredients	Are all excipients are free from human or animal origin?	Yes
22	Ingredients	Other Substances	Thiotepa Injection 15 mg/ml and 100 mg/ml were free from Dairy, Latex, Casein, Whey, Corn, Rye, Sugar, Oats, Wheat, Spelt, Barley and Rennet
23	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
24	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
25	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.
27	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.
28	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
29	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