NELARABINE INJECTION 250 mg/50 mL (5 mg/mL)

S.No.	Category	Question	Answer
		Clinical Particulars	
1	Use/Indication	What is the product indicated for?	Nelarabine injection is indicated for the treatment of T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) in adult and pediatric patients age 1 year and older whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens.
2	Dosage	What is the recommended dosage?	This product is for intravenous use only. **Adult Dosage:** The recommended adult dose of nelarabine injection is 1,500 mg/m² administered intravenously over 2 hours on Days 1, 3, and 5 repeated every 21 days. Administer nelarabine injection undiluted. **Pediatric Dosage:** The recommended pediatric dose of nelarabine injection is 650 mg/m² administered intravenously over 1 hour daily for 5 consecutive days repeated every 21 days. Administer nelarabine injection undiluted. The recommended duration of treatment for adult and pediatric patients has not been clearly established. In clinical trials, treatment was generally continued until there was evidence of disease progression, the patient experienced unacceptable toxicity, the patient became a candidate for hematopoietic stem cell transplantation (HSCT), or the patient no longer continued to benefit from treatment.
3	Administration	How do I take it?	Administer nelarabine injection undiluted. Transfer the appropriate dose of nelarabine injection into polyvinylchloride (PVC) infusion bags or glass containers and administer as a 2-hour infusion in adult patients and as a 1-hour infusion in pediatric patients.Prior to administration, inspect the drug product visually for particulate matter and discoloration.
4	Formulation	Can tablet be crushed?	No
5	Administration	What do I do if I miss a dose?	If you miss a dose of nelarabine injection continue your prescribed course of therapy, and contact your physician immediately.

6	Administration	Use in Pediatric Population	Nelarabine has been established as a safe and effective treatment for relapsed or refractory T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) in pediatric patients aged 1 year and older. The evidence supporting its efficacy comes from a single-arm clinical trial involving 84 patients aged 21 years and younger, along with safety data from 165 pediatric patients across multiple Phase I and II trials. In these studies, the most common adverse reactions observed were hematologic laboratory abnormalities, with hematologic toxicity being more pronounced in the pediatric population compared to adults. Additionally, nervous system adverse reactions were reported in 42% of pediatric patients across the trials, although their incidence was lower than that seen in adults. In a Phase III study assessing nelarabine combined with multi-agent chemotherapy as first-line therapy, 411 patients with T-ALL or T-LBL were treated, and the safety profile in pediatric patients aged 1 to 16 years was consistent with that in older patients. However, there is a lack of long-term follow-up data, preventing any conclusions about the effects of nelarabine on growth and pubertal development in this population.
7	Administration	Use in Geriatric Population	Clinical studies of nelarabine did not include sufficient numbers of patients age 65 and over to determine whether they respond differently from younger patients. In an exploratory analysis, increasing age, especially age 65 years and older, appeared to be associated with increased rates of neurologic adverse reactions. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection.
8	Mechanism	Mechanism of Action	Nelarabine is a prodrug of the deoxyguanosine analogue 9-b-D-arabinofuranosylguanine (ara-G), a nucleoside metabolic inhibitor. Nelarabine is demethylated by adenosine deaminase (ADA) to ara-G, mono-phosphorylated by deoxyguanosine kinase and deoxycytidine kinase, and subsequently converted to the active 5'-triphosphate, ara-GTP. Accumulation of ara-GTP in leukemic blasts allows for incorporation into deoxyribonucleic acid (DNA), leading to inhibition of DNA synthesis and cell death. Other mechanisms may contribute to the cytotoxic and systemic toxicity of nelarabine..
9	Warning	Black Box Warning	**Severe neurologic adverse reactions have been reported with the use of nelarabine. These adverse reactions have included altered mental states including severe**

			somnolence, central nervous system effects including convulsions, **and peripheral neuropathy ranging from numbness and paresthesias to motor weakness and paralysis. There have also been reports of adverse reactions associated with demyelination, and ascending peripheral neuropathies similar in appearance to Guillain-Barré syndrome/Full recovery from these adverse reactions has not always occurred with cessation of therapy with nelarabine. Monitor** **frequently for signs and symptoms of neurologic toxicity during treatment with nelarabine. Discontinue nelarabine for neurologic adverse reactions of NCI Common Toxicity Criteria for Adverse Events (CTCAE) Grade 2 or greater.**
10	Lactation	Use in Lactation	There are no data on the presence of nelarabine or ara-G in human or animal milk, the effect on the breastfed child, or the effect on milk production. Because of the potential for serious adverse reactions in the breastfed child from nelarabine, such as severe neurological reactions, advise women not to breastfeed during treatment with nelarabine.
11	Pregnancy	Use in Pregnancy	Based on its mechanism of action and findings in animal studies, nelarabine can cause fetal harm when administered to a pregnant woman. Limited available data with nelarabine use in pregnant women are insufficient to determine a drug-associated risk for major birth defects, miscarriage or adverse maternal or fetal outcomes. There are risks to the pregnant woman associated with untreated leukemia or lymphoma. In animal reproduction studies, intravenous administration of nelarabine to pregnant rabbits during the period of organogenesis resulted in teratogenicity at maternal doses below the recommended human adult dose of 1500 mg/m2/day (see Data). Advise pregnant women of the potential risk to the fetus. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies are 2% to 4% and 15% to 20%, respectively.
12	Precautions	Is there any interaction between medication and alcohol?	No
13	Interaction	Is there any interaction with food?	No

14	Side effects	What are the common side effects?	The most common (≥ 20%) adverse reactions were: • Adult: anemia, thrombocytopenia, neutropenia, nausea, diarrhea, vomiting, constipation, fatigue, pyrexia, cough, and dyspnea • Pediatric: anemia, neutropenia, thrombocytopenia, and leukopenia (6.1) The most common (> 10%) neurological adverse reactions were: • Adult: somnolence, dizziness, peripheral neurologic disorders, hypoesthesia, headache, and paresthesia. • Pediatric: headache and peripheral neurologic disorders.
15	Storage	What are the storage conditions?	Store Nelarabine Injection at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). See USP Controlled Room Temperature. Discard Unused Portion.
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	No
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Nelarabine Injection is supplied as a clear, colorless, sterile, solution free from visible particles in a 50 mL Type I, clear colorless moulded glass vial with 20 mm rubber stopper and sealed with 20mm aluminium seal having polypropylene disc. Each vial contains 250 mg of nelarabine (5 mg nelarabine per mL) and the inactive ingredient sodium chloride (4.5 mg per mL) in 50 mL Water for Injection, USP**.** **250 mg/ 50 mL (5 mg/mL)** **50 mL Single-Dose Vial 72205-154-01** **6 x 50 mL Single-Dose Vials 72205-154-04**
19	Ingredients	Active and Inactive Ingredients	**Active**: nelarabine **Inactive** sodium chloride .
20	Coating	What is the type of coating?	No
Allergens			
21	Ingredients	Is it Vegetarian?	Yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No.

24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	No
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	No
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	No
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No
44	Ingredients	Does it contain Soy products?	No
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
Miscellaneous			
47	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.
48	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
49	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.

50	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.
51	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.
52	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** **MSN laboratories Private Limited** **Telangana – 509 228,** **INDIA** **Distributed by:** **Novadoz Pharmaceuticals LLC** **Piscataway, NJ 08854-3714**