FIRST TIME GENERIC APPROVAL

Brand Name	nelarabine
Generic Name	nelarabine
Drug Manufacturer	Zydus Pharmaceuticals (USA) Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

November 17, 2021

LAUNCH DATE

November 19, 2021

REVIEW DESIGNATION

Abbreviated New Drug Application (ANDA): 215037

TYPE OF REVIEW

Standard

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

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.

MECHANISMS OF ACTION

Nelarabine is a prodrug of the deoxyguanosine analogue 9-β-*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.

DOSE FORM AND STRENGTH

Injection: 250 mg/50 mL (5 mg/mL) single-dose vial

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DOSE & ADMINISTRATION

Adult Dosage: The recommended adult dose of nelarabine injection is 1,500 mg/m 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/m administered intravenously over 1 hour daily for 5 consecutive days repeated every 21 days. Administer nelarabine injection undiluted.