

NELARABINE - nelarabine injection
Zydus Lifesciences Limited

NELARABINE INJECTION

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1685-1

Nelarabine Injection 250 mg/5 mL (5 mg/mL)

50 mL Single-Dose Vial

For Intravenous Infusion Only

Rx Only

NDC 70771-1685-1

Nelarabine Injection

250 mg/50 mL
(5 mg/mL)

For Intravenous Infusion Only
Discard Unused Portion

zydus pharmaceuticals

50 mL Single-Dose Vial
Rx only

Each mL contains 5 mg of nelarabine. Also contains: 4.5 mg sodium chloride USP for tonicity adjustment, sodium hydroxide NF and/or hydrochloric acid NF for pH adjustment.
Do not dilute.
Contains no preservative.
The vial stoppers are not made with natural rubber latex.

Store at 25°C (77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [see USP Controlled Room Temperature].

Usual dose: See package insert.

Product of India Lot: [REDACTED]

Manufactured by: Cadila Healthcare Ltd. Exp: [REDACTED]
Ahmedabad, India

Rev: 11/21
GUJ/DRUGS/G/28/1304

NDC 70771-1685-1

Nelarabine Injection 250 mg/5 mL (5 mg/mL)

50 mL Single-Dose Vial Carton

For Intravenous Infusion Only

Rx Only

NELARABINE

nelarabine injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1685
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NELARABINE (UNII: 60158CV180) (NELARABINE - UNII:60158CV180)	NELARABINE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1685-1	1 in 1 CARTON	11/17/2021	
1		50 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:70771-1685-8	6 in 1 CARTON	11/17/2021	
2		50 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215037	11/17/2021	

Labeler - Zydus Lifesciences Limited (918596198)**Establishment**

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650348852	ANALYSIS(70771-1685) , MANUFACTURE(70771-1685)

Revised: 11/2022

Zydus Lifesciences Limited