

ARSENIC TRIOXIDE - arsenic trioxide injection, solution
Zydus Lifesciences Limited

ARSENIC TRIOXIDE INJECTION

PRINCIPAL DISPLAY PANEL - Vial Label

NDC 49315-005-01

Arsenic Trioxide Injection

10 mg/10 mL

(1 mg/mL)

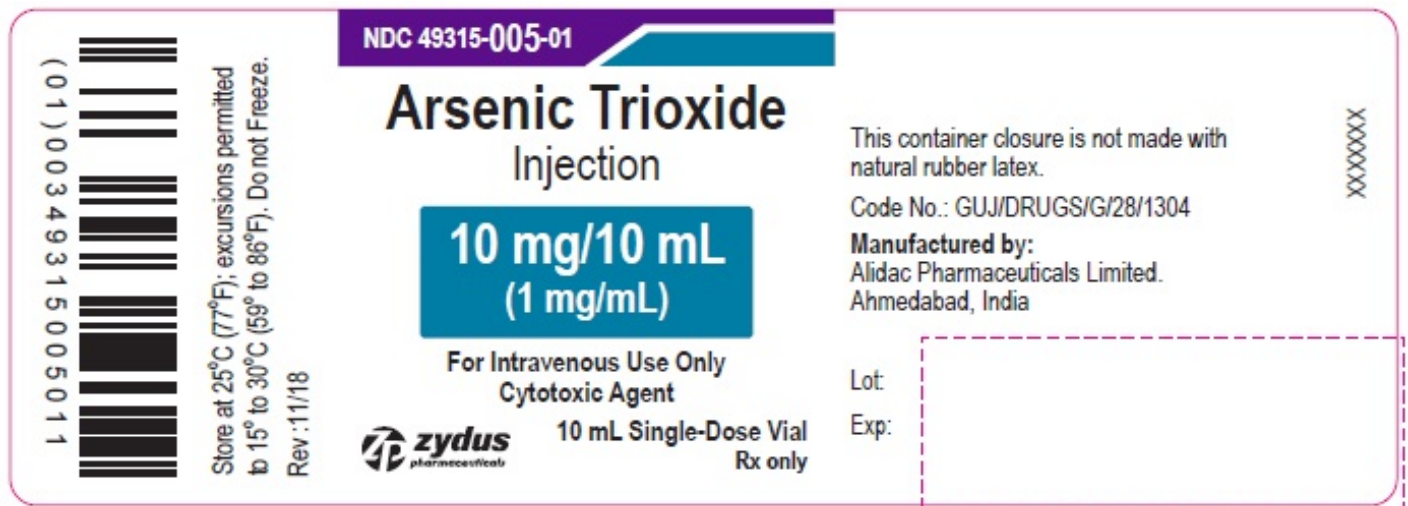
For Intravenous Use Only

Cytotoxic Agent

10 mL Single-Dose Vial

Rx only

Zydus Pharmaceuticals



PRINCIPAL DISPLAY PANEL - Carton Label

NDC 49315-005-10

Arsenic Trioxide Injection

10 mg/10 mL

(1 mg/mL)

For Intravenous Use Only

10 X 10 mL Single-Dose Vials

Rx only



ARSENIC TRIOXIDE

arsenic trioxide injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49315-005
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	1 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49315-005-10	10 in 1 CARTON	11/14/2018	
1	NDC:49315-005-	10 mL in 1 VIAL; Type 0: Not a Combination		

01	Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206228	11/14/2018	

Labeler - Zydus Lifesciences Limited (650348852)

Registrant - Zydus Lifesciences Limited (650348852)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650348852	ANALYSIS(49315-005) , MANUFACTURE(49315-005)

Revised: 11/2022

Zydus Lifesciences Limited