

ARSENIC TRIOXIDE - arsenic trioxide injection, solution
Zydus Lifesciences Limited

ARSENIC TRIOXIDE INJECTION

PRINCIPAL DISPLAY PANEL - Vial Label

NDC 49315-007-01

Arsenic Trioxide Injection

12 mg/6 mL

(2 mg/mL)

NEW CONCENTRATION

For Intravenous Use Only

Cytotoxic Agent

6 mL Single-Dose Vial

Rx only

Zydus Pharmaceuticals

3
4
9
3
1
5
0
0
7
0
1
5
3

NDC 49315-007-01

Arsenic Trioxide Injection

12 mg/6 mL
(2 mg/mL)

NEW CONCENTRATION

For Intravenous Use Only
Cytotoxic Agent

6 mL Single-Dose Vial
Rx only

Store at 20° to 25° C (68° to 77° F);
excursions permitted to 15° to 30° C
(59° to 86° F). Do Not Freeze.
Discard Unused Portion.

zydus
pharmaceuticals

This container closure is not made with
natural rubber latex.

Code No.: GUJ/DRUGS/G/28/1304

Manufactured by:
Alidac Pharmaceuticals Limited.
Ahmedabad, India

Lot: [REDACTED]

Exp: [REDACTED]

Rev: 09/19

PRINCIPAL DISPLAY PANEL - Carton Label

NDC 49315-007-10

Arsenic Trioxide Injection

12 mg/6 mL

(2 mg/mL)

NEW CONCENTRATION

For Intravenous Use Only

10 X 6 mL Single-Dose Vials

Rx only

Zyus Pharmaceuticals



ARSENIC TRIOXIDE

arsenic trioxide injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49315-007
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	2 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:49315-007-10	10 in 1 CARTON	09/03/2019	
1	NDC:49315-007-01	6 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	ANDA206228	09/03/2019	

Labeler - Zydus Lifesciences Limited (650348852)

Registrant - Zydus Lifesciences Limited (650348852)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650348852	ANALYSIS(49315-007) , MANUFACTURE(49315-007)

Revised: 11/2022

Zydus Lifesciences Limited