CLOFARABINE - clofarabine injection
Zydus Lifesciences Limited

Clofarabine Injection, for Intravenous use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 49315-003-06

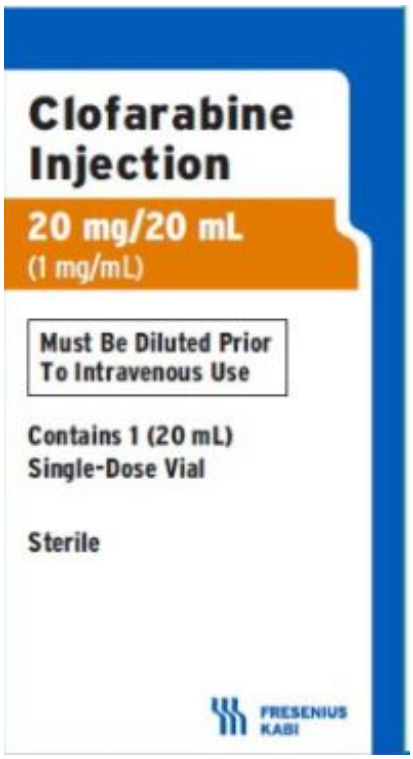
Rx only

Clofarabine Injection 20 mg/20 mL (1 mg/mL)

Must Be Diluted Prior To Intravenous Use

Contains 1 (20 mL) Single-Dose Vial

Sterile



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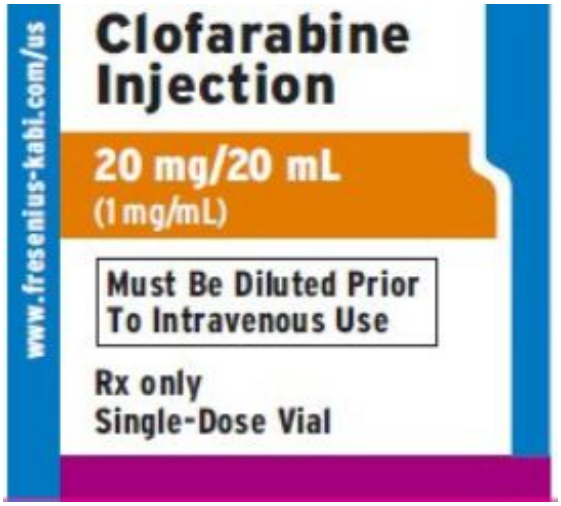

CLOFARABINE

clofarabine injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49315-003
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CLOFARABINE (UNII: 762RDY0Y2H) (CLOFARABINE - UNII:762RDY0Y2H)	CLOFARABINE	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49315-003-06	1 in 1 CARTON	05/10/2017	
1		20 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204029	05/10/2017	

Labeler - Zydus Lifesciences Limited (650348852)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650348852	ANALYSIS(49315-003) , MANUFACTURE(49315-003)

Revised: 10/2022 Zydus Lifesciences Limited