DECITABINE - decitabine injection, powder, lyophilized, for solution
Zydus Lifesciences Limited

DECITABINE for injection, for intravenous use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1713-1

Decitabine for Injection

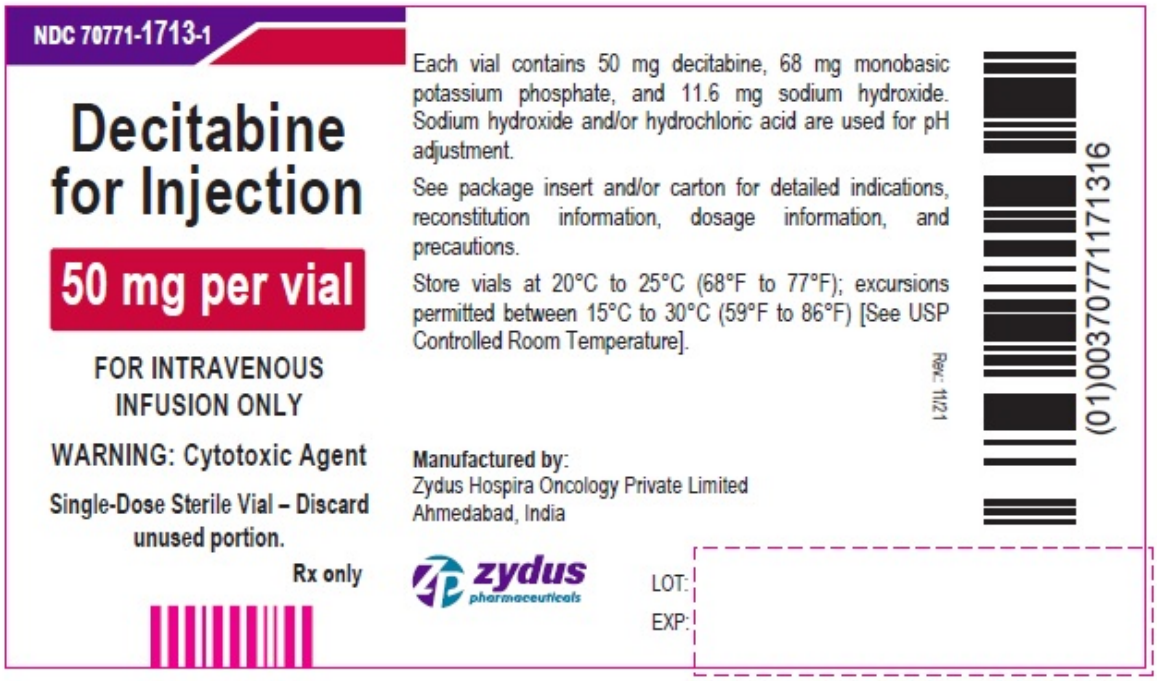
50 mg per vial

FOR INTRAVENOUS INFUSION ONLY

WARNING: Cytotoxic Agent

Single-Dose Sterile Vial – Discard unused portion.

Rx only



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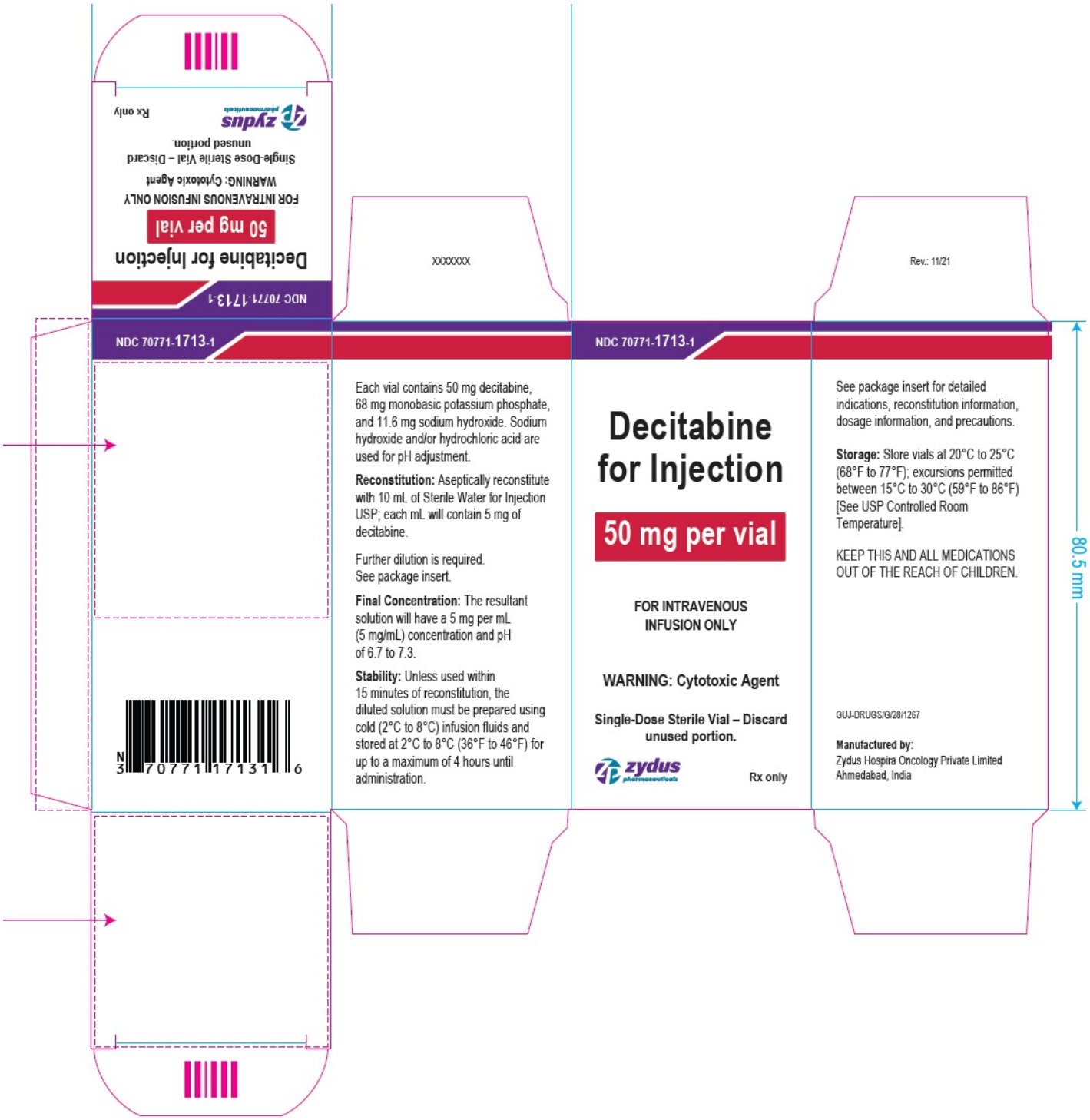

DECITABINE

decitabine injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1713
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DECITABINE (UNII: 776B62CQ27) (DECITABINE - UNII:776B62CQ27)	DECITABINE	50 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1713-1	1 in 1 CARTON	05/11/2023	
1		20 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	ANDA214486	05/11/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Pharmaceuticals USA Inc. (156861945)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Hospira Oncology Private Limited		676190889	ANALYSIS(70771-1713) , LABEL(70771-1713) , MANUFACTURE(70771-1713) , PACK(70771-1713)

Revised: 10/2022 Zydus Lifesciences Limited