

DECITABINE - decitabine injection, powder, lyophilized, for solution
Zyudus 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

NDC 70771-1713-1

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for Injection**

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Each vial contains 50 mg decitabine, 68 mg monobasic potassium phosphate, and 11.6 mg sodium hydroxide. Sodium hydroxide and/or hydrochloric acid are used for pH adjustment.

See package insert and/or carton for detailed indications, reconstitution information, dosage information, and precautions.

Store vials at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

Rev: 11/21

Manufactured by:
Zyudus Hospira Oncology Private Limited
Ahmedabad, India

zydus
pharmaceuticals

LOT: _____

EXP: _____

(01)00370771171316

NDC 70771-1713-1

Decitabine for Injection

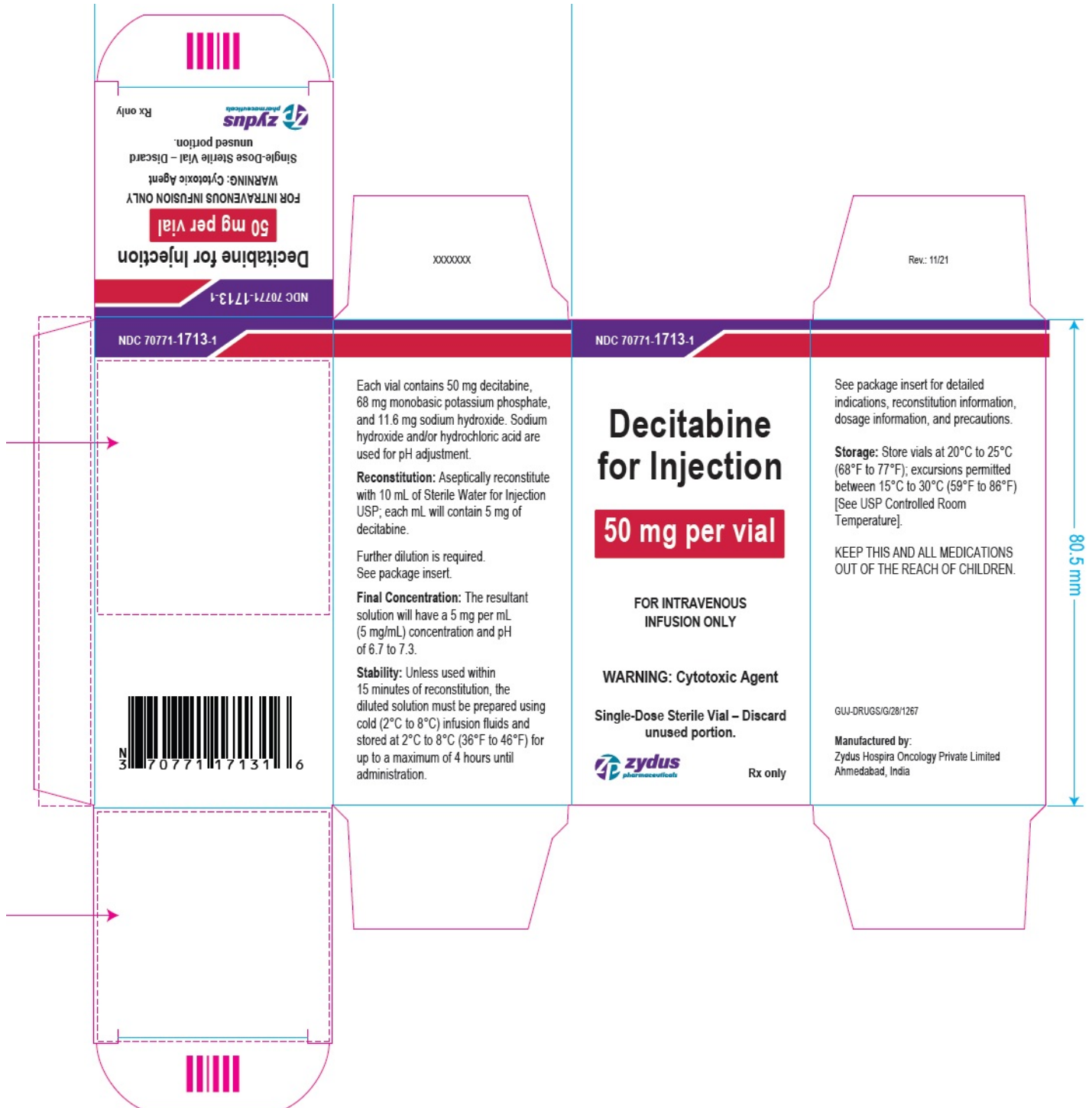
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DECITABINE

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