RANITIDINE HYDROCHLORIDE - ranitidine hydrochloride injection, solution
Zydus Lifesciences Limited

Ranitidine Injection, USP
Pharmacy Bulk Package—Not for Direct Infusion
Rx only

PRINCIPAL DISPLAY PANEL - 40 mL Vial Container Label

NDC 72785-0001-1

Ranitidine Injection USP

1000 mg/40 mL

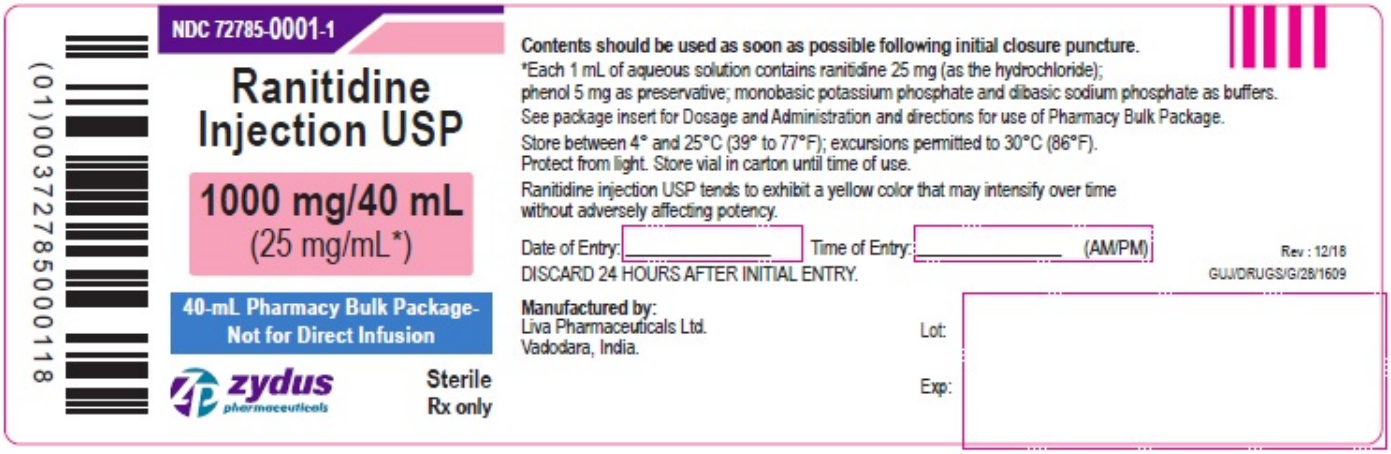
(25 mg/mL*)

40-mL Pharmacy Bulk package – Not for Direct Infusion

Sterile

Rx only

Zydus pharmaceuticals



PRINCIPAL DISPLAY PANEL - 40 mL Vial Carton Label

NDC 72785-0001-1

Ranitidine Injection USP

1000 mg/40 mL

(25 mg/mL*)

40-mL Pharmacy Bulk Package – Not for Direct Infusion

Sterile

Rx only

Zydus pharmaceuticals

RANITIDINE HYDROCHLORIDE

ranitidine hydrochloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72785-0001
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Product Characteristics

Color	YELLOW (colorless to yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72785-0001-1	1 in 1 CARTON	02/21/2019	
1		40 mL in 1 VIAL, PHARMACY BULK PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091534	02/21/2019	

Labeler - Zydus Lifesciences Limited (873671928)

Registrant - Zydus Lifesciences Limited (873671928)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		873671928	ANALYSIS(72785-0001) , MANUFACTURE(72785-0001)