RANITIDINE HYDROCHLORIDE - ranitidine hydrochloride injection
Zydus Lifesciences Limited

Ranitidine Injection, USP

PRINCIPAL DISPLAY PANEL - 2 mL Vial Container Label

NDC 65841-763-02

Ranitidine Injection, USP

50 mg/2 mL (25 mg/mL)*

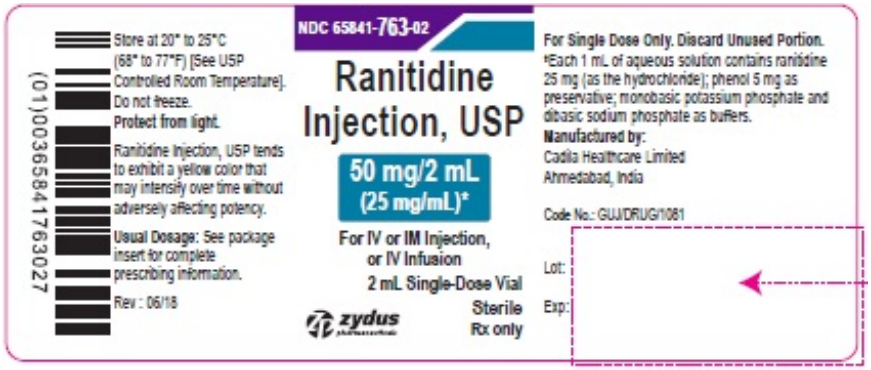
For IV or IM Injection, or IV Infusion

2 mL Single-Use Vial

Sterile

Rx only

Zydus Pharmaceuticals



PRINCIPAL DISPLAY PANEL - 2 mL Vial Carton Label

NDC 65841-763-02

Ranitidine Injection, USP

50 mg/2 mL (25 mg/mL)*

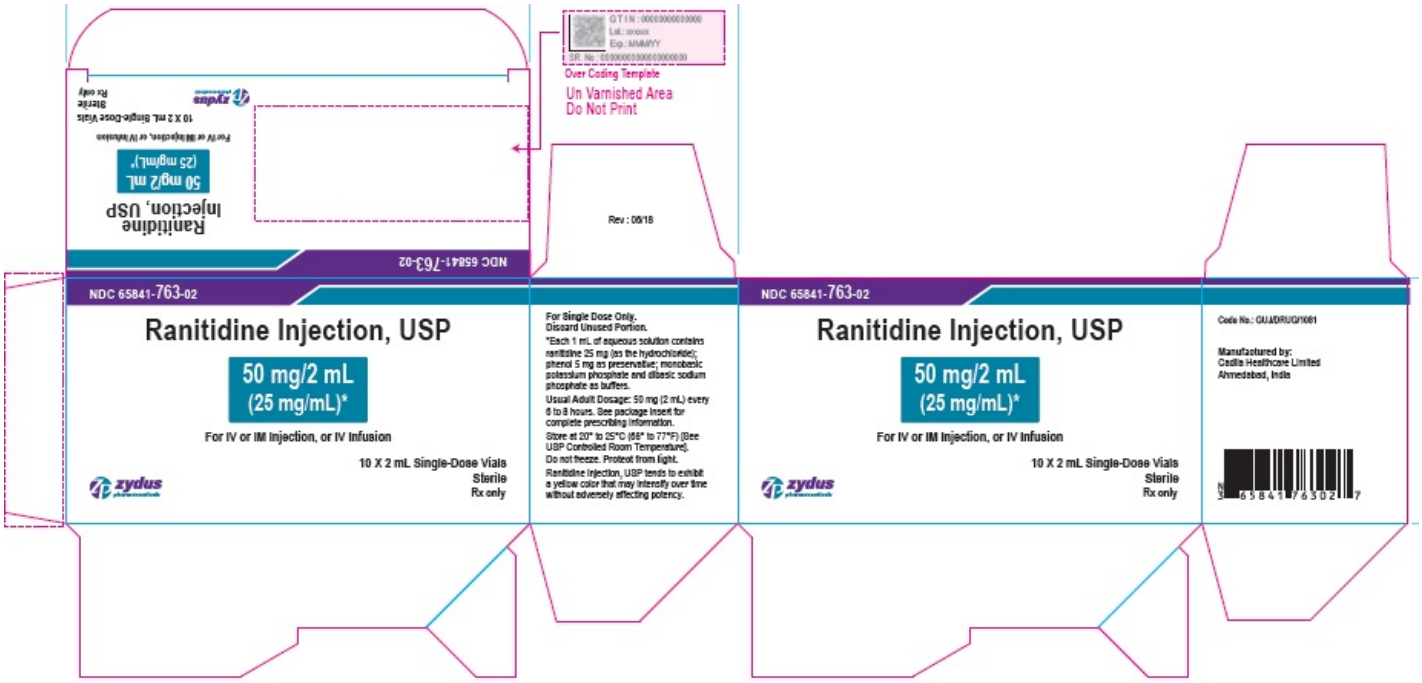
For IV or IM Injection, or IV Infusion

10 X 2 mL Single-Use Vials

Rx only

Sterile

Zydus Pharmaceuticals



PRINCIPAL DISPLAY PANEL - 6 mL Vial Container Label

NDC 65841-764-06

Ranitidine Injection, USP

150 mg/6 mL (25 mg/mL)*

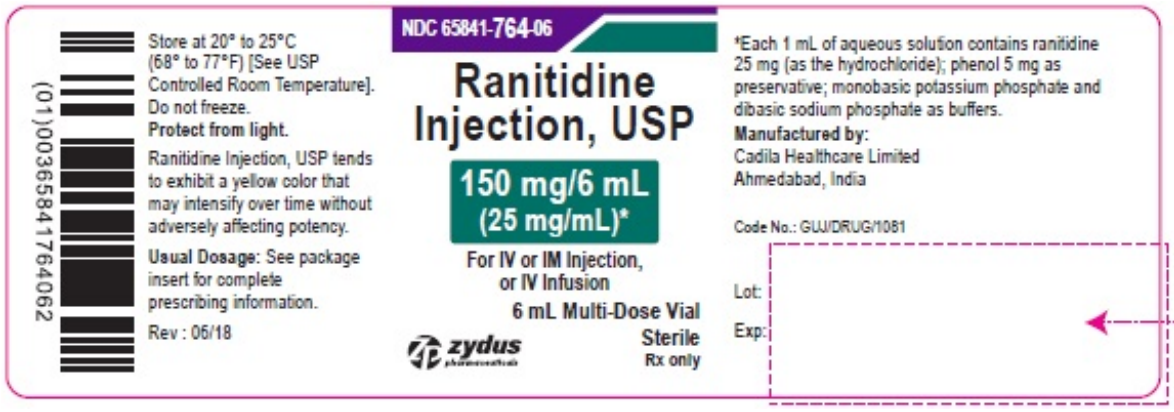
For IV or IM Injection, or IV Infusion

6 mL Multi-Dose Vial

Sterile

Rx only

Zydus Pharmaceuticals



PRINCIPAL DISPLAY PANEL - 6 mL Vial Carton Label

NDC 65841-764-06

Ranitidine Injection, USP

150 mg/6 mL (25 mg/mL)*

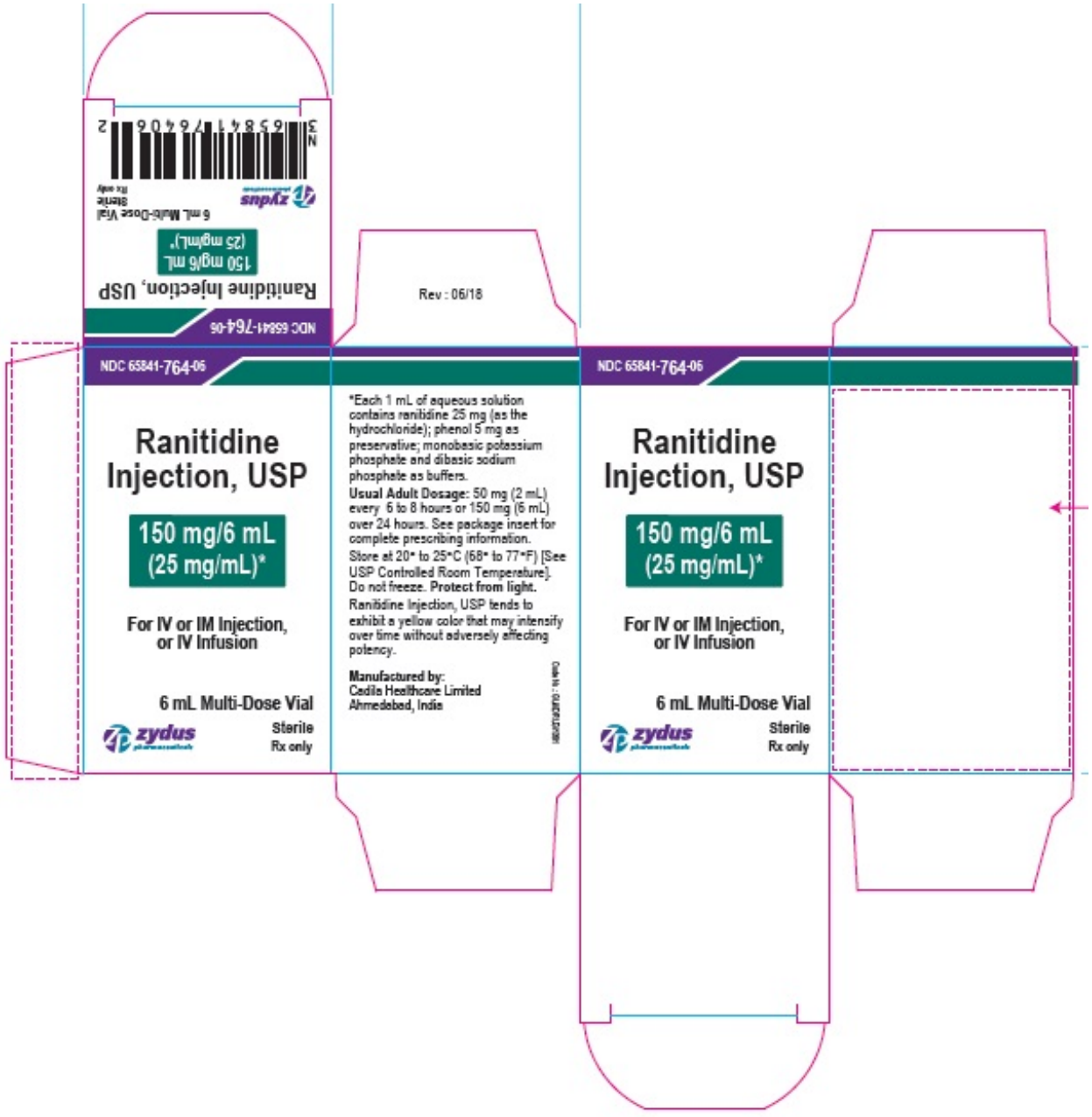
For IV or IM Injection, or IV Infusion

6 mL Multi-Dose Vial

Sterile

Rx only

Zydus Pharmaceuticals



RANITIDINE HYDROCHLORIDE
ranitidine hydrochloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-763
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)	5 mg in 1 mL
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-763-02	10 in 1 CARTON	03/01/2013	
1		2 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	ANDA091534	03/01/2013	

RANITIDINE HYDROCHLORIDE

ranitidine hydrochloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-764
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)	5 mg in 1 mL
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-764-06	6 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product	03/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091534	03/01/2013	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-763, 65841-764) , MANUFACTURE(65841-763, 65841-764)

Revised: 11/2022 Zydus Lifesciences Limited