FAMOTIDINE- famotidine injection
Zydus Lifesciences Limited

Famotidine Injection, USP
Rx Only

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

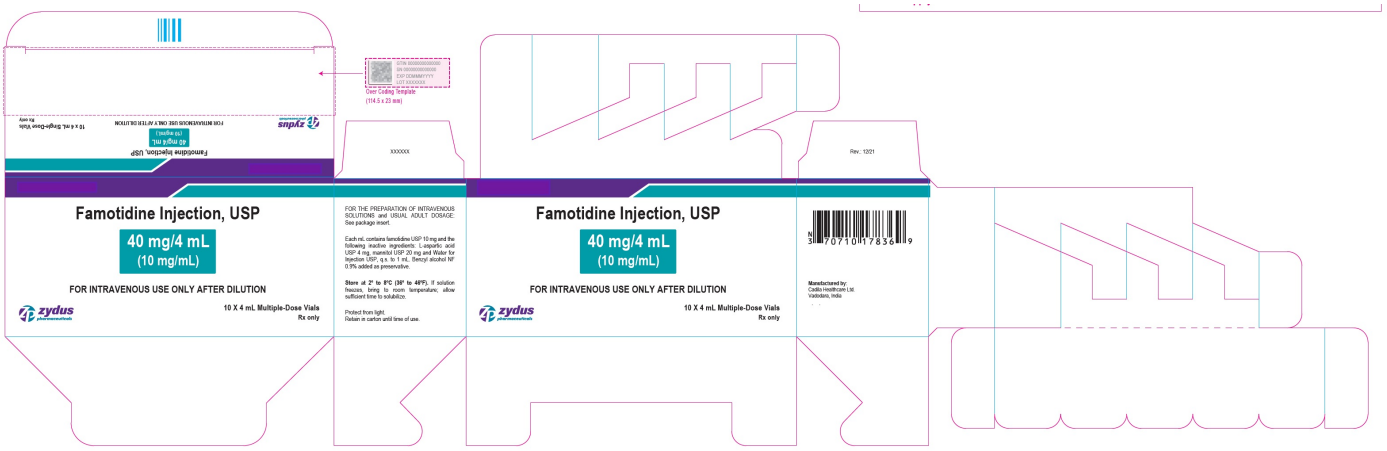
NDC 70771-1846-6

Famotidine Injection USP, 40 mg/4 mL (10 mg/mL)

FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS

10 X 4 mL Multiple-Dose Vials

Rx Only



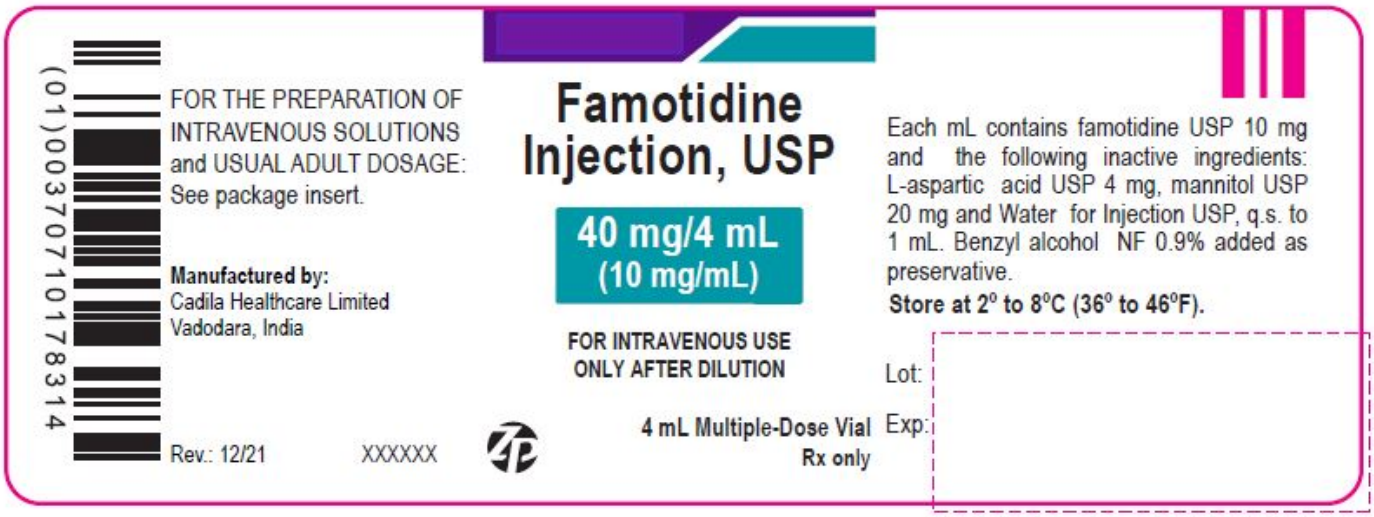
NDC 70771-1846-1

Famotidine Injection USP, 40 mg/4 mL (10 mg/mL)

FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS

4 mL Multiple-Dose Vials

Rx only



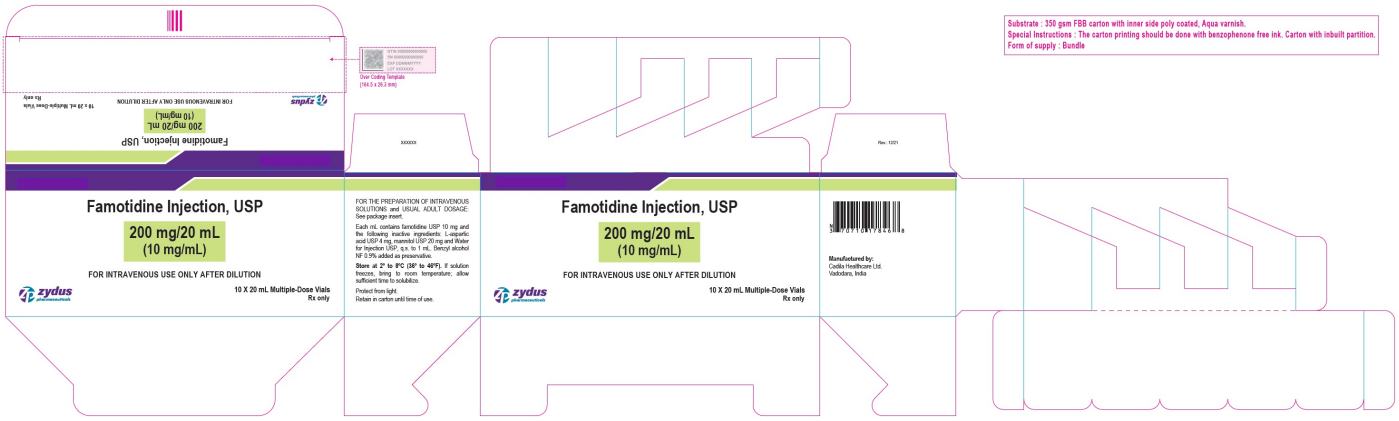
NDC 70771-1847-6

Famotidine Injection USP, 200 mg/20 mL (10 mg/mL)

FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS

10 X 20 mL Multiple-Dose Vials

Rx only



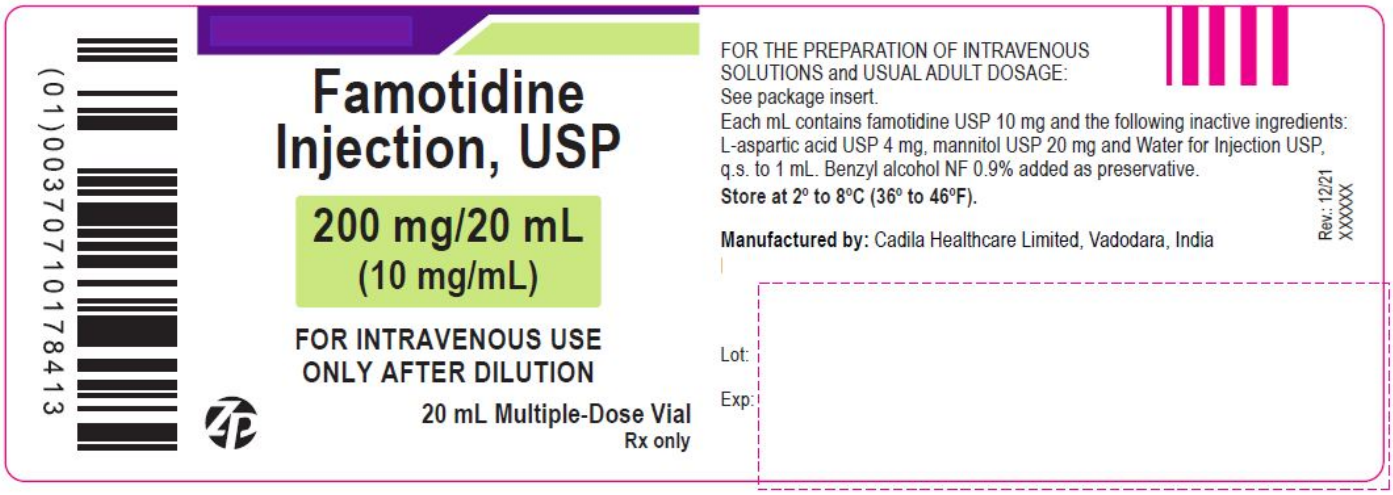
NDC 70771-1847-1

Famotidine Injection USP, 200 mg/20 mL (10 mg/mL)

FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS

20 mL Multiple-Dose Vials

Rx only



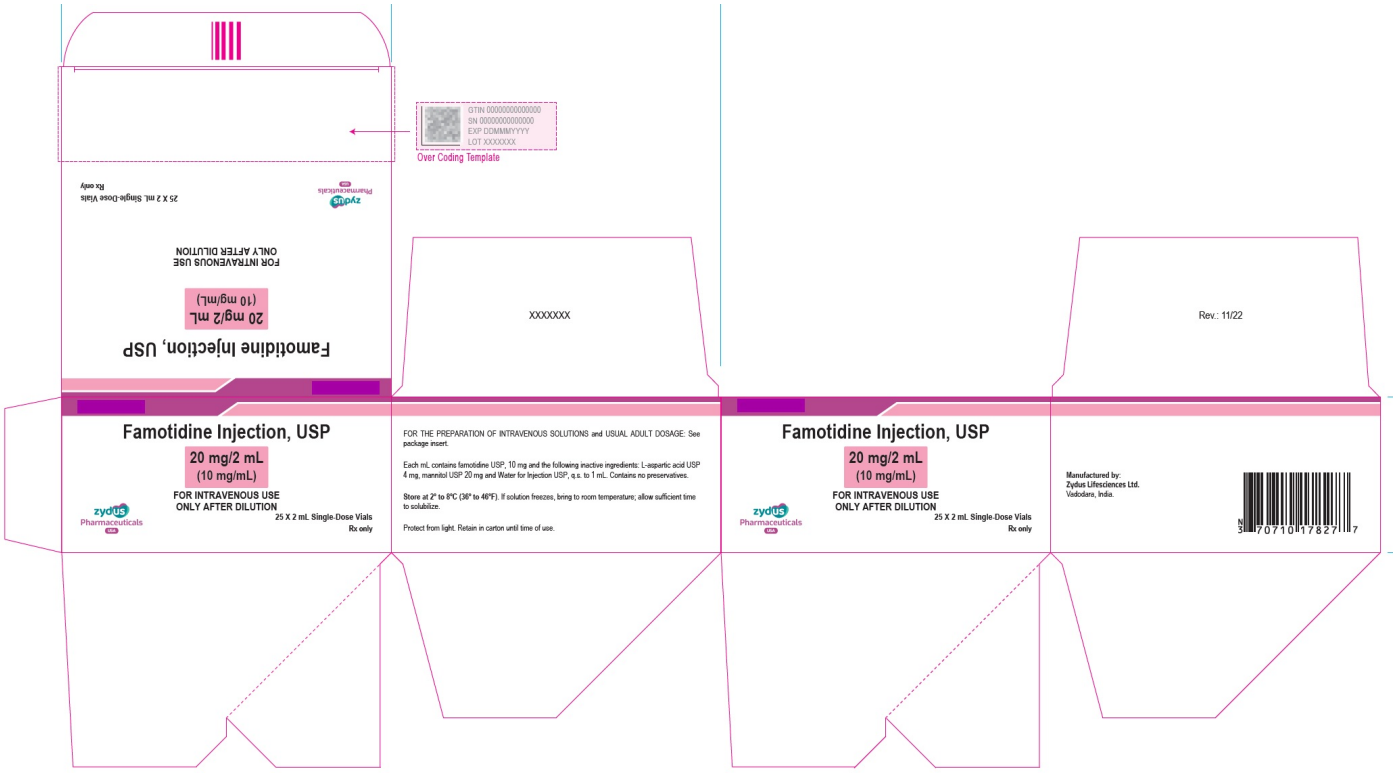
NDC 70771-1845-7

Famotidine Injection USP, 20 mg/2 mL (10 mg/mL)

FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS

25 X 2 mL Single-Dose Vials

Rx only



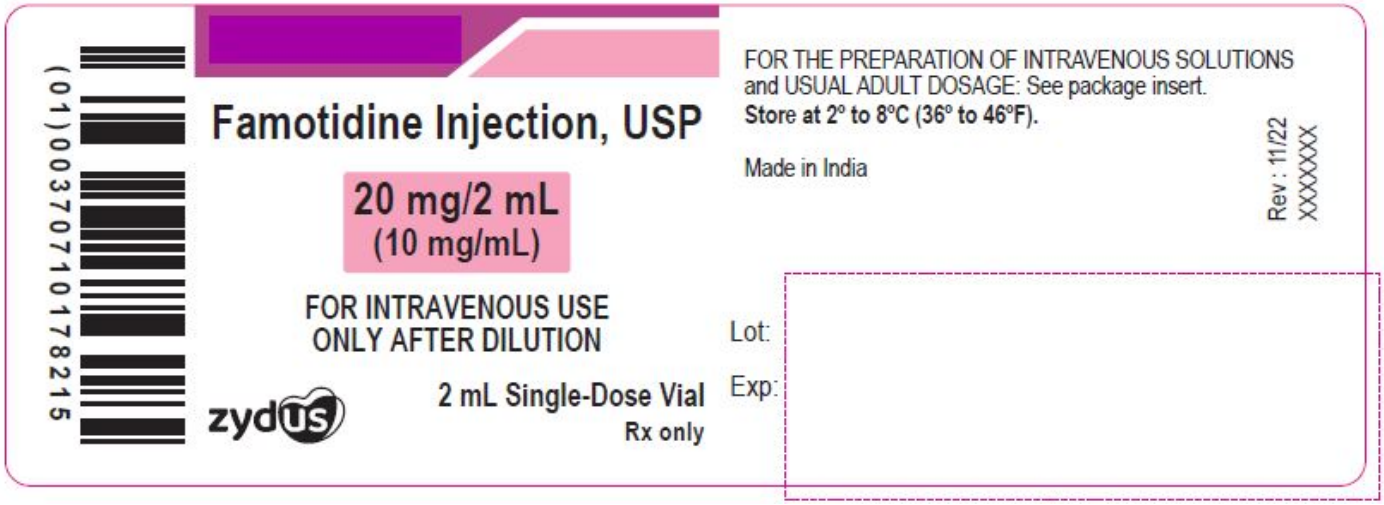
NDC 70771-1845-1

Famotidine Injection USP, 20 mg/2 mL (10 mg/mL)

FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS

2 mL Single-Dose Vials

Rx only



FAMOTIDINE

famotidine injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1846
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	40 mg in 4 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ASPARTIC ACID (UNII: 30KYC7MIAI)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MANNITOL (UNII: 3OWL53L36A)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1846-6	10 in 1 CARTON	02/11/2024	
1	NDC:70771-1846-1	4 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	ANDA215828	02/11/2024	

FAMOTIDINE

famotidine injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1847
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	200 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ASPARTIC ACID (UNII: 30KYC7MIAI)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MANNITOL (UNII: 3OWL53L36A)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1847-6	10 in 1 CARTON	02/11/2024	
1	NDC:70771-1847-1	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	ANDA215828	02/11/2024	

FAMOTIDINE

famotidine injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1845
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg in 2 mL

Inactive Ingredients

Ingredient Name	Strength
ASPARTIC ACID (UNII: 30KYC7MIAI)	
MANNITOL (UNII: 3OWL53L36A)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1845-7	25 in 1 CARTON	02/11/2024	
1	NDC:70771-1845-1	2 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215828	02/11/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		873671928	MANUFACTURE(70771-1846, 70771-1847, 70771-1845) , ANALYSIS(70771-1846, 70771-1847, 70771-1845)

Revised: 8/2023 Zydus Lifesciences Limited