FAMOTIDINE - famotidine tablet, film coated
Zydus Lifesciences Limited

Famotidine Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1702-3

Famotidine Tablets USP, 20 mg

30 Tablets

Rx only

NDC 70771-1703-3

Famotidine Tablets USP, 40 mg

30 Tablets

Rx only

FAMOTIDINE

famotidine tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1702
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (off white)	**Score**	no score

Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	Z21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1702-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	
2	NDC:70771-1702-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	
3	NDC:70771-1702-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	
4	NDC:70771-1702-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	
5	NDC:70771-1702-4	10 in 1 CARTON	06/06/2022	
5	NDC:70771-1702-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216441	06/06/2022	

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1703
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	40 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (off white)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	Z41
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1703-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	
2	NDC:70771-1703-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	
3	NDC:70771-1703-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	
4	NDC:70771-1703-4	10 in 1 CARTON	06/06/2022	
4	NDC:70771-1703-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:70771-1703-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216441	06/06/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1702, 70771-1703) , MANUFACTURE(70771-1702, 70771-1703)