

IBUPROFEN AND FAMOTIDINE- ibuprofen and famotidine tablet
Zydus Lifesciences Limited

Ibuprofen and Famotidine Tablets

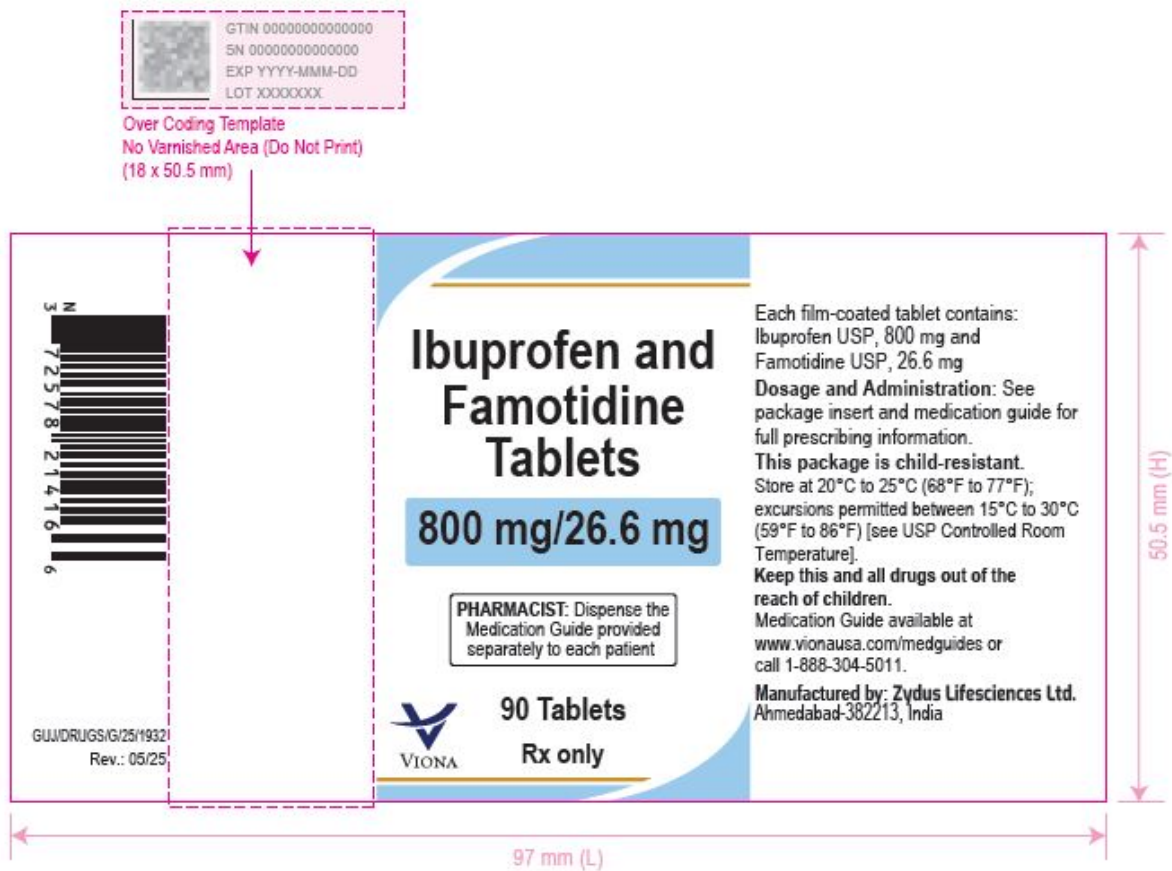
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ibuprofen and famotidine tablets, 800 mg/26.6 mg

90 Tablets

NDC 70771-1924-9

Rx only



IBUPROFEN AND FAMOTIDINE			
ibuprofen and famotidine tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1924
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	800 mg
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	26.6 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White to off-white)	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	777
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1924-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218684	06/01/2025	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (650199482)

Establishment			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1924) , MANUFACTURE(70771-1924)

Revised: 5/2025

Zydus Lifesciences Limited