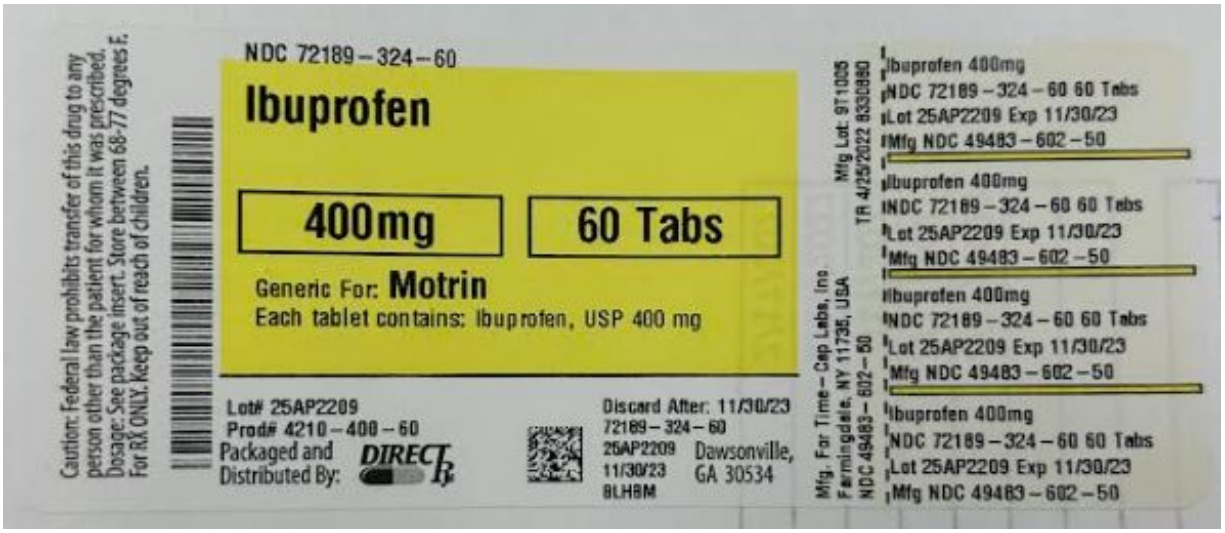
IBUPROFEN- ibuprofen tablet, film coated
Direct Rx

Ibuprofen

400mg (white to of white, round, biconvex, film coated tablets debossed with '121' on one side and plain on the other side) Bottles of 100 & 500

600mg (white to off white, capsule shaped, biconvex, film coated tablets debossed with '122' on one side and plain on the other side) Bottles of 30, 50, 100 & 500

800 mg (white to off-white, capsule shaped, biconvex, film-coated tablets debossed with ‘123’ on one side and plain on other side)



IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-324(NDC:49483-602)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	400 mg

Inactive Ingredients	
Ingredient Name	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	121
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-324-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2022	
2	NDC:72189-324-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090796	02/21/2022	

Labeler - Direct Rx (079254320)

Registrant - Direct Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct Rx		079254320	relabel(72189-324)

Revised: 1/2025 Direct Rx