

IBUPROFEN- ibuprofen tablet, film coated Direct Rx

Ibuprofen

400mg (white to off 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)

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.

Lot: 17FE2218
Prod# 4210-400-30
Packaged and Distributed By: **DIRECT Rx**

General For: **Motrin**
Each tablet contains: Ibuprofen, USP 400 mg

Ibuprofen
400mg
30 Tabs

Direct Agent: 7/31/23
72189-324-30
17FE2218
49483-802-50
KALF

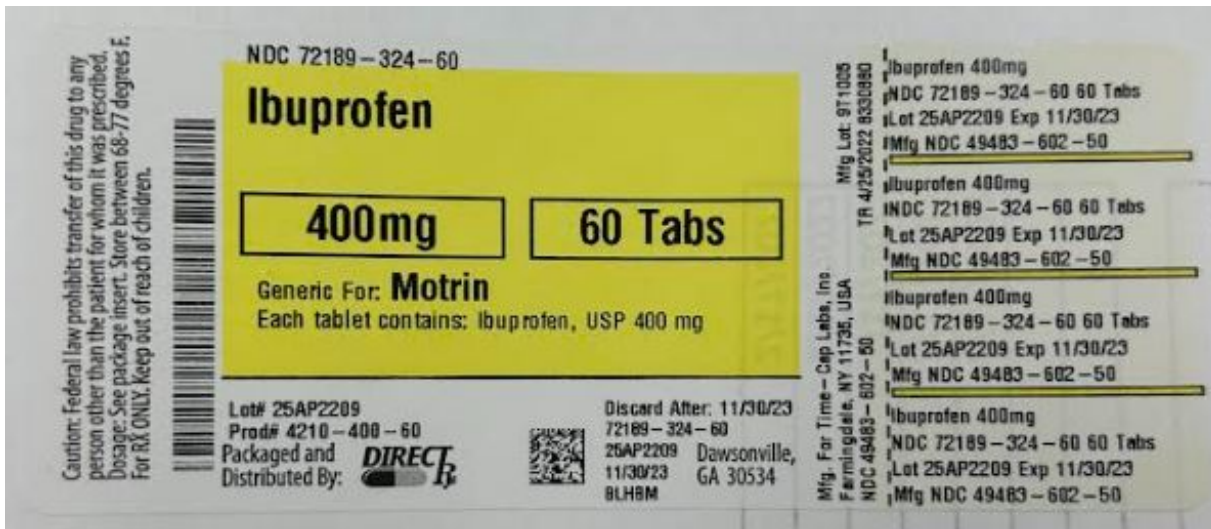
Mfg. For Time - Cap Labs, Inc.
Farringdale, NY 11735, USA
NDC 49483-802-50
Lot: 17FE2218 Exp 7/31/23
Mfg NDC 49483-802-50

Mfg Lot: 911004
TR 3/16/2022 8250892
NDC 72189-324-30 30 Tabs
Lot 17FE2218 Exp 7/31/23
Mfg NDC 49483-802-50

Ibuprofen 400mg
NDC 72189-324-30 30 Tabs
Lot 17FE2218 Exp 7/31/23
Mfg NDC 49483-802-50

Ibuprofen 400mg
NDC 72189-324-30 30 Tabs
Lot 17FE2218 Exp 7/31/23
Mfg NDC 49483-802-50

Ibuprofen 400mg
NDC 72189-324-30 30 Tabs
Lot 17FE2218 Exp 7/31/23
Mfg NDC 49483-802-50



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: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	400 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
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