

IBUPROFEN- ibuprofen tablet, film coated DIRECT RX

IBUPROFEN

[MEDGUIDE IBUPROFEN TABLETS]

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.

NDC 72189-231-21

IBUPROFEN

600mg **21 Tabs**

Generic For: **MOTRIN**
Each tablet contains: Ibuprofen, USP 600mg

Lot# 04JU2108
Prod# 4210-600-21
Packaged and Distributed By: **DIRECT RX**

Discard After: 1/31/23
72189-231-21
04JU2108 Dawsonville, GA 30534
BCAQH

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-21 21 Tabs
Lot 04JU2108 Exp 1/31/23
Mfg NDC 49483-603-50

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NDC 72189-266-40

IBUPROFEN

800mg **40 Tabs**

Generic For: **MOTRIN**
Each tablet contains: Ibuprofen, USP 800 mg.

Lot# 25AU2120
Prod# 4210-800-40
Packaged and Distributed By: **DIRECT RX**

Discard After: 1/31/23
72189-266-40
25AU2120 Dawsonville, GA 30534
BEKE6

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-40 40 Tabs
Lot 25AU2120 Exp 1/31/23
Mfg NDC 49483-604-50

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NDC 72189-266-30

IBUPROFEN

800mg **30 Tabs**

Generic For: **MOTRIN**
Each tablet contains: Ibuprofen, USP 800 mg.

Lot# 21SE2118
Prod# 4210-800-30
Packaged and Distributed By: **DIRECT RX**

Discard After: 2/28/23
72189-266-30
21SE2118 Dawsonville, GA 30534
BE35M

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-30 30 Tabs
Lot 21SE2118 Exp 2/28/23
Mfg NDC 49483-604-50

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NDC 72189-266-90

IBUPROFEN

800mg

90 Tabs

Generic For: **MOTRIN**
Each tablet contains: Ibuprofen, USP 800 mg.

Lot# 25AU2130
Prod# 4210-800-90
Packaged and Distributed By: **DIRECT Rx**

Discard After: 1/31/23
72189-266-90
25AU2130 Dawsonville, GA 30534
1/31/23
BCKYW

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-90 90 Tabs
Lot 25AU2130 Exp 1/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-90 90 Tabs
Lot 25AU2130 Exp 1/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-90 90 Tabs
Lot 25AU2130 Exp 1/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-90 90 Tabs
Lot 25AU2130 Exp 1/31/23
Mfg NDC 49483-604-50

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NDC 72189-266-71

IBUPROFEN

800mg

100 Tabs

Generic For: **MOTRIN**
Each tablet contains: Ibuprofen, USP 800 mg.

Lot# 190C2106
Prod# 4210-800-71
Packaged and Distributed By: **DIRECT Rx**

Discard After: 7/31/22
72189-266-71
190C2106 Dawsonville, GA 30534
7/31/22
BFGMG

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-604-01

IBUPROFEN 800mg
NDC 72189-266-71 100 Tabs
Lot 190C2106 Exp 7/31/22
Mfg NDC 49483-604-01

IBUPROFEN 800mg
NDC 72189-266-71 100 Tabs
Lot 190C2106 Exp 7/31/22
Mfg NDC 49483-604-01

IBUPROFEN 800mg
NDC 72189-266-71 100 Tabs
Lot 190C2106 Exp 7/31/22
Mfg NDC 49483-604-01

IBUPROFEN 800mg
NDC 72189-266-71 100 Tabs
Lot 190C2106 Exp 7/31/22
Mfg NDC 49483-604-01

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NDC 72189-266-72

IBUPROFEN

800mg

120 Tabs

Generic For: **MOTRIN**
Each tablet contains: Ibuprofen, USP 800 mg.

Lot# 22DE2123
Prod# 4210-800-72
Packaged and Distributed By: **DIRECT Rx**

Discard After: 5/31/23
72189-266-72
22DE2123 Dawsonville, GA 30534
5/31/23
BG832

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-72 120 Tabs
Lot 22DE2123 Exp 5/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-72 120 Tabs
Lot 22DE2123 Exp 5/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-72 120 Tabs
Lot 22DE2123 Exp 5/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-72 120 Tabs
Lot 22DE2123 Exp 5/31/23
Mfg NDC 49483-604-50

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NDC 72189-266-60

IBUPROFEN

800mg

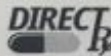
60 Tabs

Generic For: **MOTRIN**

Each tablet contains: ibuprofen, USP 800 mg.

Lot# 22DE2124
Prod# 4210-800-60

Packaged and
Distributed By:



Discard After: 5/31/23
72189-266-60

22DE2124
5/31/23
BGB4F

Dawsonville,
GA 30534

Mfg Lot: 9S1040
TR 12/22/2021 8202796

IBUPROFEN 800mg
NDC 72189-266-60 60 Tabs
Lot 22DE2124 Exp 5/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-60 60 Tabs
Lot 22DE2124 Exp 5/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-60 60 Tabs
Lot 22DE2124 Exp 5/31/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-60 60 Tabs
Lot 22DE2124 Exp 5/31/23
Mfg NDC 49483-604-50

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-604-50

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.

NDC 72189-231-90

IBUPROFEN

600mg

90 Tabs

Generic For: **MOTRIN**

Each tablet contains: ibuprofen, USP 600mg

Lot# 16AU2130
Prod# 4210-600-90

Packaged and
Distributed By:



Discard After: 1/31/23
72189-231-90
16AU2130
1/31/23
BGB4F

Dawsonville,
GA 30534

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-90 90 Tabs
Lot 16AU2130 Exp 1/31/23
Mfg NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-90 90 Tabs
Lot 16AU2130 Exp 1/31/23
Mfg NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-90 90 Tabs
Lot 16AU2130 Exp 1/31/23
Mfg NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-90 90 Tabs
Lot 16AU2130 Exp 1/31/23
Mfg NDC 49483-603-50

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NDC 72189-231-60

IBUPROFEN

600mg

60 Tabs

Generic For: **MOTRIN**

Each tablet contains: ibuprofen, USP 600mg

Lot# 16AU2128
Prod# 4210-600-60

Packaged and
Distributed By:



Discard After: 1/31/23
72189-231-60
16AU2128
1/31/23
BGB4F

Dawsonville,
GA 30534

Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-60 60 Tabs
Lot 16AU2128 Exp 1/31/23
Mfg NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-60 60 Tabs
Lot 16AU2128 Exp 1/31/23
Mfg NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-60 60 Tabs
Lot 16AU2128 Exp 1/31/23
Mfg NDC 49483-603-50

IBUPROFEN 600mg
NDC 72189-231-60 60 Tabs
Lot 16AU2128 Exp 1/31/23
Mfg NDC 49483-603-50



IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72189-266(NDC:49483-604)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		800 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

TALC (UNII: 7SEV7J4R1U)				
STARCH, CORN (UNII: O8232NY3SJ)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
Product Characteristics				
Color	white	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	123	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-266-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2021	
2	NDC:72189-266-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2021	
3	NDC:72189-266-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2021	
4	NDC:72189-266-71	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2021	
5	NDC:72189-266-72	120 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2021	
6	NDC:72189-266-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2021	
7	NDC:72189-266-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA090796		09/16/2021	

IBUPROFEN			
ibuprofen tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72189-231(NDC:49483-603)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	600 mg	
Inactive Ingredients				
Ingredient Name			Strength	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
Product Characteristics				
Color	white	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	122	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-231-21	21 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2021	
2	NDC:72189-231-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2021	
3	NDC:72189-231-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2021	
4	NDC:72189-231-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2021	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA090796	06/04/2021	

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(72189-231, 72189-266)

