

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,
1/31/23 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

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

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

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

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 72189-266-40

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,
1/31/23 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

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

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

IBUPROFEN 800mg
NDC 72189-266-40 40 Tabs
Lot 25AU2120 Exp 1/31/23
Mfg 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 72189-266-30

IBUPROFEN

800mg **30 Tabs**

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

Lot# 215E2118
Prod# 4210-800-30
Packaged and Distributed By: **DIRECT Rx**

Discard After: 2/28/23
72189-266-30
215E2118 Dawsonville,
2/28/23 GA 30534
BE30M

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

IBUPROFEN 800mg
NDC 72189-266-30 30 Tabs
Lot 215E2118 Exp 2/28/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-30 30 Tabs
Lot 215E2118 Exp 2/28/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-30 30 Tabs
Lot 215E2118 Exp 2/28/23
Mfg NDC 49483-604-50

IBUPROFEN 800mg
NDC 72189-266-30 30 Tabs
Lot 215E2118 Exp 2/28/23
Mfg 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 72189-266-90

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
4/31/23
BEKYW

Mfg. For Time - Cep 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

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 72189-266-71

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
8F0MG

Mfg. For Time - Cep 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

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 72189-266-72

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
8G832

Mfg. For Time - Cep 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

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 72189-266-60

IBUPROFEN

800mg

60 Tabs

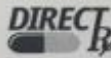
Generic For: **MOTRIN**

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 Dawsonville,
BGB4F GA 30534

Mfg Lot: 9S1040
TR 12/22/2021 8202796
Mfg. For Time - Cap Labs, Inc.
Farmingdale, NY 11735, USA
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

IBUPROFEN 800mg
NDC 72189-266-60 60 Tabs
Lot 22DE2124 Exp 5/31/23
Mfg 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 Dawsonville,
1/31/23 GA 30534
8EADN

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

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 72189-231-60

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 Dawsonville,
1/31/23 GA 30534
8055V

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

NDC 72189-231-30



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	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	800 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE 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: 70097M6I30)	
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	
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)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
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)

