

IBUPROFEN- ibuprofen tablet, film coated
TIME CAP LABORATORIES, INC

IBUPROFEN 400 MG - 600 MG AND 800 MG TABLETS

ibuprofen tablets 400 mg - 600 mg- 800 mg medguide

HOW SUPPLIED

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

HOW SUPPLIED

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)

400mg Ibuprofen 100 count label

NDC 49483-602-01

 **Time-Cap Labs, Inc.**

**IBUPROFEN
TABLETS, USP
400 mg**

Rx only 100 Tablets

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Each tablet contains:
Ibuprofen, USP 400 mg

DOSAGE AND USE
See package insert for complete product
information.

**Store at Controlled Room Temperature
20° to 25°C (68° to 77°F) [See USP].**

**Dispense in a tight container as defined
in the USP.**

Manufactured for: **Time-Cap Labs, Inc.**
7 Michael Avenue
Farmingdale, NY 11735, USA

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403 722, India
602R 0717



3 49483-602-01 2

Varnish Omit
Serialization Area

400 mg 500 count label

NDC 49483-602-50

 **Time-Cap Labs, Inc.**

**IBUPROFEN
TABLETS, USP
400 mg**

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Rx only 500 Tablets

Each tablet contains:
Ibuprofen, USP 400 mg

DOSAGE AND USE
See package insert for complete product
information.

**Store at Controlled Room Temperature
20° to 25°C (68° to 77°F) [See USP].**

**Dispense in a tight container as defined
in the USP.**

Manufactured for:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735, USA

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403 722, India
602R 0717



3 49483-602-50 0

Varnish Omit
Serialization Area

600 mg 100 count label

NDC 49483-603-01

 **Time-Cap Labs, Inc.**

**IBUPROFEN
TABLETS, USP
600 mg**

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Rx only **100 Tablets**
(Capsule Shaped)

Each tablet contains:
Ibuprofen, USP 600 mg

DOSAGE AND USE
See package insert for complete product
information.

Store at Controlled Room Temperature
20° to 25°C (68° to 77°F) (See USP).

**Dispense in a tight container as defined
in the USP.**

Manufactured for: **Time-Cap Labs, Inc.**
7 Michael Avenue
Farmingdale, NY 11735, USA

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403 722, India
603R 0717



Varnish Omit
Serialization Area

800 mg 100 count label

NDC 49483-604-01

 **Time-Cap Labs, Inc.**

**IBUPROFEN
TABLETS, USP
800 mg**

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Rx only 100 Tablets
(Capsule Shaped)

Each tablet contains:
Ibuprofen, USP 800 mg

DOSAGE AND USE
See package insert for complete product information.

Store at Controlled Room Temperature
20° to 25°C (68° to 77°F) (See USP).

Dispense in a tight container as defined in the USP.

Manufactured for:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735, USA

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Varna Indl. Estate,
Varna, Goa-403 722, India
604R 0717



Varnish Omit
Serialization Area

600 MG 500 COUNT LABEL

NDC 49483-603-50

 **Time-Cap Labs, Inc.**

**IBUPROFEN
TABLETS, USP
600 mg**

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Rx only **500 Tablets**
(Capsule Shaped)

Each tablet contains:
Ibuprofen, USP 600 mg

DOSE AND USE

See package insert for complete product information.

**Store at Controlled Room Temperature 20° to 25°C
(68° to 77°F) [See USP].**

Dispense in a tight container as defined in the USP.

Manufactured for:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735, USA


Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403 722, India
603R 0717



Varnish Omit
Serialization Area

800 MG 500 COUNT LABEL

NDC 49483-604-50



**IBUPROFEN
TABLETS, USP
800 mg**

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Rx only **500 Tablets**
(Capsule Shaped)

Each tablet contains:
Ibuprofen, USP 800 mg


DOSAGE AND USE
See package insert for complete product information.

**Store at Controlled Room Temperature 20° to 25°C
(68° to 77°F) [See USP].**

Dispense in a tight container as defined in the USP.

Manufactured for:
Time Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735, USA

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403 722, India
604R 0717



3 49483-604-504

Varnish Omit
Serialization Area

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:49483-602-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
2	NDC:49483-602-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090796	12/30/2015	

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:49483-603-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
2	NDC:49483-603-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
3	NDC:49483-603-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
4	NDC:49483-603-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090796	12/30/2015	

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

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:49483-604-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
2	NDC:49483-604-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
3	NDC:49483-604-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
4	NDC:49483-604-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090796	12/30/2015	

Labeler - TIME CAP LABORATORIES, INC (037052099)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-602, 49483-603, 49483-604)

Revised: 12/2019

TIME CAP LABORATORIES, INC