

IBUPROFEN- ibuprofen tablet, film coated
RedPharm Drug, Inc.

IBUPROFEN 400 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**

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

Rx only 100 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 49483-602-01 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 4 9483-602-50 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 Indi. 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



6048360401

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



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Varnish Omit
Serialization Area

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



(01)00367206168525
(21)100000000000082
(17)220131
(10)HK0001X1

NDC: 67296-1685-2

IBUPROFEN

400MG

20 Tablets

Rx Only

Lot: HK0001X1

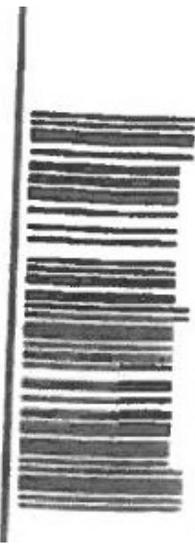
Exp: 01/22

Usual adult dosage: See package insert
Store at controlled room temperature: 20-25 C (68-77 F)

Mfg: **Marksans Pharma Ltd**
Verna Goa 403 722 India
49483-602-50

Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN 98133



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IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67296-1685(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)	
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	ROUND	Size	13mm
Flavor		Imprint Code	121
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1685-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	
2	NDC:67296-1685-3	30 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 - RedPharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
RedPharm Drug		828374897	repack(67296-1685)

Revised: 8/2024

RedPharm Drug, Inc.