

**IBUPROFEN- ibuprofen tablet, film coated**  
**UNIT DOSE SERVICES**

-----

**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)

NDC: 50436-0323-1

IBUPROFEN

800 MG / 30 TAB

Each tablet contains: Ibuprofen, USP 800 mg  
Dispense in a light container  
as defined in The USP.

**Pharmacist:** Dispense the Medication Guide  
provided separately to each patient.

WARNING: KEEP OUT OF REACH OF CHILDREN.  
STORE AT 20-25 ° C ( 68-77 ° F ) CONTROLLED  
ROOM TEMPERATURE. AVOID EXCESSIVE HEAT  
ABOVE 40 ° C (104 ° F ). SEE PACKAGE  
INSERT FOR DOSAGE INFORMATION.



MFG FOR:  
TIME CAP LABS, INC.  
FARMINGDALE, NY 11735, USA  
MFG NDC: 49483-604-50  
MFG LOT: XXXXXX  
SERIAL: XXXXX999999  
LOT: XXXXX EXP: XXXXX

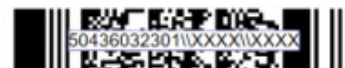
Pkg by: Unit Dose Services, LLC Dania, FL 33004

Rev. 1 RX ONLY

NDC: 50436-0323-1  
DRUG: IBUPROFEN 800 MG / 30 TAB  
LOT: XXXXX EXP: XXXXX

NDC: 50436-0323-1  
DRUG: IBUPROFEN 800 MG / 30 TAB  
LOT: XXXXX EXP: XXXXX

NDC: 50436-0323-1  
DRUG: IBUPROFEN 800 MG / 30 TAB  
LOT: XXXXX EXP: XXXXX



NDC: 50436-0323-2

IBUPROFEN

800 MG / 60 TAB

Each tablet contains: Ibuprofen, USP 800 mg  
Dispense in a light container  
as defined in The USP.

**Pharmacist:** Dispense the Medication Guide  
provided separately to each patient.

WARNING: KEEP OUT OF REACH OF CHILDREN.  
STORE AT 20-25 ° C ( 68-77 ° F ) CONTROLLED  
ROOM TEMPERATURE. AVOID EXCESSIVE HEAT  
ABOVE 40 ° C (104 ° F ). SEE PACKAGE  
INSERT FOR DOSAGE INFORMATION.



MFG FOR:  
TIME CAP LABS, INC.  
FARMINGDALE, NY 11735, USA  
MFG NDC: 49483-604-50  
MFG LOT: XXXXXX  
SERIAL: XXXXX999999  
LOT: XXXXX EXP: XXXXX

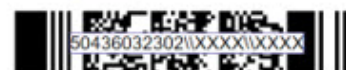
Pkg by: Unit Dose Services, LLC Dania, FL 33004

Rev. 1 RX ONLY

NDC: 50436-0323-2  
DRUG: IBUPROFEN 800 MG / 60 TAB  
LOT: XXXXX EXP: XXXXX

NDC: 50436-0323-2  
DRUG: IBUPROFEN 800 MG / 60 TAB  
LOT: XXXXX EXP: XXXXX

NDC: 50436-0323-2  
DRUG: IBUPROFEN 800 MG / 60 TAB  
LOT: XXXXX EXP: XXXXX



NDC: 50436-0323-3

IBUPROFEN

800 MG / 90 TAB

Each tablet contains: Ibuprofen, USP 800 mg  
Dispense in a light container  
as defined in The USP.

**Pharmacist:** Dispense the Medication Guide  
provided separately to each patient.

WARNING: KEEP OUT OF REACH OF CHILDREN.  
STORE AT 20-25 ° C ( 68-77 ° F ) CONTROLLED  
ROOM TEMPERATURE. AVOID EXCESSIVE HEAT  
ABOVE 40 ° C (104 ° F ). SEE PACKAGE  
INSERT FOR DOSAGE INFORMATION.



MFG FOR:  
TIME CAP LABS, INC.  
FARMINGDALE, NY 11735, USA  
MFG NDC: 49483-604-50  
MFG LOT: XXXXXX  
SERIAL: XXXXX999999  
LOT: XXXXX EXP: XXXXX

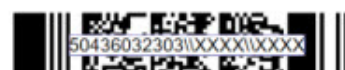
Pkg by: Unit Dose Services, LLC Dania, FL 33004

Rev. 1 RX ONLY

NDC: 50436-0323-3  
DRUG: IBUPROFEN 800 MG / 90 TAB  
LOT: XXXXX EXP: XXXXX

NDC: 50436-0323-3  
DRUG: IBUPROFEN 800 MG / 90 TAB  
LOT: XXXXX EXP: XXXXX

NDC: 50436-0323-3  
DRUG: IBUPROFEN 800 MG / 90 TAB  
LOT: XXXXX EXP: XXXXX



## IBUPROFEN

ibuprofen tablet, film coated

### Product Information

|                         |                            |                       |                                   |
|-------------------------|----------------------------|-----------------------|-----------------------------------|
| Product Type            | HUMAN PRESCRIPTION<br>DRUG | Item Code<br>(Source) | NDC:50436-0323(NDC:49483-<br>604) |
| Route of Administration | ORAL                       |                       |                                   |

| Active Ingredient/Active Moiety                            |                  |                                                   |                      |                    |
|------------------------------------------------------------|------------------|---------------------------------------------------|----------------------|--------------------|
| Ingredient Name                                            |                  | Basis of Strength                                 | Strength             |                    |
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) |                  | IBUPROFEN                                         | 800 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                                              | 19mm                 |                    |
| Flavor                                                     |                  | Imprint Code                                      | 123                  |                    |
| Contains                                                   |                  |                                                   |                      |                    |
|                                                            |                  |                                                   |                      |                    |
| Packaging                                                  |                  |                                                   |                      |                    |
| #                                                          | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
| 1                                                          | NDC:50436-0323-1 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 06/28/2023           |                    |
| 2                                                          | NDC:50436-0323-2 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 06/28/2023           |                    |
| 3                                                          | NDC:50436-0323-3 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 06/28/2023           |                    |
|                                                            |                  |                                                   |                      |                    |
| Marketing Information                                      |                  |                                                   |                      |                    |
| Marketing Category                                         |                  | Application Number or Monograph Citation          | Marketing Start Date | Marketing End Date |
| ANDA                                                       |                  | ANDA090796                                        | 12/30/2015           |                    |

**Labeler** - UNIT DOSE SERVICES (831995316)

## Establishment

| Name               | Address | ID/FEI    | Business Operations |
|--------------------|---------|-----------|---------------------|
| UNIT DOSE SERVICES |         | 831995316 | repack(50436-0323)  |

