

IBUPROFEN- ibuprofen tablet, film coated
Topco Associates, LLC

TopCare 44-393

Active ingredient (in each orange caplet)

Ibuprofen USP, 200 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - menstrual cramps
 - backache
 - toothache
 - the common cold
 - minor pain of arthritis
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- have had stomach ulcers or bleeding problems
- are age 60 or older
- take a blood thinning (anticoagulant) or steroid drug
- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs [aspirin,

ibuprofen, naproxen, or others]

- have 3 or more alcoholic drinks every day while using this product

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - weakness in one part or side of body
 - leg swelling
 - trouble breathing
 - slurred speech
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen at 20

weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 1 caplet every 4 to 6 hours while symptoms persist
 - if pain or fever does not respond to 1 caplet, 2 caplets may be used
 - do not exceed 6 caplets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)
- use by expiration date on package

Inactive ingredients

carnauba wax, colloidal silicon dioxide, corn starch, FD&C yellow #6 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

Call 1-888-423-0139

Principal Display Panel

+TopCare®
health

NDC 36800-993-06

COMPARE TO MOTRIN® IB CAPLETS
ACTIVE INGREDIENT†

Ibuprofen

Tablets USP, 200 mg

- PAIN RELIEVER
 - FEVER REDUCER
- (NSAID)**

200 CAPLETS

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007

©TOPCO LNKA0521 QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

Visit here for more information: <http://topbrnds.com/48ZZSN>

†This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Motrin® IB Caplets. 50844 REV1221C39306



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No Print / No Varnish Area
Lot # and Exp. Info

Drug Facts Purpose

Active ingredient (in each orange caplet) Ibuprofen USP, 200 mg (NSAID)*. *Pain reliever/fever reducer, nonsteroidal anti-inflammatory drug

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- right before or after heart surgery

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- you are taking a diuretic

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PEEL HERE FOR MORE DRUG FACTS

STOP PEELING

Inactive ingredients: carnuba wax, colloidal silicon dioxide, corn starch, FD&C yellow #6 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments? Call 1-888-423-0139

Drug Facts (continued)

■ you have problems or serious side effects from taking pain relievers or fever reducers

■ you have a history of stomach problems, such as heartburn

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TopCare 44-393

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-993

Route of Administration ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|--------|--------------|----------|
| Color | orange | Score | no score |
| Shape | OVAL | Size | 14mm |
| Flavor | | Imprint Code | 44;393 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:36800-993-06 | 200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/01/1999 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA075139 | 03/01/1999 | |

Labeler - Topco Associates, LLC (006935977)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| LNK International, Inc. | | 038154464 | pack(36800-993) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| LNK International, Inc. | | 832867837 | manufacture(36800-993) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| LNK International, Inc. | | 832867894 | manufacture(36800-993) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| LNK International, Inc. | | 868734088 | manufacture(36800-993) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| LNK International, Inc. | | 967626305 | pack(36800-993) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| LNK International, Inc. | | 117025878 | manufacture(36800-993) |