IBUPROFEN- ibuprofen tablet, film coated
Topco Associates, LLC

TopCare 44-292

Active ingredient (in each brown 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, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

Call 1-888-423-0139

Principal Display Panel

+TopCare®
health

NDC 36800-292-06

COMPARE TO ADVIL® 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

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topcare@topco.com www.topcarebrand.com
Visit here for more information: http://topbrnds.com/48ZZSM

†This product is not manufactured or distributed by PF Consumer Healthcare 1 LLC, owner of the registered trademark Advil® Caplets.

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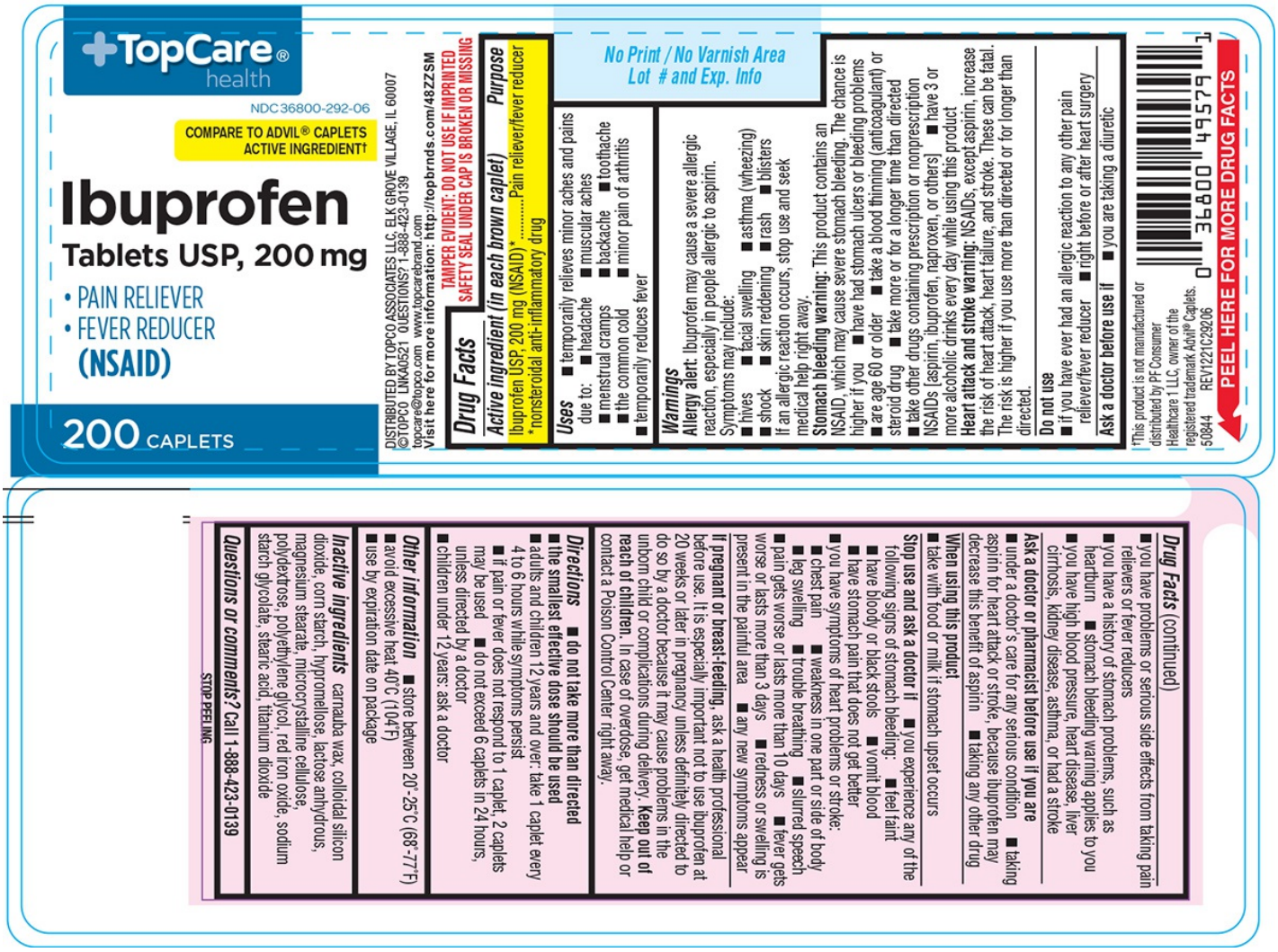

TopCare 44-292

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-292
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	44;292
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-292-06	200 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/1988	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	05/24/1988	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(36800-292)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(36800-292)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-292)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-292)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(36800-292)

Revised: 6/2025 Topco Associates, LLC