IBUPROFEN- ibuprofen tablet, film coated
L.N.K. International, Inc.

Ibuprofen Tablets USP, 200 mg

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
  - toothache
  - backache
  - menstrual cramps
  - the common cold
  - muscular aches
  - 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)
- skin reddening
- shock
- 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:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- 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
- take more or for a longer time than directed

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

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

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- 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
  - vomit blood
  - have bloody or black stools
  - 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
  - trouble breathing
  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- any new symptoms appear
- redness or swelling is present in the painful area

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of 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 (1-800-222-1222) 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 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal Display Panel

Quality
+ Plus

NDC 50844-292-16

†Compare to active ingredient
in Advil® Caplets

IBUPROFEN TABLETS
USP, 200 mg

PAIN RELIEVER/
FEVER REDUCER (NSAID)

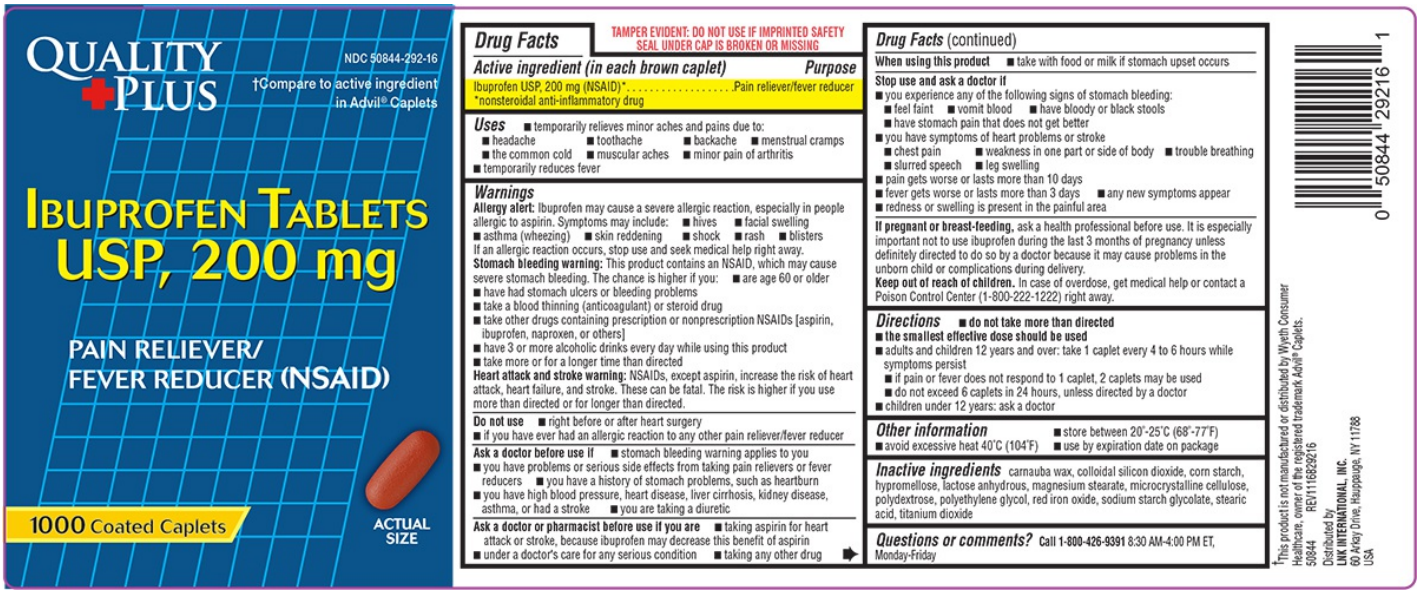
1000 Coated Caplets

ACTUAL
SIZE

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

†This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Advil® Caplets.
50844 REV1116B29216

Distributed by
LNK INTERNATIONAL, INC.
60 Arkay Drive, Hauppauge, NY 11788
USA



Quality Plus 44-292 REV1116

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-292
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

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:50844-292-02	1 in 1 CARTON	05/24/1988	
1		12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50844-292-08	1 in 1 CARTON	05/24/1988	
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:50844-292-01	1 in 1 CARTON	05/24/1988	
3		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:50844-292-15	1 in 1 CARTON	05/24/1988	
4		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:50844-292-11	1 in 1 CARTON	05/24/1988	
5		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:50844-292-12	1 in 1 CARTON	05/24/1988	
6		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:50844-292-13	1 in 1 CARTON	05/24/1988	
7		250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:50844-292-00	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1988	
9	NDC:50844-292-14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1988	
10	NDC:50844-292-16	1000 in 1 BOTTLE, PLASTIC; 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 - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-292)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(50844-292)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(50844-292)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(50844-292)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-292)

Revised: 4/2020 L.N.K. International, Inc.