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

Quality Plus 44-744

Active ingredient (in each tablet)

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

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains associated with

- headache
- menstrual cramps
- toothache
- backache
- minor arthritis pain
- the common cold
- muscular aches

Temporarily reduces fever.

Warnings

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

- hives
- shock
- skin reddening
- asthma (wheezing)
- facial swelling
- 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
- 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 have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- 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
  - trouble breathing

- leg swelling
- slurred speech
- weakness in one part or side of body

- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling is present in the painful area
- any new or unexpected symptoms occur

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 specifically 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 use more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)

Adults and children 12 years and over:	Take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used. Do not exceed 6 tablets in

	24 hours, unless directed by a doctor.
Children under 12 years:	Ask a doctor.

Other information

- read all product information before using
- store at 68°-77°F (20°-25°C)
- avoid excessive heat 104°F (above 40°C)
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

carnauba wax*, corn starch, hypromellose*, iron oxide red, lactose*, magnesium stearate*, microcrystalline cellulose*, polydextrose*, polyethylene glycol, polyvinyl alcohol*, povidone (K-30)*, silicon dioxide, sodium starch glycolate, stearic acid, talc*, titanium dioxide

*may contain

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET,

Monday-Friday

Principal display panel

NDC 50844-269-24

QUALITY PLUS

†Compare to active ingredient in Advil® Tablets

IBUPROFEN
TABLETS, 200 mg

PAIN RELIEVER/
FEVER REDUCER (NSAID)

60 Packets of 2 Tablets each
200 mg each

ACTUAL SIZE

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF PACKET IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

†This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Advil® Tablets.

50844 ORG

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

44-744

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-269
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)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (reddish brown)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-269-24	60 in 1 CARTON	11/18/2019	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	11/18/2019	

Labeler - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(50844-269)

Revised: 12/2023 L.N.K. International, Inc.