

**IBUPROFEN- ibuprofen tablet**  
**Wildman Business Group**

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**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 due to:

- headache
- muscular aches
- the common cold
- backache
- minor pain of arthritis
- temporarily reduces fever
- toothache
- menstrual cramps

**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:**

- 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:**

- 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
  - leg swelling
  - slurred speech
  - trouble breathing
- 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 at 20

weeks or later in 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**

Adults and children 12 years and over:

- **do not take more than directed**
- **the smallest effective dose should be used**
- 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
- tamper evident. Do not use if packet is torn or opened
- store between 68°-77°F (20°-25°C)
- avoid excessive heat 104°F (40°C)
- use by expiration date on package

### **Inactive Ingredients**

carnauba wax, silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

### **Principal Display Panel - 250 Tablet Box Label**

**2525**

Flex-Prin

Ibuprofen

Compare to Advil

- Fast Acting Fever Reducer
- Relieves Headaches & Joint Pains
- Compare to Advil

The Provision

First Aid

Line™

BY WILDMAN



# IBUPROFEN

ibuprofen tablet

## Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:84269-2525

**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: 3WJQ0SDW1A)	
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 (brown)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	44;291
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84269-2525-2	125 in 1 BOX	08/19/2024	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:84269-2525-1	50 in 1 BOX	08/19/2024	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	08/19/2024	

**Labeler** - Wildman Business Group (016677338)

## Establishment

Name	Address	ID/FEI	Business Operations
Future Pak, Ltd.		087737672	PACK(84269-2525)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	MANUFACTURE(84269-2525)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(84269-2525)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(84269-2525)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(84269-2525)

Revised: 8/2024

Wildman Business Group