

**IBUPROFEN- ibuprofen tablet, film coated**  
**WALGREEN CO.**

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**Walgreens 44-392**

***Active ingredient (in each orange tablet)***

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)
- 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:

- are age 60 or older
- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

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

#### **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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

#### **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
- redness or swelling is present in the painful area
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- any new symptoms appear

#### **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 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 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***

- store between 20°-25°C (68°-77°F)

- avoid excessive heat 40°C (104°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

carnauba wax, cellulose, corn starch, FD&C yellow #6 aluminum lake, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, 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**

Well at

**Walgreens**

WALGREENS PHARMACIST RECOMMENDED<sup>□</sup>

NDC 0363-0392-12

### **Ibuprofen 200**

Ibuprofen Tablets

USP 200 mg / Pain Reliever /

Fever Reducer (**NSAID**)

**100**

TABLETS

**Compare to Motrin<sup>®</sup> IB Tablets active ingredient<sup>□□</sup>**

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

<sup>□</sup>Walgreens Pharmacist Survey Study, November 2010.

<sup>□□</sup>This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Motrin<sup>®</sup> IB Tablets.

50844 ORG041139212



**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (IBUPROFEN)	IBUPROFEN	200 mg

**Inactive Ingredients**

Ingredient Name	Strength
CARNAUBA WAX	
FD&C YELLOW NO. 6	
HYPROMELLOSES	
LACTOSE	
MAGNESIUM STEARATE	
POLYDEXTROSE	
POLYETHYLENE GLYCOLS	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STEARIC ACID	
TITANIUM DIOXIDE	

**Product Characteristics**

Color	ORANGE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	44;392
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0392-15	1 in 1 CARTON		
1		50 in 1 BOTTLE; Combination Product Type = C112160		
2	NDC:0363-0392-12	1 in 1 CARTON		
2		100 in 1 BOTTLE; Combination Product Type = C112160		
3	NDC:0363-0392-14	500 in 1 BOTTLE; Combination Product Type = C112160		
4	NDC:0363-0392-16	1000 in 1 BOTTLE; Combination Product Type = C112160		
5	NDC:0363-0392-17	300 in 1 BOTTLE; Combination Product Type = C112160		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075139	03/30/2002	

**Labeler** - WALGREEN CO. (008965063)**Establishment**

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		038154464	PACK(0363-0392)
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## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0392)

Revised: 12/2014

WALGREEN CO.