# DYE FREE IBUPROFEN- ibuprofen tablet WALGREEN CO.

-----

Walgreens 44-438

## Active ingredient (in each white 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 pains 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
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspiring, 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

#### 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

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

## Ask a doctor or pharmacist before use if

- 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
- 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 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
- 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 pains 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 and lot number

## **Inactive ingredients**

corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, triacetin

#### 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

NDC 0363-0438-12

## Ibuprofen

200

**Ibuprofen** Tablets

USP 200 mg / Pain Reliever /

Fever Reducer (NSAID)

100 TABLETS

DYE FREE

Compare to Motrin® IB Tablets active ingredient III

Walgreens Pharmacist Survey Study, November 2010

IIIThis product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Motrin® IB Tablets.

50844 ORG041143812

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



Walgreens 44-438

# **DYE FREE IBUPROFEN** ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0363-0438
Route of Administration	ORAL	DEA Schedule	

## **Active Ingredient/Active Moiety**

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

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSES	
LACTOSE	
TRIACETIN	
MAGNESIUM STEARATE	
STEARIC ACID	

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	44;438
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:0363-0438-12	1 in 1 CARTON			
1	100 in 1 BOTTLE			
2 NDC:0363-0438-15	1 in 1 CARTON			
2	50 in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075139	03/11/2004		

## Labeler - WALGREEN CO. (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0438)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0438)

Revised: 9/2013 WALGREEN CO.