

DYE FREE IBUPROFEN- ibuprofen tablet, film coated
Walgreen Company

Walgreens 44-438-ADR

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 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:

- rash
- facial swelling
- asthma (wheezing)
- hives
- skin reddening
- shock
- 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:

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

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 a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- 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

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
- you have symptoms of heart problems or stroke
 - chest pain
 - slurred speech
 - leg swelling
 - trouble breathing
 - weakness in one part or side of body
- 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 (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 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

corn starch, colloidal silicon dioxide, hypromellose, lactose anhydrous, 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 0363-0438-99

Dye-Free

Ibuprofen

Ibuprofen Tablets USP, 200 mg /

Pain Reliever / Fever Reducer (**NSAID**)

100 TABLETS

DYE

FREE

Compare to Advil[®] Tablets
active ingredient^{¶¶}

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

[‡] Walgreens Pharmacist Survey Study, November 2016.

^{¶¶} This product is not manufactured or distributed by
Wyeth Consumer Healthcare, owner of the registered
trademark Advil[®] Tablets.

50844 REV1116C43812

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED

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Do not print/Warnish
No Print Area
Lot no. & Exp. Date

ITEM 550376
3 119177 08820 4
TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

B-2201-438-12-ADR
REV1116C43812

ORG1012-F_R05

Drug Facts (continued)

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- any new symptoms appear

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When using this product

- take with food or milk if stomach upset occurs
- Stop use and ask a doctor if
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 - nausea or black stools
 - vomit blood
 - stomach pain that does not get better
 - you have symptoms of heart problems or stroke
 - chest pain
 - stuffed speech
 - leg swelling
 - trouble breathing
 - weakness in one part or side of body
 - pain gets worse or lasts more than 10 days
 - fever gets worse or lasts more than 3 days

Questions or comments?
Monday-Friday
Call 1-800-426-9391 8:30 AM-4:00 PM ET.
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- disorders

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Drug Facts (continued)

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*Walgreens Pharmacist Survey Study, November 2016.
†This product is not manufactured or distributed by Walgreen Consumer Healthcare, owner of the registered trademark, Advil® Tablets.
50644 REV1116C43812

NDC 0363-0438-99

Dye-Free
Ibuprofen

WALGREENS PHARMACIST RECOMMENDED*

Ibuprofen Tablets USP, 200 mg /
Pain Reliever / Fever Reducer (NSAID)

100 TABLETS

Compare to Advil® Tablets
active ingredient**

Well at Walgreens

DYE FREE

Walgreens 44-438

DYE FREE IBUPROFEN		
ibuprofen tablet, film coated		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	ORAL	NDC:0363-0438
Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	10mm
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	03/01/1999	04/07/2019
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0438-15	1 in 1 CARTON	03/01/1999	10/08/2016
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-0438-99	1 in 1 CARTON	03/01/1999	08/02/2021
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075139	03/01/1999	08/02/2021

Labeler - Walgreen Company (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)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0363-0438)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-0438)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0363-0438)

Revised: 4/2020

Walgreen Company