IBUPROFEN 200- ibuprofen tablet, film coated Walgreen Company

Walgreens 44-393

Active ingredient (in each orange caplet)

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

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - the common cold
 - minor pain of arthritis
 - backache
 - menstrual cramps
 - toothache
 - muscular aches
- temporarily reduces fever

Warnings

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

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

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
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- are age 60 or older

- 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 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
- 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 at 20

weeks or later in 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 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets 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)
- use by expiration date on package

Inactive ingredients

carnauba wax, colloidal silicon dioxide, corn starch, FD&C yellow #6 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, 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

NDC 0363-0393-20

Walgreens Compare to the active ingredient in Motrin® IB Caplets^{††}

• WALGREENS • PHARMACIST RECOMMENDED[†]

EASY OPEN

Ibuprofen 200

IBUPROFEN TABLETS USP, 200 mg/ PAIN RELIEVER/FEVER REDUCER (NSAID) **ACTUAL SIZE**

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

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

50844 ORG122139320

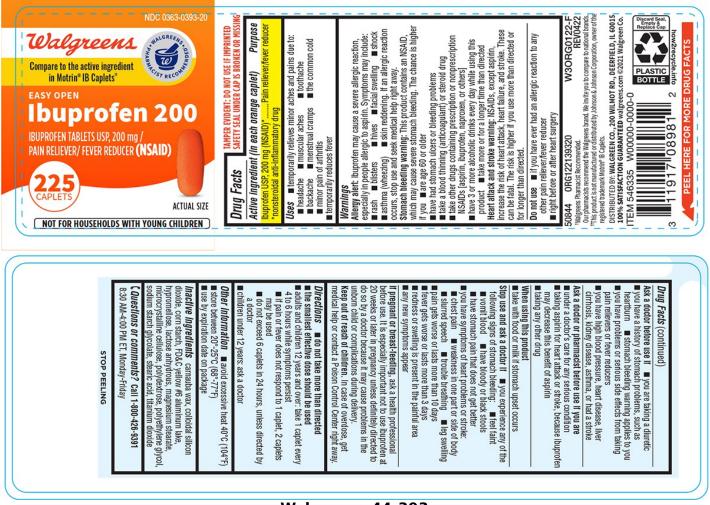
[†]Walgreens Pharmacist Recommended.

Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

††This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the

registered trademark Motrin® IB Caplets.

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Walgreens 44-393

IBUPROFEN 200

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-0393

Route of Administration ORAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	BUPROFEN (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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics					
Color	orange	Score	no score		
Shape	OVAL	Size	14mm		
Flavor		Imprint Code	44;393		
Contains					

P	Packaging						
#	# Item Code Package Description		Marketing Start Date	Marketing End Date			
1	NDC:0363- 0393-20	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/1999				
2	NDC:0363- 0393-15	1 in 1 CARTON	03/01/1999	01/08/2022			
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product					
3	NDC:0363- 0393-14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/1999	04/22/2023			
4	NDC:0363- 0393-37	1 in 1 CARTON	03/01/1999	02/07/2021			
4		75 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product					

5	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product						
Marketing	Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
ANDA	ANDA075139	03/01/1999					

03/01/1999

04/07/2023

Labeler - Walgreen Company (008965063)

1 in 1 CARTON

5 NDC:0363-0393-12

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	pack(0363-0393)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867837	manufacture(0363-0393)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867894	manufacture(0363-0393)		

Establishment						
Name	Address	ID/FEI	Business Operations			
LNK International, Inc.		868734088	manufacture(0363-0393)			

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		967626305	pack(0363-0393)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		117025878	manufacture(0363-0393)		

Revised: 7/2023 Walgreen Company