IBUPROFEN- ibuprofen tablet, film coated Walgreen Company

Walgreens 44-291

Active ingredient (in each brown 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
 - backache
 - toothache
 - the common cold
 - muscular aches
 - menstrual cramps
 - 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:

- 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

- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- 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

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 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
 - 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
 - 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
- 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 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)
- use by expiration date on package

Inactive ingredients

carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, 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

Walgreens

Compare to Advil® Tablets active ingredient††

NDC 0363-0291-08

Ibuprofen

IBUPROFEN USP, 200 mg / PAIN RELIEVER / FEVER REDUCER (NSAID)

TABLETS

24 TABLETS

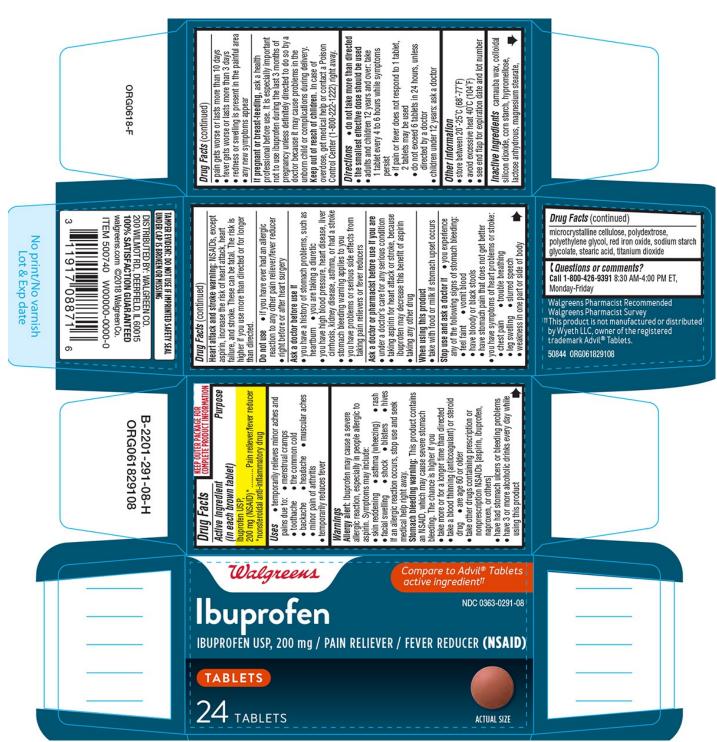
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

††This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Advil® Tablets.

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Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

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Walgreens 44-291

IBUPROFEN

ibuprofen tablet, film coated

Product Information HUMAN OTC DRUG NDC:0363-0291 Product Type Item Code (Source) ORAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
STARCH, CORN (UNII: O8232NY3SJ)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				

Product Characteristics				
Color	BROWN	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	44;291	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363-0291- 08	1 in 1 CARTON	05/24/1988		
1		24 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:0363-0291- 12	1 in 1 CARTON	05/24/1988		
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
3	NDC:0363-0291- 15	1 in 1 CARTON	05/24/1988		
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
4	NDC:0363-0291- 99	2 in 1 CARTON	05/24/1988		
4		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
5	NDC:0363-0291- 37	1 in 1 CARTON	05/24/1988	02/07/2021	
5		75 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
6	NDC:0363-0291- 57	1 in 1 CARTON	05/24/1988	02/07/2021	
		13E in 1 DOTTLE DI ACTIC. Tuna O. Nata Combination			

6		Product		
7	NDC:0363-0291- 03	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/1988	
8 NDC:0363-0291-		500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1988	07/08/2018
9	NDC:0363-0291- 16	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1988	07/08/2018
10	NDC:0363-0291- 29	150 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/1988	

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA075010	05/24/1988				

Labeler - Walgreen Company (008965063)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	PACK(0363-0291)		

Establishment						
Name	Address	ID/FEI	Business Operations			
LNK International, Inc.		832867894	MANUFACTURE(0363-0291)			

Establishment						
Name	Address	ID/FEI	Business Operations			
LNK International, Inc.		967626305	PACK(0363-0291)			

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867837	PACK(0363-0291)		

Establishment						
Name	Address	ID/FEI	Business Operations			
LNK International, Inc.		868734088	PACK(0363-0291)			

Revised: 2/2020 Walgreen Company