

IBUPROFEN DYE FREE- ibuprofen tablet, film coated
CVS Pharmacy

Ibuprofen

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
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- are age 60 or older

- 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

- 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 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

colloidal silicon dioxide, corn starch, 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

♥CVSHealth®

Compare to the active
ingredient in Advil® Tablets†

Coated Tablets

DYE
FREE

Ibuprofen

IBUPROFEN TABLETS USP, 200 mg
Pain reliever, Fever reducer **(NSAID)**

100 COATED TABLETS

Actual Size

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

†This product is not manufactured or distributed by
PF Consumer Healthcare 1 LLC, owner of the registered
trademark Advil® Tablets. 50844 REV1221C43812

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

Drug Facts (continued)

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■ any new symptoms appear

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Drug Facts (continued)

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PLEASE RECYCLE

B-0231-438-12-ADH
REV1221C43812

Drug Facts (continued)

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
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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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■ 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
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PLEASE RECYCLE

CVS 44-438

IBUPROFEN DYE FREE

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-438
Route of Administration	ORAL		

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

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

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:59779-438-12	1 in 1 CARTON	03/01/1999	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59779-438-15	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/1999	07/20/2023
3	NDC:59779-438-13	1 in 1 CARTON	03/01/1999	01/23/2019
3		250 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	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(59779-438)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(59779-438)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(59779-438)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(59779-438)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(59779-438)

Revised: 5/2023

CVS Pharmacy