

**IBUPROFEN- ibuprofen tablet, film coated**  
**CVS Pharmacy**

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**CVS 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:
  - backache
  - muscular aches
  - menstrual cramps
  - toothache
  - the common cold
  - headache
  - 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:

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

- 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
  - 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
  - trouble breathing
  - leg swelling
  - slurred speech
  - 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 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)
- see end flap for expiration date and lot number

***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**

**CVS Health™**

Compare to the active ingredient in Motrin® IB Caplets†

**Coated Caplets\*\***

NDC 59779-393-15

**Ibuprofen**

IBUPROFEN TABLETS USP, 200 mg

**Pain reliever, Fever reducer (NSAID)**

**50 COATED CAPLETS\*\***

\*\*Capsule-shaped tablets

Actual Size

**Distributed by: CVS Pharmacy, Inc.**

One CVS Drive, Woonsocket, RI 02895

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CVS.com®

1-800-SHOP-CVS

V-11112

✓ **CVS Quality**

Money Back Guarantee

50844 REV1116A39315

†This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Motrin® IB Caplets.

**CVS 44-393**

IBUPROFEN

ibuprofen tablet, film coated

Product Information					
<b>Product Type</b>		HUMAN OTC DRUG	<b>Item Code (Source)</b>		NDC:59779-393
<b>Route of Administration</b>		ORAL			
Active Ingredient/Active Moiety					
<b>Ingredient Name</b>				<b>Basis of Strength</b>	<b>Strength</b>
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPROFEN - UNII:WK2XYI10 QM)				IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-393-15	1 in 1 CARTON	03/01/1999	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59779-393-20	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/1999	

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(59779-393)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(59779-393)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(59779-393)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(59779-393)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(59779-393)