

**IBUPROFEN- ibuprofen tablet, film coated**  
**Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-438**

***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
- hives
- facial swelling
- skin reddening
- asthma (wheezing)
- 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**

- 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
  - 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***

**LEADER™**

NDC 70000-0291-1

**Ibuprofen**

Tablets USP, 200 mg

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

**100 TABLETS**

ACTUAL SIZE

100% Money Back Guarantee

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

**CIN 5331681 REV. 5/22**

50844 REV1221B43812

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-6313

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.

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no print / no varnish area  
lot no. & exp. date

0 962951 3196 3

CIN 5331681 REV. 5/22

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

KEEP OUTER PACKAGE FOR  
COMPLETE PRODUCT INFORMATION

**Drug Facts**

**Active ingredient**  
(in each white tablet)  
Ibuprofen USP  
200 mg (NSAID)\* ..... Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**Uses**

■ temporarily relieves minor aches and pains due to:  
■ headache ■ backache  
■ toothache ■ menstrual cramps  
■ the common cold  
■ 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 ■ are age 60 or older ■ 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  
■ 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.

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LEADER<sup>2</sup>

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**Drug Facts (continued)**

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.

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**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

**Drug Facts (continued)**

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**  
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■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin  
■ taking any other drug  
**When using this product**  
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**Stop use and ask a doctor if**  
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■ 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

Leader 44-438

## IBUPROFEN

ibuprofen tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0291
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: 3S5YLH9PMK)	
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:70000-0291-1	1 in 1 CARTON	03/01/1999	
1		100 in 1 BOTTLE, PLASTIC; 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** - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0291)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0291)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0291)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0291)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0291)

Revised: 6/2023

Cardinal Health 110, LLC. DBA Leader