

IBUPROFEN- ibuprofen capsule, liquid filled

P & L Development, LLC

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt)

*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 ache
 - 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:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- 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
- 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]
- 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 problems or serious side effects from taking pain relievers or fever reducers
- 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

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
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- 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 (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 capsule every 4 to 6 hours while symptoms persist
 - if pain or fever does not respond to 1 capsule, 2 capsules may be used
 - do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- **each capsule contains:**potassium 20 mg
- read all warnings and directions before use.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

FD&C blue #1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol

Questions & Comments

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to the active ingredient in Advil® Liqui-Gels® †

Ibuprofen Capsules, 200 mg

pain reliever/fever reducer (NSAID)

softgels**

(**liquid-filled capsules)

†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Advil® Liqui-Gels®.

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

Distributed by:
 PL Developments
 200 Hicks Street
 Westbury, NY 11590

Product Label

Compare to the active ingredient in Advil® Liqui-Gels®†
 NDC 59726-123-16

ready in case

ibuprofen
 capsules 200 mg

pain reliever/
 fever reducer
 (NSAID)

160 softgels**
 (**liquid-filled capsules)

actual size

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Active ingredient (in each capsule)
 Solubilized ibuprofen (NSAID).....Pain reliever/
 200 mg ibuprofen (NSAID).....fever reducer
 *nonsteroidal anti-inflammatory drug

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: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin reddening ■ rash ■ blisters. If an allergic reaction occurs, stop use and seek medical help right away.
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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.

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Drug Facts (continued under label)
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Distributed by:
 PL Developments
 200 Hicks Street
 Westbury, NY 11590

PLD-A-739B LB009361
 Lot No.:
 Exp. Date:

3 59726 74506 2

PEEL HERE →

Drug Facts (continued)

Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ 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

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Other information ■ each capsule contains: potassium 20 mg ■ read all warnings and directions before use ■ store at 20° to 25°C (68° to 77°F) ■ avoid excessive heat above 40°C (104°F)

Inactive ingredients FD&C blue #1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol

Questions or comments?
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READYinCASE Ibuprofen 200 mg Capsules

IBUPROFEN			
ibuprofen capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-123
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	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
Product Characteristics				
Color	green (Blue)	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	A356	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-123-16	160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2023	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA202300	03/31/2023		

Labeler - P & L Development, LLC (800014821)

Revised: 4/2023

P & L Development, LLC