

IBUPROFEN- ibuprofen capsule, liquid filled

Cardinal Health (Leader) 70000

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
 - muscular aches
 - minor pain of arthritis
 - toothache
 - backache
 - the common cold
 - muscular cramps
- 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 problem or stroke:
 - chest pain
 - slurred speech
 - trouble breathing
 - leg swelling
 - 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 del

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 keep carton.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.
- swallow whole; do not crush, chew, or dissolve

Inactive ingredients

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

Questions & Comments

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

Principal Display Panel

COMPARE TO ADVIL® LIQUI-GELS® active ingredient†

Ibuprofen

Capsules, 200 mg

Pain Reliever / Fever Reducer (NSAID)

Gluten-Free

Paraben-Free

SOFTGELS**

(**Liquid-Filled Capsules)

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

DISTRIBUTED BY

CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

Product Label

LEADER²

NDC 70000-0571-3

Ibuprofen

Capsules, 200 mg
Pain Reliever / Fever Reducer
(NSAID)

**COMPARE TO
ADVIL[®]
LIQUI-GELS[®]**
active ingredient*

**100% Money
Back Guarantee**

80 SOFTGELS**
**Liquid-Filled Capsules

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

Gluten-Free
Paraben-Free

Drug Facts

Active Ingredient (in each capsule)
Sulfobutylated 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:

- muscular aches
- minor pain of arthritis
- toothache
- the common cold
- menstrual cramps
- 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 redness
- 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 thinner (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.

Drug Facts (continued under label)

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100% Money Back Guarantee
Return to place of purchase if not satisfied.

CIN 5712344 **REV. 1/23**

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Lot. No.: Exp. Date:

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DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6303
Rev# 02/22
PLD-876
L8008155

PEEL HERE →

Drug Facts (continued)

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 ■ the 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 ■ slurred speech ■ trouble breathing ■ leg swelling ■ 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 (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). Protect from light. ■ swallow whole; do not crush, chew, or dissolve

Inactive ingredients F8&C blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol

Questions or comments?
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LEADER Ibuprofen 200 mg Softgels

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0571
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: 3WJQ05DW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	IB200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0571-3	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2021	
2	NDC:70000-0571-1	1 in 1 BOX	04/30/2021	
2		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:70000-0571-2	1 in 1 BOX	04/30/2021	
3		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA078682	04/30/2021	

Labeler - Cardinal Health (Leader) 70000 (063997360)

Revised: 3/2023

Cardinal Health (Leader) 70000