

# **IBUPROFEN- ibuprofen capsule, liquid filled Cardinal Health (Leader) 70000**

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## **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 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 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**

Solubilized Capsules, 200 mg

Pain Reliever / Fever Reducer (NSAID)

SOFTGELS\*\*

(\*\*Liquid Filled Capsules)

**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 Pfizer Consumer Healthcare,  
distributor Advil® Liqui-Gels®.

DISTRIBUTED BY

CARDINAL HEALTH

DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com)

**Product Label**

P.D.-ATF  
 F2010729  
 Rev# 09/17  
 Exp. Date:

Ldl No.:  
 0

All LEADER™ Brand Products Have A  
**100% Money Back Guarantee**  
 CIN 5712336  
 REV. 5/21

Return to place of purchase if not satisfied.

96295114093

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 200 mg ibuprofen (NSAID)\*  
 (present as the free acid and potassium salt)  
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 fever reducer

**Uses**  
 ■ temporarily relieves minor aches and pains due to:  
 ■ headache  
 ■ muscular aches  
 ■ toothache  
 ■ backache  
 ■ the common cold  
 ■ menstrual cramps  
 ■ temporarily reduces fever

**Warnings**  
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 ■ hives  
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 ■ 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  
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NDC 70000-0571-2  
**Ibuprofen**  
 Solubilized Capsules, 200 mg  
 Pain Reliever / Fever Reducer (NSAID)

**40 SOFTGELS\*\***  
 (\*\*Liquid-Filled Capsules)



**COMPARE TO ADVIL® LIQUI-GELS®**  
 active ingredient\*

**100% Money Back Guarantee**

**LEADER™**

**LEADER™**

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



**Essential to Care™ since 1979**

**Drug Facts (continued)**  
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**Other information**  
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 ■ store at 20° to 25° (68° to 77°)  
 ■ 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 or comments?**  
 Call 1-877-752-3835 Monday-Friday 9AM-5PM EST

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**Drug Facts (continued)**  
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**Ask a doctor before use if**  
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 ■ have stomach pain that does not get better  
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**LEADER Ibuprofen Solubilized Capsules 200 mg**

**IBUPROFEN**

ibuprofen capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0571
<b>Route of Administration</b>	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)	
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:70000-0571-1	1 in 1 BOX	04/30/2021	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:70000-0571-2	1 in 1 BOX	04/30/2021	
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:70000-0571-3	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2021	

**Marketing Information**

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

**Labeler** - Cardinal Health (Leader) 70000 (063997360)