

**IBUPROFEN- ibuprofen capsule, liquid filled  
Cardinal Health (Leader) 37205**

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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
  - 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 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

**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 or asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

**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
  - 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 right away 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° - 25°C (68°- 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.

## Inactive ingredients

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

## Questions or Comments ?

Call toll free **1-800-200-6313 Monday-Friday 9AM-5PM EST**

## Principal Display Panel

Compare to Advil® Liqui-Gels® active ingredient †

IBUPROFEN LIQUID SOFTGELS\*\*

### **Ibuprofen Capsules, 200 mg**

Pain reliever/ fever reducer (NSAID)\*

Softgels\*\*

\*\* (LIQUID FILLED CAPSULES)

## **KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**Do not use if tamper-evident seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing**

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® Liqui-Gels®

## **Manufactured by:**

Banner Pharmacaps

4125 premier drive

Product Label

PLDA  
F020082  
Lot No.:  
Exp. Date:

0 962951 12310 4



**LEADER**

**Ibuprofen**  
LIQUID SOFTGELS\*\*

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

40 SOFTGELS\*\* (\*\*LIQUID FILLED CAPSULES)

NDC 37205-736-58

*Compare to Advil<sup>®</sup> Liquid-Gels<sup>®</sup> active ingredient!*

**Drug Facts**

**Active ingredient (in each capsule)**  
Sulfonilized ibuprofen equal to 200 mg ibuprofen (NSAID)\* .....Pain reliever/fever reducer (present as the free acid and potassium salt) nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - toothache
- minor pain of arthritis
- backache
- menstrual cramps
- temporarily reduces fever

**Warnings**

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- rash
- skin redness
- asthma (wheezing)
- blisters

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- 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, etc.)
- have 3 or more alcoholic drinks every day while using this product

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery

**Drug Facts (continued)**

**Directions**

- do not take more than directed
- the smallest recommended dose should be used
- take capsules 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**
- keep 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.

**Inactive ingredients:** FD&C blue #1, gelatin, croscarmellose sodium, hydroxypropyl methylcellulose, potassium hydroxide, purified water, sorbitol, sorbitol

**Questions or comments?** Call toll free: **1-800-200-5313 Monday-Friday 9AM-5PM EST**

**Drug Facts (continued)**

**Ask a doctor before use if**

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- you have problems or serious side effects from taking aspirin or other NSAIDs
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- 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
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  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
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  - fever gets worse or lasts more than 3 days
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**Drug Facts (continued)**

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**Do not use if tamper-evident seal under bubble cap is broken or missing.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

**DISTRIBUTED BY**  
**CARDINAL HEALTH**  
DUBLIN, OHIO 43017  
CN 45939  
www.mylsdr.com

Manufactured by: Bamber Pharmapsia Inc.  
High Point, NC 27265  
Rev# 0312

Ibuprofen capsules 200 mg

**IBUPROFEN**

ibuprofen capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-736
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	IB200
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-736-58	1 in 1 BOX	12/11/2012	01/26/2024
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:37205-736-57	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2012	01/26/2024

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA078682	12/11/2012	01/26/2024

**Labeler** - Cardinal Health (Leader) 37205 (097537435)**Registrant** - P & L Development, LLC (079765031)

