

# **IBUPROFEN- ibuprofen capsule, liquid filled**

## **P & L Development, LLC**

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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

**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**

- 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 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
- store between 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 green #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitan solution, sorbitol, white ink

### **Questions or comments?**

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

### **Principal Display Panel**

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

#### **ibuprofen**

solubilized ibuprofen capsules, 200 mg

liquid filled softgels

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 GlaxoSmithKline Consumer  
Healthcare Holdings (US) LLC, distributor of Advil® Liqui-Gels®.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

**Product Label**

Exp. Date:

Lot No.:

PLD-AS240  
FD0008762



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PL Developments  
200 Hicks Street  
Westbury, NY 11590

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  - toothache
  - backache
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- skin redness
- shock
- skin reddening
- asthma (wheezing)
- rash
- blisters

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**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 other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take a blood thinning (anticoagulant) or steroid drug
- take 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)

**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**

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- 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**

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  - feel faint
  - vomit blood
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  - chest pain
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- 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.**

### Drug Facts (continued)

**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 between 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 green #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution, white ink

### Questions or comments?

Call 1-877-733-3835 Monday-Friday 9AM-5PM EST

\*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.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.



liquid filled softgels

pain reliever/  
fever reducer (NSAID)

40 softgels\*\*  
(\*\*liquid filled capsules)

Compare to the active ingredient in Advil® Liqui-Gels®  
NDC 59726-745-40

# Ibuprofen

solubilized ibuprofen capsules, 200 mg



actual size

## READYinCASE Ibuprofen 200 mg Softgels

### IBUPROFEN

ibuprofen capsule, liquid filled

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59726-745
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

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

#### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<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>	PC16
<b>Contains</b>			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-745-10	1 in 1 BOX	09/30/2018	
1		10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59726-745-20	1 in 1 BOX	09/30/2018	
2		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59726-745-16	160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2018	
4	NDC:59726-745-40	1 in 1 BOX	09/30/2018	

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40 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	ANDA206568	09/30/2018	

**Labeler** - P & L Development, LLC (800014821)

Revised: 7/2023

P & L Development, LLC