

**IBUPROFEN- ibuprofen capsule, liquid filled**  
**PuraCap Pharmaceutical LLC**

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**Ibuprofen Capsules (Liquid Filled), 200 mg**

**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 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.

**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 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.

### **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°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

### Inactive ingredients

FD&C green #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution, and white ink

### Questions or comments ?

Call toll free: 1-855-215-8180

### Principle display panel

Market Basket Ibuprofen 200mg 20ct

NDC 51013-421-15

**Market Basket**  
MORE FOR YOUR DOLLAR

NDC 51013-421-15  
Compare to the active ingredient of Advil® Liqui-Gels®\*

# Ibuprofen

Fast Relief Medication for Pain

Ibuprofen Capsules, 200 mg  
Liquid Filled Softgels  
Pain Reliever/  
Fever Reducer (NSAID)

**20** Softgels<sup>†</sup>  
Actual size  
Liquid Filled Capsules

**Do Not Use if imprinted safety seal under cap is broken or missing.**

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

DISTRIBUTED BY: DEMOLAS SUPERMARKETS INC.  
TEWKSBURY, MA 01876  
Product Made in China

MB24-00  
0 49705 73350 9

**Drug Facts**  
READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

**Active ingredient (in each capsule)**  
Sulbited, ibuprofen equivalent  
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 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 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

**Drug Facts (continued)**  
 ■ read all warnings and directions before use. Keep carton.  
 ■ store at 20°-25°C (68°-77°F)  
 ■ avoid excessive heat above 40°C (104°F)

**Inactive ingredients**  
 FD&C green #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution and white ink

**Questions or comments?** Call toll free: 1-855-215-8180

## Drug Facts (continued)

- 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

## Drug Facts (continued)

- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - leg swelling
  - weakness in one part or side of body
  - slurred speech
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
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**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.

## 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
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- children under 12 years: ask a doctor

## Other information

- each capsule contains: potassium 20 mg



NDC 51013-421-15

# Ibuprofen

**Ibuprofen Capsules, 200 mg  
Liquid Filled Softgels  
Pain Reliever/  
Fever Reducer (NSAID)**

**Fast Relief Medication for Pain**

**20** Softgels/  
Liquid Filled Capsules

### READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

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

### Warnings

- Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems.
- This product 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.

■ **Do not use this product if you have ever had an allergic reaction to any pain reliever/fever reducer.**

■ **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding.

*Drug Facts (continued under label)*

DISTRIBUTED BY:

**DEMOULAS SUPERMARKETS INC.**  
TEWKSBURY, MA 01876

Made in China  
MB23-00

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.

**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

Each capsule contains: potassium 20 mg

**Questions or comments?**  
call toll free: 1-855-215-8180

## IBUPROFEN

ibuprofen capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-421
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	

### Product Characteristics

Color	green (Clear)	Score	no score
Shape	CAPSULE (Oblong)	Size	18mm
Flavor		Imprint Code	PC16
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-421-15	1 in 1 CARTON	08/29/2017	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:510 13-421-25	1 in 1 CARTON	08/29/2017	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:510 13-421-26	80 in 1 BOTTLE; Type 0: Not a Combination Product	08/29/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206568	08/29/2017	

**Labeler** - PuraCap Pharmaceutical LLC (962106329)

## Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-421) , analysis(510 13-421)

Revised: 12/2019

PuraCap Pharmaceutical LLC