

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

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**Ibuprofen Capsules, 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: **1-877-290-4008**

### PRINCIPAL DISPLAY PANEL

Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID) 120 SOFTGELS

NDC: 51013-422-39

NDC 51013-422-39

ANTI-THEFT DEVICE

**IBUPROFEN**  
CAPSULES, 200 mg

Pain Reliever /  
Fever Reducer (NSAID)

Compare to the following relief of ADVIL® LIQUID GELS

Actual size

**120 SOFTGELS†**

†LIQUID FILLED CAPSULES

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

**Drug Facts**

**Purpose**  
Solubilized ibuprofen equal to 200 mg  
Ibuprofen (NSAID)\*\* ..... Pain reliever/fever reducer  
(present as the free acid and potassium salt)  
\*\*non steroidal anti-inflammatory drug

**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  
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

**Drug Facts (continued under label)**

Distributed by:  
Drug Mart - Food Fair  
Medina, Ohio 44136  
www.discount-drugmart.com  
Made in China  
DOM940

0 93351 02660 7

**Drug Facts (continued)**

- 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**

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**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)

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

# IBUPROFEN

ibuprofen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-422
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 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: 059QF0KO0R)			
Product Characteristics			
Color	green (Clear)	Score	no score
Shape	CAPSULE (Oblong)	Size	18mm
Flavor		Imprint Code	PC16
Contains			
Packaging			

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-422
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10 QM) (IBUPROFEN - UNII:WK2XYI10 QM)	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 HYDRO XIDE (UNII: WZH3C48M4T)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-422-39	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2017	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA		ANDA206568	11/01/2017	

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

<b>Establishment</b>				
<b>Name</b>		<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.			421293287	manufacture(51013-422) , analysis(51013-422)

Revised: 12/2019

PuraCap Pharmaceutical LLC