

**IBUPROFEN- ibuprofen capsule, liquid filled**  
**Topco Associates 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: 1-888-423-0139

**PRINCIPAL DISPLAY PANEL**

Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID)

360 Liquid Filled Capsules

NDC 36800-440-80



**READ AND KEEP CARTON FOR COMPLETE WARNING AND INFORMATION**  
**Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient (in each capsule)</b> Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)** -----Pain reliever/Fever reducer (present as the free acid and potassium salt) **nonsteroidal anti-inflammatory drug		<b>Purpose</b>	
<b>Uses</b> <ul style="list-style-type: none"> <li>■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> <li>■ headache</li> <li>■ toothache</li> <li>■ backache</li> <li>■ menstrual cramps</li> </ul> </li> <li>■ the common cold</li> <li>■ muscular aches</li> <li>■ minor pain of arthritis</li> <li>■ temporarily reduces fever</li> </ul>		<b>When using this product</b> <ul style="list-style-type: none"> <li>■ take with food or milk if stomach upset occurs</li> </ul>	
<b>Warnings</b> <b>Allergy alert:</b> Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: <ul style="list-style-type: none"> <li>■ hives</li> <li>■ facial swelling</li> <li>■ asthma (wheezing)</li> <li>■ shock</li> <li>■ skin reddening</li> <li>■ rash</li> <li>■ blisters</li> </ul> If an allergic reaction occurs, stop use and seek medical help right away. <b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you <ul style="list-style-type: none"> <li>■ are age 60 or older</li> <li>■ have had stomach ulcers or bleeding problems</li> <li>■ take a blood thinning (anticoagulant) or steroid drug</li> <li>■ take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]</li> <li>■ have 3 or more alcoholic drinks every day while using this product</li> <li>■ take more or for a longer time than directed</li> </ul> <b>Heart attack and stroke warning:</b> 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. <b>Do not use</b> <ul style="list-style-type: none"> <li>■ if you have ever had an allergic reaction to any other pain reliever/fever reducer</li> <li>■ right before or after heart surgery</li> </ul> <b>Ask a doctor before use if</b> <ul style="list-style-type: none"> <li>■ stomach bleeding warning applies to you</li> <li>■ you have problems or serious side effects from taking pain relievers or fever reducers</li> <li>■ you have a history of stomach problems, such as heartburn</li> <li>■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke</li> <li>■ you are taking a diuretic</li> </ul> <b>Ask a doctor or pharmacist before use if you are</b> <ul style="list-style-type: none"> <li>■ under a doctor's care for any serious condition</li> <li>■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin</li> <li>■ taking any other drug</li> </ul>		<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>■ you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> <li>■ feel faint</li> <li>■ vomit blood</li> <li>■ have bloody or black stools</li> <li>■ have stomach pain that does not get better</li> </ul> </li> <li>■ you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> <li>■ chest pain</li> <li>■ trouble breathing</li> <li>■ leg swelling</li> <li>■ weakness in one part or side of body</li> <li>■ slurred speech</li> </ul> </li> <li>■ pain gets worse or lasts more than 10 days</li> <li>■ fever gets worse or lasts more than 3 days</li> <li>■ redness or swelling is present in the painful area</li> <li>■ any new symptoms appear</li> </ul> <b>If pregnant or breast-feeding,</b> 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. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
		<b>Directions</b> <ul style="list-style-type: none"> <li>■ do not take more than directed</li> <li>■ the smallest effective dose should be used</li> <li>■ adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist</li> <li>■ if pain or fever does not respond to 1 capsule, 2 capsules may be used</li> <li>■ do not exceed 6 capsules in 24 hours, unless directed by a doctor</li> <li>■ children under 12 years: ask a doctor</li> </ul>	
		<b>Other information</b> <ul style="list-style-type: none"> <li>■ each capsule contains: potassium 20 mg</li> <li>■ read all warnings and directions before use. Keep carton.</li> <li>■ store at 20-25°C (68-77°F)</li> <li>■ avoid excessive heat above 40°C (104°F)</li> </ul>	
		<b>Inactive ingredients</b> FD&C green #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution and white ink	
		<b>Questions or comments?</b> Call toll free: 1-888-423-0139	
		*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® Liqui-Gels®	

## IBUPROFEN

ibuprofen capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-440
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110 QM) (IBUPROFEN - UNII:WK2XY110 QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength

<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYETHYLENE GLYCOL</b> (UNII: 3WJQ0SDW1A)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-440-80	2 in 1 PACKAGE	05/30/2018	
1		180 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-440-29	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206568	05/30/2018	

**Labeler** - Topco Associates LLC (006935977)

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(36800-440) , analysis(36800-440)