

**IBUPROFEN- ibuprofen capsule, liquid filled**  
**Western Family Foods, Inc.**

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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
  - vomit blood
  - have bloody or black stools
  - 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.

**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° 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, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

### **Questions or comments?**

**1-503-639-6300 Monday-Friday 8AM-4PM PST**

### **Principal Display Panel**

***PAIN RELIEVER/FEVER REDUCER (NSAID)***

***Ibuprofen***

**Softgels\*\***

***†Compare to the Active Ingredient in Advil® Liqui-Gels®***

Ibuprofen Capsules, 200 mg

SOFTGELS \*\*

\*\* (LIQUID FILLED CAPSULES)

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

**Proudly distributed by: Western Family Foods, Inc.**

**PO Box 4057, Portland, OR 97208**

**[www.westernfamily.com](http://www.westernfamily.com)**

**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.**

### **Product Label**

Lot No.:  
Exp. Date:

0 15400 07241 0



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www.westernfamily.com

P.O.D  
FC001136  
Rev.# 03/12




**Drug Facts (continued)**

**Directions**

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07241-D-PLD

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have problems or serious side effects from taking aspirin or other drugs
- 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
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**Drug Facts (continued)**

**Active ingredient (in each capsule) Purpose**

Solubilized 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
  - minor pain of arthritis
  - toothache
  - backache
  - menstrual cramps
  - temporarily reduces fever

**Warnings**

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms include hives, facial swelling, asthma (wheezing), shock, skin reddening, 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 a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or over-the-counter 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

Lot No.:  
Exp. Date:

0 15400 07241 0



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07241-D-PLD



**Western Family Ibuprofen 200 mg Capsule**

## IBUPROFEN

ibuprofen capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-197
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 BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

### Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	IB200
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-197-40	1 in 1 BOX		
1		40 in 1 BOTTLE		
2	NDC:55312-197-80	1 in 1 BOX		
2		80 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	03/13/2010	

**Labeler** - Western Family Foods, Inc. (192166072)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 3/2013

Western Family Foods, Inc.