

**IBUPROFEN- ibuprofen tablet**  
**Western Family Foods, Inc.**

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**DRUG FACTS**

**Active Ingredient (in each tablet)**

Ibuprofen USP, 200 mg (NSAID)\*

\*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 a nonsteroidal anti-inflammatory drug (NSAID) which may cause severe stomach bleeding. The chance are higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks everyday while using this product
- take more or for a longer time than directed.

**Do not use**

- if you ever had an allergic reaction to any other pain reliever/fever reducer

- right before or after heart surgery

### **Ask a doctor before use if**

- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic.

### **Ask a doctor or pharmacist before use if you are**

- taking aspirin to prevent heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- 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 last more than 10 days
  - Fever gets worse or last 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 (1-800-222-1222)

### **Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**

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Adults and children 12 years and older

- take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor

children under 12 years

- ask a doctor

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**Other information**

- store between 20°- 25° C (68°- 77° F)
- read all warnings and directions before use. Keep carton
- **do not use if imprinted foil under cap is broken or missing**
- †This product is not manufactured or distributed by Pfizer consumer healthcare, owner of the registered trademark Advil®

**Inactive Ingredients**

colloidal silicon dioxide, corn starch, dextrose monohydrate, hypromellose, iron oxide red, lactose monohydrate, lecithin, maltodextrin, povidone (K-30), pregelatinized starch, sodium carboxymethylcellulose, sodium starch glycolate, stearic acid, titanium dioxide, and triacetin

**Questions or comments?**

Call: 1-503-639-6300 Monday- Friday 9AM-5PM PST

**Principal Display Panel**

Compare to the active ingredient in ADVIL®†

SEE NEW WARNINGS INFORMATION

Ibuprofen Tablets

Pain Reliever/ Fever Reducer (NSAID)\*

**Proudly distributed by Western family foods, Inc.**

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

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

**Manufactured by:**

**Granules India limited**

**Madhapur, Hyderabad- 500081, India**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**Product Label**

**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** you have problems or serious side effects from taking pain relievers or fever reducers, the stomach bleeding warning applies to you, you have a history of stomach or liver problems such as heartburn, you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, you have asthma, you are taking a diuretic, taking aspirin to prevent heart attack or stroke, because ibuprofen may decrease the benefit of aspirin, under a doctor's care for any serious condition, 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 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.

**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.

**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** you have problems or serious side effects from taking pain relievers or fever reducers, the stomach bleeding warning applies to you, you have a history of stomach or liver problems such as heartburn, you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, you have asthma, you are taking a diuretic, taking aspirin to prevent heart attack or stroke, because ibuprofen may decrease the benefit of aspirin, under a doctor's care for any serious condition, taking any other drug.

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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.

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Lot No.:  
Exp. Date:

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

**Drug Facts (continued)**

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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.

**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. If an allergic reaction occurs, stop use and seek medical help right away. Each strength 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.

**Uses**

Ibuprofen USP, 200 mg (NSAID).....Pain reliever/fever reducer  
nonsteroidal anti-inflammatory drug

**Active ingredient (in each tablet)**

**Purpose**

Ibuprofen USP, 200 mg (NSAID).....Pain reliever/fever reducer  
nonsteroidal anti-inflammatory drug

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

PLD-A  
FC000519

Manufactured by:  
Granules India Limited  
Madhapur, Hyderabad-500 081, India

SEE NEW WARNINGS INFORMATION

**WESTERN FAMILY**

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

**Ibuprofen**

**TABLETS**

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL®!      100 COATED TABLETS-200 mg each

**Drug Facts (continued)**

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**Ask a doctor before use if** you have problems or serious side effects from taking pain relievers or fever reducers, the stomach bleeding warning applies to you, you have a history of stomach or liver problems such as heartburn, you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, you have asthma, you are taking a diuretic, taking aspirin to prevent heart attack or stroke, because ibuprofen may decrease the benefit of aspirin, under a doctor's care for any serious condition, taking any other drug.

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**Directions**

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. (1-800-222-1222).

**Do not take more than directed** the smallest effective dose should be used.

Adults and children 12 years and older

- take 1 tablet every 4 to 6 hours while symptoms persist
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Children under 12 years

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**Other information**

- store between 20° - 25°C (68° - 77°F)
- read all warnings and directions before use. Keep carton.
- do not use if imprinted foil under cap is broken or missing
- This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil®.

**Inactive ingredients** colloidal silicon dioxide, corn starch, dextrose monohydrate, hypromellose, iron oxide red, lactose monohydrate, leucithin, maltoedextrin, povidone (K-30), pregelatinized starch.

Ibuprofen tablets 200 mg tablets

## IBUPROFEN

ibuprofen tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-218
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

### Product Characteristics

Color	BROWN (reddish)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G2
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-218-10	1 in 1 BOX		
1		100 in 1 BOTTLE		
2	NDC:55312-218-24	1 in 1 BOX		
2		24 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	07/05/2012	

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