

IBUPROFEN- ibuprofen tablet
Western Family Foods, Inc.

DRUG FACTS

Active Ingredient (in each caplet)

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 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 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 for 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**

Adults and children 12 years and older

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

children under 12 years

- ask a doctor
-

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 Wyeth 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 toll free: **1-503-639-6300 Monday-Friday 9AM-5PM PST**

Principal Display Panel

Compare to the active ingredient in ADVIL®†

Ibuprofen Caplets

Pain Reliever/ Fever Reducer (NSAID)*

Proudly distributed by Western family foods, Inc.

PO Box 4057, Portland, OR 97208 USA

www.westernfamily.com

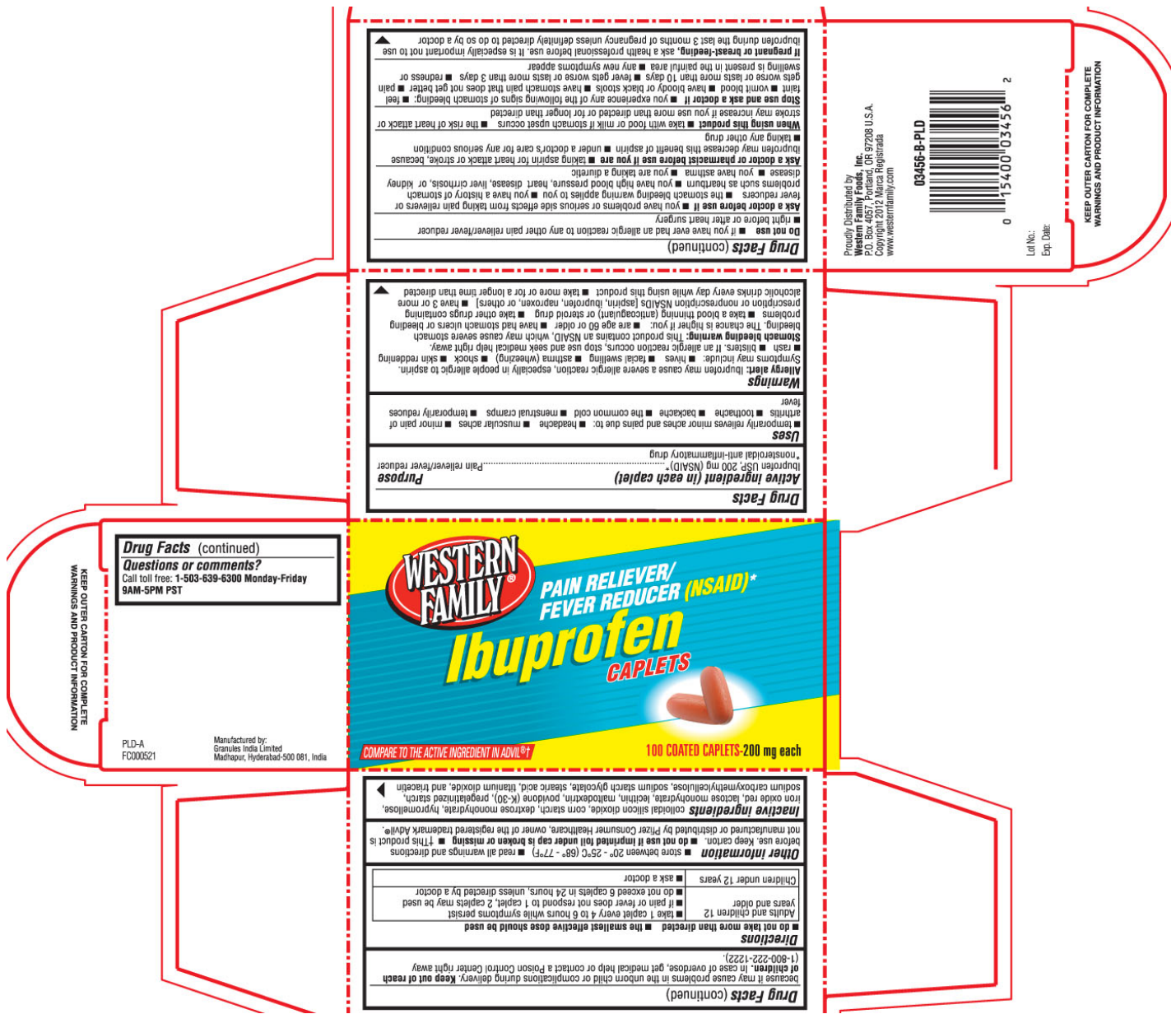
Manufactured by:

Granules India Limited

Madhapur, Hyderabad- 500 081, India.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product Label



Ibuprofen caplets 200 mg

IBUPROFEN			
ibuprofen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-216(NDC:62207-366)
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
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	CAPSULE	Size	14mm
Flavor		Imprint Code	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-216-10	1 in 1 BOX		
1		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	12/15/2011	

Labeler - Western Family Foods, Inc. (192166072)

Revised: 10/2012

Western Family Foods, Inc.