

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

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 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
- 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 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 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
-

:

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

Principal Display Panel

Ibuprofen Coated Tablets 200 mg each

Pain Reliever/ Fever Reducer (NSAID)*

Compare to the active ingredient in ADVIL®†

SEE NEW WARNINGS INFORMATION

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Proudly distributed by

Western Family Foods, Inc.

P.O Box 4057, Portland, OR 97208 U.S.A

www.westernfamily.com

Manufactured by:

Granules India Limited

Madhapur, Hyderabad- 500081, INDIA

Package Labeling

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-219
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)	
POVIDONE K30 (UNII: U725QWY32X)	
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:55312-219-20	2 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	09/01/2011	

Labeler - Western Family Foods, Inc. (192166072)

Revised: 10/2012

Western Family Foods, Inc.