IBUPROFEN- ibuprofen tablet, coated
AAA Pharmaceutical, Inc.

RES - 1109B - 2019-0912

Drug Facts

Active ingredient (in each tablet)

Ibuprofen, USP 200 mg (NSAID [1])

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[1] 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

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, 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
- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)

	• take 1 tablet every 4 to 6 hours while symptoms persist

adults and children 12 years and over	• 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)
- avoid excessive heat above 40°C (104°F)
- read all warnings and directions before use
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, corn starch, dextrose monohydrate, hypromellose, iron oxide red, lactose monohydrate, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone K30, pregelatinized starch, sodium carboxymellose, sodium starch glycolate, stearic acid, talc, titanium dioxide, triacetin

Distributed by:
AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Carton

RESTORE u

NDC 57344-109-03

†COMPARE TO THE ACTIVE
INGREDIENT IN ADVIL ®

Ibuprofen
Tablets, USP 200 mg

Pain Reliever, Fever Reducer

(NSAID)

100 COATED TABLETS

IBUPROFEN

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57344-109
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	brown	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	IBU;200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-109-02	1 in 1 CARTON	05/01/2019	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:57344-109-03	1 in 1 CARTON	10/01/2012	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:57344-109-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	10/01/2012	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 9/2019 AAA Pharmaceutical, Inc.