IBUPROFEN- ibuprofen tablet
Rebel Distributors Corp

Drug Facts

Active Ingredient (In each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti- inflammatory drug

Purpose

Pain reliever/ fever reducer

Uses

temporarily relieves minor aches and pain due to

- minor pain of arthritis
- headache
- toothache
- backache
- the common cold
- menstrual cramps
- muscular aches
- 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 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 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 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 for 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.

This package is not for households with young children.

Directions

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

Adults and children	• take 1 tablet every4 to 6 hours while symptoms persist

12 years and older	• 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 high humidity and excessive heat above 40°C (104°F)

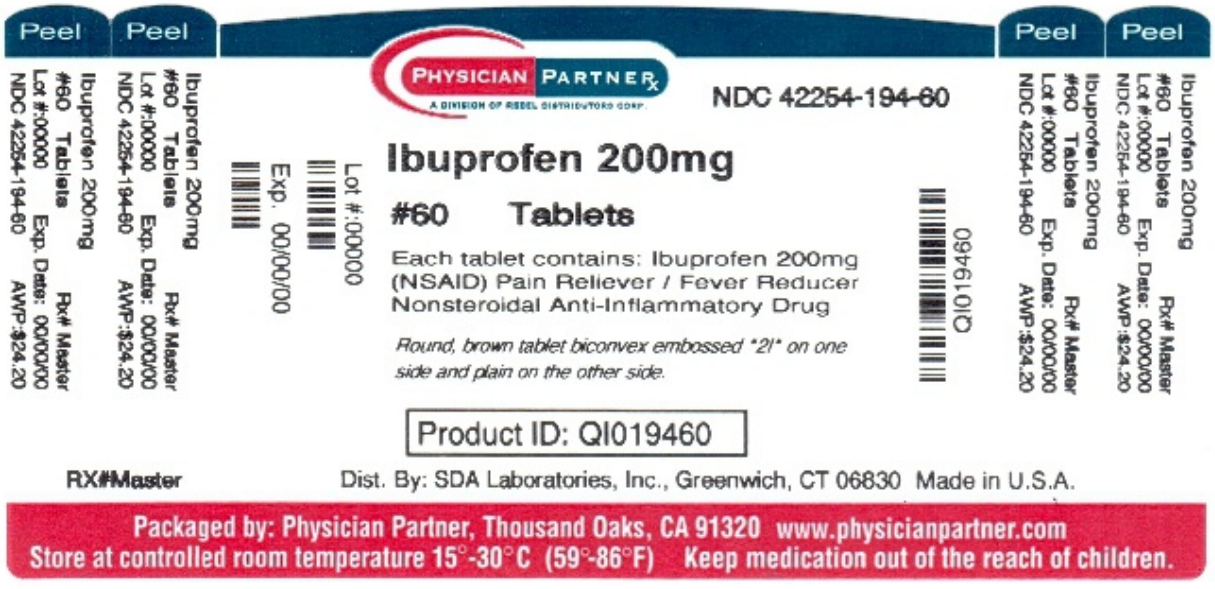
Inactive Ingredients:

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, DC yellow# 10, FDC blue# 2, FDC red# 40, FDC yellow# 6, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate 80, red iron oxide, titanium dioxide

Questions? Adverse drug event call: (800)687-0176

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark ADVIL®.

Principal Display Panel



IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42254-194(NDC:66424-996)
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	2I
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42254-194-60	60 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA075661	01/27/2011	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 3/2012 Rebel Distributors Corp