IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER- ibuprofen (nsaid) tablet
Rebel Distributors Corp

Ibuprofen Tablets, USP
Fever reducer/ Pain Reliever (NSAID)

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Ibuprofen USP, 200 mg (NSAID)**

**nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

Keep out of reach of children

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 chances are 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
- 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
- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug

When using this product
- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

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 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 (1-800-222-1222) right away.

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

INACTIVE INGREDIENTS

- Brown Tablets: Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Hypromellose, Iron Oxide Red, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Corn Starch Corn, Titanium Dioxide
- Orange Tablets: Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, FD&C Yellow #6, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Corn Starch, Titanium Dioxide

Questions or Comments

Call 1-877-835-5472

Monday through Friday 9AM - 5PM EST.

*Amneal Pharmaceuticals is not affiliated with the owner of the trademark Advil®

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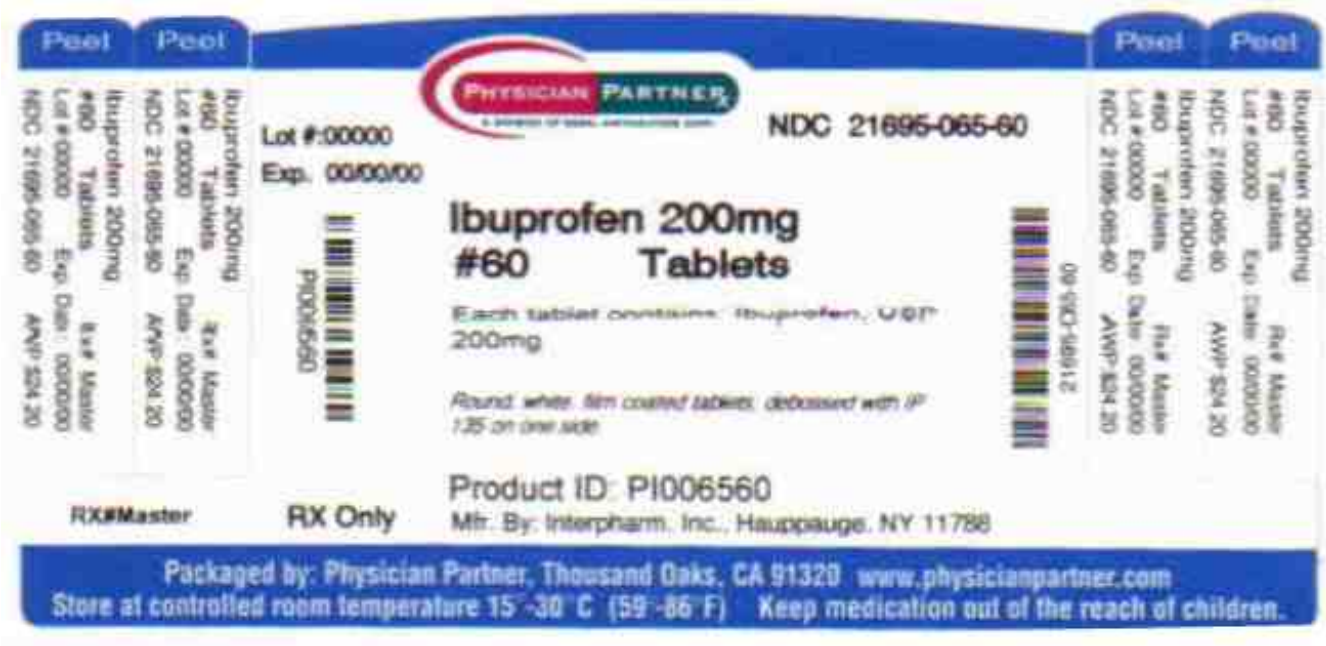
PRINCIPAL DISPLAY PANEL



IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER

ibuprofen (nsaid) tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21695-065(NDC:53746-140)
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**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	IP;140
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-065-06	6 in 1 BOTTLE		
2	NDC:21695-065-14	14 in 1 BOTTLE		
3	NDC:21695-065-28	28 in 1 BOTTLE		
4	NDC:21695-065-30	30 in 1 BOTTLE		
5	NDC:21695-065-50	50 in 1 BOTTLE		
6	NDC:21695-065-60	60 in 1 BOTTLE		
7	NDC:21695-065-90	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA071333	12/16/2009	

Labeler - Rebel Distributors Corp (118802834)

Establishment

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

Revised: 2/2011 Rebel Distributors Corp