

**IBUPROFEN- ibuprofen tablet**  
**Proficient Rx LP**

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**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**

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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
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## 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®.



NDC 63187-139-30

Lot #:00000  
Exp. 00/00/00  
SN# MASTER

# Ibuprofen 200mg

**#30 Tablets**Each tablet contains: Ibuprofen 200mg (NSAID)  
Pain reliever / fever reducer*Round, brown unscored tablet with "IBU 200" imprinted on one side and plain on other side*

Product ID: PI013930

Dist. By: SDA Laboratories, Inc., Greenwich, CT 06830  
Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Ibuprofen 200mg  
#30 Tablets SN# MASTER  
Lot #:00000 Exp:00/00/00  
NDC 63187-139-30Ibuprofen 200mg  
#30 Tablets SN# MASTER  
Lot #:00000 Exp:00/00/00  
NDC 63187-139-30Ibuprofen 200mg  
#30 Tablets SN# MASTER  
Lot #:00000 Exp:00/00/00  
NDC 63187-139-30Packaged By: Proficient Rx LP  
Thousand Oaks, CA 91320

## IBUPROFEN

ibuprofen tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-139(NDC:66424-996)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	2I
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-139-06	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
2	NDC:63187-139-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
3	NDC:63187-139-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
4	NDC:63187-139-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
5	NDC:63187-139-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075661	01/27/2011	

**Labeler** - Proficient Rx LP (079196022)

### Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079502574	REPACK(63187-139) , RELABEL(63187-139)

Revised: 1/2019

Proficient Rx LP