

**IBUPROFEN 200MG- ibuprofen 200mg tablet**  
**Allegiant Health**

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**467 - Ibuprofen 200mg Tablet**

**Active ingredient(s)**

Ibuprofen USP, 200mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain Reliever/Fever reducer

**Use(s)**

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 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.

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Contains FD&C Yellow No. 5 (tartrazine) as a color additive.**

### **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**

- 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

### **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

### **If pregnant or breastfeeding,**

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 over: 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
- do not use if seal under bottle cap is broken or missing

### **Inactive ingredients**

Colloidal Silicon Dioxide, Croscarmellose Sodium, FD&C Blue #2, FD&C Yellow #5, FD&C Yellow #6, Iron Oxide Red, Lecithin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregelatinized Starch, Talc, Titanium Dioxide.

### **Questions/Comments**

Call 1-888-952-0050 Monday through Friday 9AM – 5PM EST

### **Principal Display Panel**



**Drug Facts**

**Active Ingredient (in each tablet)** **Purpose**  
Ibuprofen 200mg (NSAID) Pain reliever/fever reducer

**Uses** Temporarily relieves minor aches and pains due to:  
 ■ headache ■ 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:  
 ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin redness/itching ■ hives ■ blisters

**Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (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 other drugs containing (aspirin) or steroid drug ■ take other drugs containing (aspirin) or steroid drug ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack and stroke. These risks may be higher if you have had a heart attack or stroke, have high blood pressure, or if you are taking a blood thinner. The risk is higher if you take more than the directed or for longer than directed.

**Contains FD&C Yellow No. 5 (tartrazine) as a color additive.**

**Do not use** ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery

**Drug Facts (continued on inside)**

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

**Lot:** LB2225  
**Exp:** R0924

**Manufactured for:** Allegiant Health  
Deer Park, NY 11729

**HealthA2Z Ibuprofen Tablets | 200mg | 500counts**

**FEEL BETTER HERE**

**Drug Facts (continued)**

**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, asthma, or had a stroke ■ 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**

**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 ■ you have symptoms of heart problems or stroke: ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling ■ 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 genital 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 over:** 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 ■ do not use if seal under bottle cap is broken or missing

**Inactive ingredients** Colloidal Silicon Dioxide, Croscarmellose Sodium, FD&C Blue #2, FD&C Yellow #5, FD&C Yellow #6, Iron Oxide Red, Lecithin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregeacolin Starch, Talc, Titanium Dioxide.

**Questions or Comments?**  
Call 1-888-882-0950 Monday through Friday 9AM - 5PM EST

**Ibuprofen**

<b>IBUPROFEN 200MG</b>			
ibuprofen 200mg tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69168-467
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	CROSCARMELOSE SODIUM (UNII: M28OL1HH48)		
	FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		

<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	BI06
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-467-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2024	
2	NDC:69168-467-32	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2024	
3	NDC:69168-467-03	250 in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2024	
4	NDC:69168-467-01	1 in 1 CARTON	08/12/2025	
4		100 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69168-467-30	1 in 1 CARTON	08/12/2025	
5		30 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207095	10/10/2024	

**Labeler** - Allegiant Health (079501930)