

**IBUPROFEN- ibuprofen tablet, film coated**  
**Allegiant Health**

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**466 - Ibuprofen 200mg Caplet**

**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 n 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

**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.

**Do not use if you have**

ever had an allergic reaction to ibuprofen or 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, kidney disease, asthma, or had a stroke
- 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

**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 painful area
- any new symptoms appear

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

**Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**
- **adults and children 12 years and older**
- take 1 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets 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**

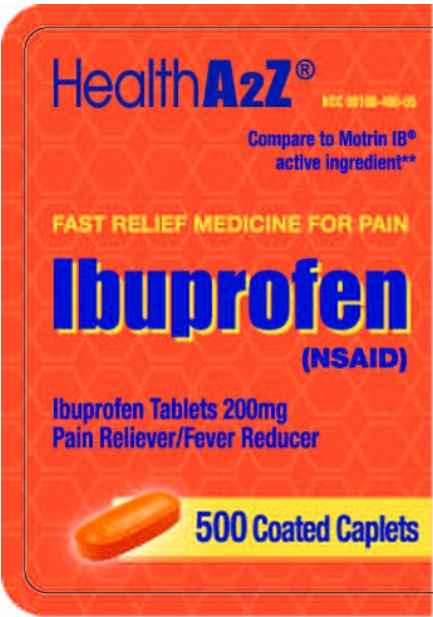
Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Yellow #10, FD&C Blue #2, FD&C Yellow #6,  
Lecithin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregelatinized Starch, Talc, Titanium Dioxide.

**Questions/Comments**

Call **1-888-952-0050**

(Monday-Friday 9 AM – 5 PM EST)

**Principal Display Panel**



**Drug Facts**


**Active ingredient (in each caplet)**  
Ibuprofen USP 200mg (NSAID)\*  
\*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 (wheezing) ■ shock ■ skin reddening ■ rash ■ 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 a blood thinner (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) 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.  
**Do not use** ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ if you have ever had an 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, 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:  
■ vomit blood ■ have bloody or black stools ■ have blood in your stool ■ feel that you are not getting better ■ you have symptoms of heart problems or stomach bleeding  
■ trouble breathing ■ weakness in one part or body  
■ stroke ■ chest pain ■ dizziness ■ fainting ■ pain ■ redness or swelling is present in the ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present in the

**Drug Facts (continued on inside)**  
\*This product is not manufactured or distributed by Johnson & Johnson Consumer, Inc., owner of the registered trademark Motrin® IB.



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

Lot:  
Exp:

852313  
R0425

NSC 13136-46605

**Drug Facts (continued)**  
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 over: take 1 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets 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, D&C Yellow #10, FD&C Blue #2, FD&C Yellow #6, Lactin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregelatinized Starch, Talc, Titanium Dioxide.

**Questions or Comments?**  
Call 1-888-862-0050 Monday through Friday 9AM – 5PM EST

Ibuprofen 200mg

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-466
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
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<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</b> (UNII: 532B59J990)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	BI;03
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-466-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207095	04/16/2025	

Labeler - Allegiant Health (079501930)