

**IBUPROFEN 200MG- ibuprofen 200mg tablet, coated**  
**Athlete's Needs, Inc.**

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**Ibuprofen 200mg**

**Active ingredient (in each tablet)**

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
- 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 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 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, 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 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 at 20 weeks or later in 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, corn starch, FD&C yellow #6, hypromellose, polydextrose, polyethylene glycol, povidone, pregelatinized starch, purified water, sodium starch glycolate, stearic acid, titanium dioxide

### **Questions or Comments?**

Call 1-888-952-0050

Monday through Friday 9AM - 5PM EST

### **Principal Display Panel**



# IBUPROFEN

MODERN PAIN MEDICINE

PAIN & FEVER RELIEF

CONTAINS NO ASPIRIN

CAFFEINE FREE

Compare To Advil®\*\*

SEE NEW WARNINGS INFORMATION

100 Tablets      200 mg Each

**Drug Facts**

**Active ingredient (in each tablet)**  
Ibuprofen USP, 200mg (NSAID)\* .....Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**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 ■ 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 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 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

**Drug Facts** (continued on inside)

**Manufactured for:**  
 Athlete's Needs  
 Novi, MI 48377

LB 1469  
 R0523

Lot No.:  
 Exp. Date:

CODE Z7541  
  
 0 92617 27541 4

SEE HERE

**Drug Facts (continued)**

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 painful area ■ any new symptoms appear

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**Inactive ingredients** colloidal silicon dioxide, corn starch, FD&C yellow #6, hypromellose, polydextrose, polyethylene glycol, polydine, pregelatinized starch, purified water, sodium starch glycolate, stearic acid, titanium dioxide

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

**Ibuprofen**  
 Clear Choice (logo)  
 IBUPROFEN  
 MODERN PAIN MEDICINE  
 PAIN & FEVER RELIEF  
 CONTAINS NO ASPIRIN  
 CAFFEINE FREE  
 Compare to Advil®\*\*  
 SEE NEW WARNINGS INFORMATION  
 100 Tablets  
 200 mg Each

<b>IBUPROFEN 200MG</b>			
ibuprofen 200mg tablet, coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53185-381

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<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>	G2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53185-381-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202312	10/07/2016	

**Labeler** - Athlete's Needs, Inc. (619703945)