

**CLEAR CHOICE IBUPROFEN- ibuprofen tablet**  
**Athlete's Needs Inc**

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**Clear Choice Ibuprofen**

**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
- 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 other pain reliever/fever reduce  
right before or after heart surgery

**Ask a doctor before use if**

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

**Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor ( **see Warnings** )
- **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 degrees Celsius (68-77 degrees Fahrenheit).
- Read all warnings and directions before use
- **Do not use if seal under bottle cap is broken or missing.**

### **Inactive ingredients**

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, Starch (Corn), Titanium Dioxide

### **Questions or Comments**

Call 1-888-634-5522 Monday through Friday 9AM - 5PM EST.

### **Package Label**

Clear Choice

IBUPROFEN

MODERN PAIN MEDICINE

PAIN AND FEVER RELIEF

CONTAINS NO ASPIRIN

CAFFEINE FREE

Compare to Advil (R)

100 Tablets

200 mg each

This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Advil (R)

Manufactured for: A.N.I. Toledo, OH 43623 CODE 27541

Lot No.:

Exp. Date:



# **IBUPROFEN**

**MODERN PAIN MEDICINE**

**PAIN & FEVER RELIEF  
CONTAINS NO ASPIRIN  
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**100 Tablets**

**200 mg Each**

## Drug Facts

### Active ingredient (in each tablet) Purpose

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

**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** ■ 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

### Drug Facts (continued on inside)

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

Manufactured for: A.N.L. Toledo, OH 43623 CODE 27541

LB632/1  
R1110



**PEEL HERE** Lot No.:  
Exp. Date:

## Drug Facts (continued)

### Ask a doctor or pharmacist before use if you are

■ taking aspirin to prevent 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 ■ 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 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.

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**Inactive ingredients** 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, Starch (Corn), Titanium Dioxide

### Questions or Comments?

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## CLEAR CHOICE IBUPROFEN

ibuprofen tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53185-003
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
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 GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	brown (brown)	Score	no score
Shape	ROUND (round)	Size	9mm
Flavor		Imprint Code	IBU200
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53185-003-00	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2013	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	10/09/2012	

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

**Registrant** - Athlete's Needs Inc (619703945)

## Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	manufacture(53185-003)