

**IBUPROFEN- ibuprofen tablet, film coated**  
**GREENBRIER INTERNATIONAL, INC.**

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**Assured 44-291**

***Active ingredient (in each brown tablet)***

Ibuprofen USP, 200 mg (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
- shock
- facial swelling
- rash
- blisters
- skin reddening
- asthma (wheezing)

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:

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- 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**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have asthma
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

#### **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
- 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
  - have bloody or black stools
  - vomit blood
  - 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.

#### ***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 12 years: ask a doctor

#### ***Other information***

- store between 20°-25°C (68°-77°F)

- avoid excessive heat 40°C (104°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

carnauba wax, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

### ***Questions or comments?***

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

### **Principal Display Panel**

**ASSURED™**

**COMPARED TO ACTIVE INGREDIENT OF  
ADVIL® TABLETS†**

### **Ibuprofen**

• **Ibuprofen Tablets USP, 200 mg**  
*Pain reliever / Fever reducer (NSAID)*

Actual Size

**100** tablets

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED  
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

†This product is not manufactured or distributed by Pfizer  
Consumer Healthcare, owner of the registered trademark Advil®  
Tablets. 50844 REV0112A29112

**DISTRIBUTED BY  
GREENBRIER INTERNATIONAL, INC.  
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320**

OMIT E



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**ASSURED**

# Ibuprofen

Ibuprofen Tablets USP, 200 mg  
Pain reliever / Fever reducer (NSAID)



Actual Size

COMPARE TO ACTIVE INGREDIENT OF  
**ADVIL® TABLETS\***

100 tablets

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ITEM# 183874

DISTRIBUTED BY  
**GREENBRIER INTERNATIONAL, INC.**  
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

**Drug Facts**

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

**Purpose**

- Uses**
- temporarily relieves minor aches and pains due to:
    - headache
    - backache
    - the common cold
    - minor pain of arthritis
    - temporarily reduces fever
  - temporarily relieves minor aches and pains due to:
    - toothache
    - menstrual cramps
    - muscular aches

**Warnings**

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.  
Symptoms may include:
 

- hives
- shock
- facial swelling
- rash
- blisters
- skin redness
- asthma (wheezing)

 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:
 

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older

 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



B-0316-291-12  
REV0112A29112

**Drug Facts (continued)**

**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer  
**Ask a doctor before use if**

- you have a history of stomach problems, such as heartburn
- you have asthma
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

**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
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**Stop use and ask a doctor if**

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**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- do not take more than directed
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- 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)
- avoid excessive heat 40° C (104°F)
- see end flap for expiration date and lot number

**Inactive ingredients** carnauba wax, corn starch, fumed silica gel, hydroxymethylcellulose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**  
Call 1-800-426-9891 8:30 AM-4:00 PM ET, Monday-Friday

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Assured 44-291

## IBUPROFEN

ibuprofen tablet, film coated

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:33992-0291

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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

**Product Characteristics**

Color	BROWN	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;291
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0291-2	1 in 1 CARTON	05/24/1988	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:33992-0291-0	1 in 1 CARTON	05/24/1988	
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:33992-0291-5	1 in 1 CARTON	05/24/1988	
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	05/24/1988	

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**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		038154464	PACK(33992-0291)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	MANUFACTURE(33992-0291)

Revised: 3/2017

GREENBRIER INTERNATIONAL, INC.