

**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

**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 a history of stomach problems, such as heartburn
- 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

**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
- you have symptoms of heart problems or stroke
  - chest pain
  - trouble breathing
  - leg swelling
  - slurred speech
  - weakness in one part or side of body
- 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 (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)
- avoid excessive heat 40°C (104°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, 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™**

**COMPARE 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 REV1116B29112

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

No print/No varnish  
Lot & Exp date

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50844 REV1116B29112  
ITEM# 183874

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

B-0316-291-12  
REV1116B29112

**Drug Facts (continued)**

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**Drug Facts (continued)**

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■ you have symptoms of heart problems or stroke  
■ chest pain ■ slurred speech  
■ leg swelling ■ trouble breathing  
■ weakness in one part or side of body  
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■ fever gets worse or lasts more than 3 days  
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■ any new symptoms appear

**Assured 44-291**

<b>IBUPROFEN</b>			
ibuprofen tablet, film coated			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:33992-0291
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
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### 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)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
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	

**Labeler** - GREENBRIER INTERNATIONAL, INC. (610322518)

### Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		038154464	PACK(33992-0291)
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### Establishment

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

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(33992-0291)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(33992-0291)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(33992-0291)

Revised: 9/2017

GREENBRIER INTERNATIONAL, INC.