

**DYE FREE IBUPROFEN- ibuprofen tablet**  
**Breeden Brothers, LLC**

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**Dye Free Ibuprofen**

***Drug Facts***

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

Ibuprofen USP, 200 mg (NSAID)\*

***Purpose***

Pain reliever/fever reducer \*nonsteroidal anti-inflammatory drug

***Uses***

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

***Drug Facts*** (continued)

***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.

***Drug Facts*** (continued)

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, kidney disease, asthma, or had a stroke
- \_ 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 any other drug

**Drug Facts** (continued)

- \_ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin

**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
  - \_ slurred speech
  - \_ leg swelling
  - \_ trouble breathing
- \_ 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
- \_ any new symptoms appear
- \_ redness or swelling is present in the painful area

**Drug Facts** (continued)

**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

***Drug Facts*** (continued)

***Other information***

**\_ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**

\_ store between 20°-25°C (68°-77°F)

\_ avoid excessive heat 40°C (104°F)

\_ use by expiration date on package

***Inactive ingredients***

corn starch, colloidal silicon dioxide, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, triacetin

***Questions or comments?***

**1-800-901-2420**

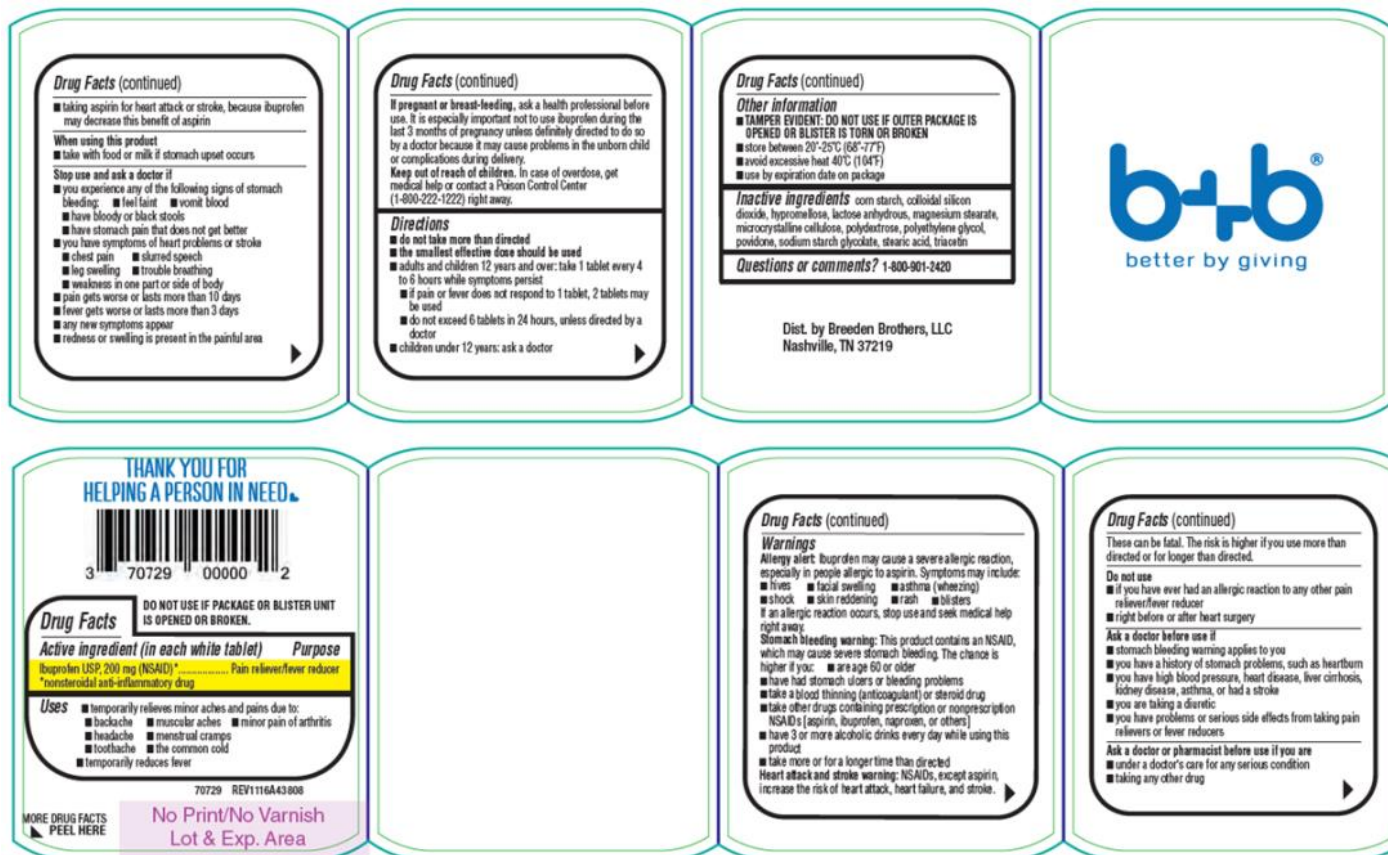
Dist. by Breeden Brothers, LLC

Nashville, TN 37219

**PRINCIPAL DISPLAY PANEL**

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better by giving



## DYE FREE IBUPROFEN

ibuprofen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70729-002
<b>Route of Administration</b>	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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

SILICON DIOXIDE (UNI: ETJ7Z6XBU4)

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	44;438
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70729-002-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/1999	
2	NDC:70729-002-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/1999	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075139	03/01/1999	

**Labeler** - Breeden Brothers, LLC (080131046)

Revised: 2/2017

Breeden Brothers, LLC