

IBUPROFEN- ibuprofen tablet, film coated
Breeden Brothers, LLC

Brown Ibuprofen Tablets

Drug Facts

22 words

Active ingredient (in each brown tablet)

Ibuprofen USP,

200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

26 words

- 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

53 words

See carton for complete warnings (short label only)

See vial card for complete warnings (vial label only)

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

74 words

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

24 words

- 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

57 words

- 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

37 words

- 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

13 words

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

89 words

- 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 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. 70 words

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

67 words

- **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

- 63 words
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING** (short label only)
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN** (blister package only)
- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)
- see end flap for expiration date and lot number (carton only)
- use by expiration date on package (vial card, vial label & label only)

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 29 words

Questions or comments?

12 words

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday (or specific to customer’s labeling guide)

Additional Information:

- Change to version 44-291.09 BBW1116
- In Legend Box update DF version to 44-291.09

PRINCIPAL DISPLAY PANEL

NDC 70729-291-12
b + b
IBUPROFEN
Ibuprofen Tablets USP, 200 mg
Pain Reliever/ Fever Reducer
(NSAID)
100 Tablets

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

Purpose
Pain reliever/fever reducer

Uses
Temporarily relieves minor aches and pains due to:
■ headache ■ muscular aches
■ menstrual cramps ■ backache ■ toothache
■ the common cold ■ 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 redness ■ 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 ■ take a blood thinner (anticoagulant) or steroid drug ■ take more or for a longer time than directed
■ 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
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 ■ right before or after heart surgery ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer
Ask a doctor before use if ■ you have problems or serious side effects from taking pain relievers or fever reducers

70729-0R611629112
Dist. by Breesden Brothers, LLC
Nashville, TN 37219

PEEL HERE FOR MORE DRUG FACTS

Adhesive Area

STOP PEELING

Drug Facts (continued)
■ stomach bleeding warning applies to you
■ you have a history of stomach problems, such as heartburn ■ you are taking a diuretic
■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
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
■ you have stomach pain that does not get better
■ you have symptoms of heart problems or stroke
■ chest pain ■ weakness in one part or side of body
■ leg swelling ■ trouble breathing ■ slurred speech
■ 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)
■ use by expiration date on package

Inactive ingredients: carmelum xan, 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 1-800-426-5391 8:30 AM-4:00 PM ET Monday-Friday

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70729-291
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:70729-291-12	1 in 1 CARTON	05/24/1988	
1		100 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 - Breeden Brothers, LLC (080131046)

Revised: 4/2018

Breeden Brothers, LLC