

IBUPROFEN- ibuprofen tablet, film coated
Better Living Brands, LLC

Safeway 44-292

Active ingredient (in each brown caplet)

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
- 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:

- 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]
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

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 asthma
- 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, or kidney disease
- 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 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets 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, 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

NDC 21130-292-08

SAFEWAY®
care

Ibuprofen

Ibuprofen Tablets USP, 200 mg
Pain Reliever / Fever Reducer
(NSAID)

Quality Guaranteed

Actual Size

24 CAPLETS

Compare to

Advil® Caplets active ingredient†

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Advil® Caplets.

50844 ORG041129208

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P.O. BOX 99, PLEASANTON, CA 94566-0009

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BROKEN OR MISSING**

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RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

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

Purpose

Uses

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

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NDC 21130-292-08

Quality Guaranteed

24 CAPLETS
Actual Size

Ibuprofen
Ibuprofen Tablets USP, 200 mg
Pain Reliever/Fever Reducer
(NSAID)

Compare to
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5044 ORG041129208

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Monday-Friday

Drug Facts (continued)
magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

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Drug Facts (continued)

- 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.

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Other information

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- see end flap for expiration date and lot number

Inactive ingredients carnauba wax, corn starch, tumbled silica gel, hypromellose, lactose.

Drug Facts (continued)

- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

Do not use

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- if you have ever had an allergic reaction to any other pain reliever/fever reducer

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- have stomach pain that does not get better
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Safeway 44-292

IBUPROFEN ibuprofen tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-292
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE (UNII: J2B2A4N98G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	BROWN	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	44;292
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-292-08	1 in 1 CARTON	05/24/1988	
1		24 in 1 BOTTLE; 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 - Better Living Brands, LLC (009137209)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(21130-292)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 11/2016

Better Living Brands, LLC