

## **IBUPROFEN- ibuprofen tablet**

Safeway

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**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

DISTRIBUTED BY SAFEWAY INC.

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

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1-888-SAFEWAY / www.safeway.com

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

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**RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION**

**Drug Facts**

**Active ingredient**  
(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

**Warnings**

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

- hives
- facial swelling
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- skin redness
- shock
- rash
- blisters

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**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

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NDC 21130-292-08



Quality Guaranteed



Actual Size 24 CAPLETS

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

Compare to  
Advil® Caplets active ingredient†

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Advil® Caplets.  
 5044 ORG041129208

**Questions or comments?**  
Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

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

**B-1817-292-08-R**  
**ORG041129208**



**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.

**Directions**

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**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.

**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**

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

**Ask a doctor before if you:**

- have asthma
- stomach bleeding or warning applies to 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
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  - 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

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Safeway 44-292

<b>IBUPROFEN</b>			
ibuprofen tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:21130-292
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (IBUPROFEN)	IBUPROFEN	200 mg

**Inactive Ingredients**

Ingredient Name	Strength
HYPROMELLOSES	
LACTOSE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYDEXTROSE	
POLYETHYLENE GLYCOLS	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STEARIC ACID	
TITANIUM DIOXIDE	

**Product Characteristics**

Color	BROWN	Score	no score
Shape	OVAL	Size	16mm
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		
1		24 in 1 BOTTLE; Combination Product Type = C112160		
2	NDC:21130-292-12	1 in 1 CARTON		
2		100 in 1 BOTTLE; Combination Product Type = C112160		
3	NDC:21130-292-15	1 in 1 CARTON		
3		50 in 1 BOTTLE; Combination Product Type = C112160		
4	NDC:21130-292-14	500 in 1 BOTTLE; Combination Product Type = C112160		

**Marketing Information**

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

**Labeler** - Safeway (009137209)**Establishment**

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

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(21130-292)

Revised: 11/2014

Safeway