

IBUPROFEN- ibuprofen capsule, coated **Safeway**

Safeway 44-393

Active ingredient (in each orange 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]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time 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 asthma
- 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

- 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 of 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 complication 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 excess heat 40°C (104°F)
- see end flap for expiration date and lot number

Inactive ingredients

carnauba wax, cellulose, corn starch, FD&C yellow #6 aluminum lake, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, 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 21130-291-08

Compare to Motrin® IB active ingredient†

Ibuprofen

ibuprofen Tablets USP, 200 mg

• Pain Reliever / Fever Reducer

(NSAID)

SEE NEW WARNINGS INFORMATION

100 CAPLETS** **Capsule-shaped tablets

SAFEWAY™

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

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



Safeway 44-393

IBUPROFEN

ibuprofen capsule, coated

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:21130-393
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX	
FD&C YELLOW NO. 6	
HYPROMELLOSES	
LACTOSE	
MAGNESIUM STEARATE	
POLYDEXTROSE	
POLYETHYLENE GLYCOLS	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STEARIC ACID	
TITANIUM DIOXIDE	

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	44;393
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-393-12	1 in 1 CARTON		
1		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075139	04/08/2002	

Labeler - Safeway (009137209)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(21130-393)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(21130-393)