IBUPROFEN- ibuprofen capsule, coated
Safeway

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 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 a blood thinning (anticoagulant) or steroid drug
- take more or for a longer time than directed
- right before or after heart surgery
- if you have ever had an allergic reaction to any other pain reliever/fever reducer

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

- 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, 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 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**
- adult 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 20º-25ºC (68º-77ºF)
- avoid excessive heat 40ºC (104ºF)

- see end flap for expiration date and lot number

Inactive ingredients

carnauba wax, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, microcrystallin cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium stach glycolate, stearic acid, titanium dioxide.

Questions or comments?

Call 1-800-426-9392 8:30 AM-4:00 PM ET, Monday - Friday

Principal Display Panel

NDC 21130-292-14
Compare to Advil® Caplets active ingredient†

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

SEE NEW WARNINGS INFORMATION

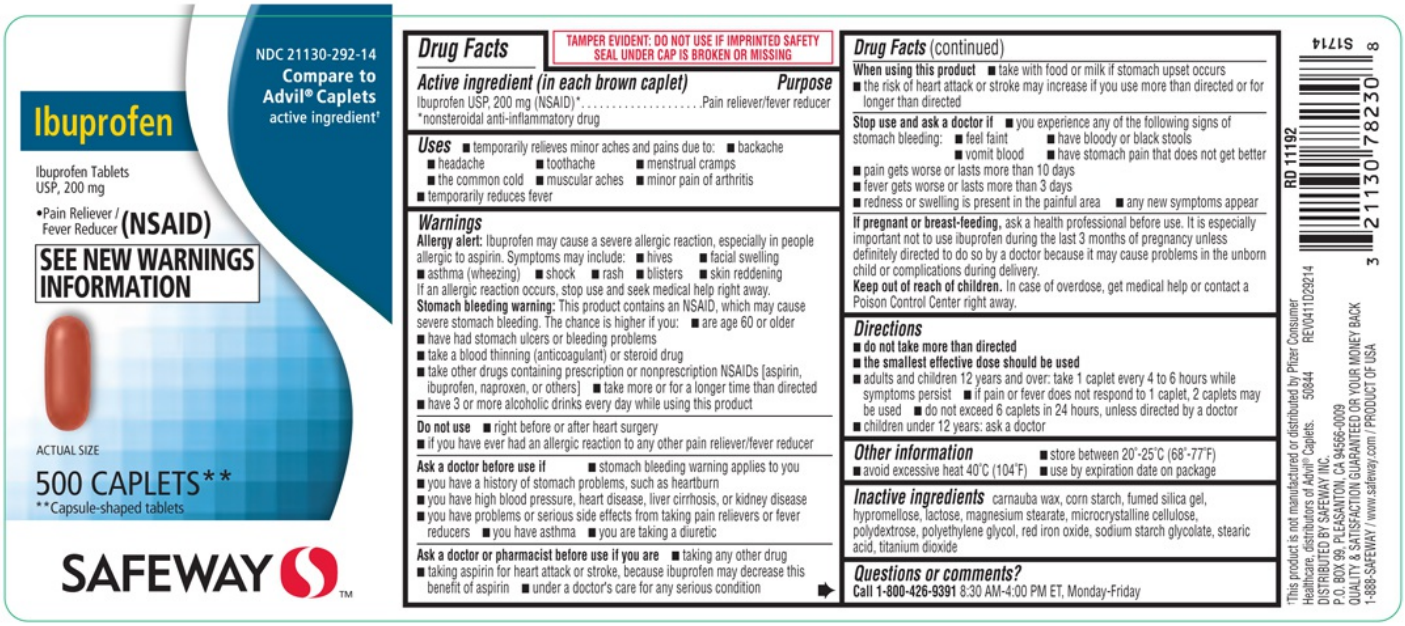
500 TABLETS

SAFEWAY™

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

50844 REV0411D29214

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



Safeway 44-292

IBUPROFEN

ibuprofen capsule, coated

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:21130-292
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
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	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	44;292
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-292-15	1 in 1 CARTON		
1		50 in 1 BOTTLE		
2	NDC:21130-292-12	1 in 1 CARTON		
2		100 in 1 BOTTLE		
3	NDC:21130-292-14	500 in 1 BOTTLE		

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)