IBUPROFEN 200 MG- ibuprofen tablet, coated Safrel Pharmaceuticals, LLC.

Drug Facts

Active ingredient(in each tablet)

Ibuprofen 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

- 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

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 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, or asthma
- you are taking a diuretic

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
- vomit blood
- have bloody or black stools
- 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 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

- each tablet contains: sodium 0.030 mg
- store at 20° to-25°C (68° to-77°F)
- avoid excessive heat above 40°C (104°F)
- read all product information before using
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive ingredients

colloidal silicon dioxide, corn starch. hypromellose, iron oxide red, lactose monohydrate, povidone k30, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

Questions or Comments

Call toll free 1-844-384-3723 Monday through Friday 9AM – 5PM EST or www.safrel.com

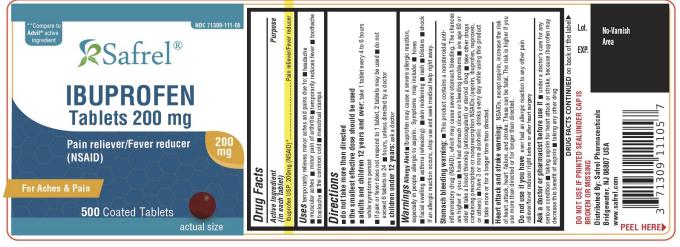
Principal Display Panel

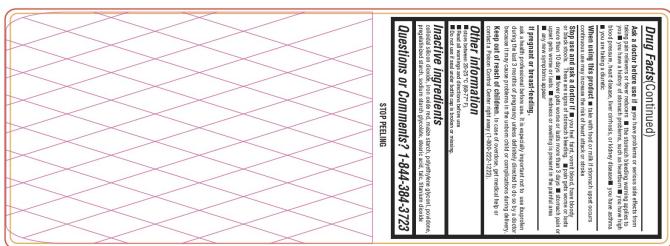
COMPARE TO ACTIVE INGREDIENT IN Advil®†

Ibuprofen 200 mg

Pain Reliever/Fever Reducer (NSAID)

†This product is not manufactured or distributed by Pfizer Healthcare, owner of the registered trademark of Advil®





IBUPROFEN 200 MG

ibuprofen tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-111	
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			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
POVIDONE K30 (UNII: U725QWY32X)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
TALC (UNII: 7SEV7J4R1U)		

Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	G2	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-111- 24	25 in 1 CARTON	04/06/2016	
1		2 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:71309-111- 50	50 in 1 CARTON	04/06/2016	
2		2 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:71309-111- 02	2 in 1 POUCH	04/06/2016	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:71309-111- 10	1000 in 1 BOTTLE	04/06/2016	
4	NDC:71309-111- 05	500 in 1 BOTTLE		
4	NDC:71309-111- 30	30 in 1 BOTTLE		
4		1 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/01/2011	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)