

**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](http://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®

**\*\*Compare to Advil® active ingredient** NDC 71309-111-05

**Safrel®**

**IBUPROFEN Tablets 200 mg**

Pain reliever/Fever reducer (NSAID) **200 mg**

For Aches & Pain

500 Coated Tablets actual size

**Drug Facts**

**Active Ingredient (in each tablet)**  
Ibuprofen USP, 200mg (NSAID)\* Pain reliever/Fever reducer

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

**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

**Warnings Allergy Alert** ■ Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ skin reddening ■ rash ■ blisters ■ shock ■ if an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** ■ This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chances are higher if you: ■ have had stomach ulcers or bleeding problems ■ are age 60 or older ■ take aspirin, aspirin-containing products, or other 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.

**Heart attack and stroke warning:** ■ NSAIDs, except aspirin, increase the risk of heart attack and stroke. The risk is higher if you use more than directed or for longer 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 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 its benefit or efficacy ■ taking any other drug

**DRUG FACTS CONTINUED on back of the label**

**Lot.**  
**EXP.**

**No-Varnish Area**

**DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING**

Distributed by: Safrel Pharmaceuticals  
Bridgewater, NJ 08807 USA  
www.safrel.com

3 71309-111-05

PEEL HERE

**Drug Facts (Continued)**

**Ask a doctor before use if** ■ you have problems or serious side effects from taking pain reliever/fever reducers ■ the 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 asthma ■ you are taking a diuretic

**When using this product** ■ take with food or milk if stomach upset occurs ■ continuous use may increase the risk of heart attack or stroke

**Stop use and ask a doctor if** ■ you feel faint, vomit blood, have bloody or black stools. These are signs of stomach bleeding. ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ stomach pain or upset gets worse or lasts ■ 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 specifically 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 (1-800-222-1222).

**Other information**  
■ See bottom of cap for lot and expiration date.  
■ Best stored at 20-25°C (68°-77°F).  
■ Do not use if seal under bottle cap is broken or missing.

**Inactive ingredients**  
colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Questions or Comments? 1-844-384-3723**

STOP PEELING

## IBUPROFEN 200 MG

ibuprofen tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71309-111
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY10QM) (IBUPROFEN - UNII:WK2XY10QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3S)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

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

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	G2
<b>Contains</b>			

### 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)