

**IBUPROFEN- ibuprofen tablet**  
**Trifecta Pharmaceuticals USA LLC**

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**Ibuprofen Tablets 200mg**

**Active Ingredient (in each tablet)**

Ibuprofen, 200mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain Reliever / Fever Reducer

nonsteroidal anti-inflammatory drug

**Do Not Use**

- If you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

**Uses**

Temporarily relieves minor aches and pains due to

- Common cold
- headache
- minor pain of arthritis
- toothache
- backache
- muscular aches
- menstrual cramps

temporarily reduces fever

**Warnings**

**Allergy alert**

Ibuprofen may cause severe allergic reactions, 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 a NSAID, which may cause severe stomach bleeding. The chances are higher if you:

- are age 60 or older
- have stomach ulcers or bleeding problems
- take 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

### **Heart attack or stroke warning**

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

### **Contains FD+C Yellow No. 5 (tartrazine) as a color additive**

### **Ask a doctor before use if**

- You have problems or serious side effects from taking pain relievers or 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, kidney disease, asthma, or had a stroke
- you are taking a diuretic

### **Ask a doctor or pharmacist before use if you are**

- Taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

### **Keep out of reach of children**

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).

### **Directions**

- Do not take more than directed.
- The smallest effective dose should be used

Adults and children 12 years and older

- Take 1 tablet every 4-6 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 of age**

- Ask a doctor

### **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

You have symptoms of heart problems or stroke

- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
  
- 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.

### **Other Information**

- Store at 20°C - 25°C (68°F - 77°F)
- Do not use if printed packet is torn or punctured.

**TAMPER EVIDENT** child resistant packets. Do not use any opened or torn packets.

### **Inactive Ingredients**

Colloidal Silicon Dioxide, Croscarmellose Sodium, FD&C Blue #2, FD&C Yellow #5, FD&C Yellow #6, Iron Oxide Red, Lecithin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregelatinized Starch, Talc, Titanium Dioxide

### **Questions or Comments?**

Call 1-888-296-9067

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP BOX FOR COMPLETE WARNINGS AND INFORMATION.

**When using this product**

Take with food or milk if stomach upset occurs

**Distributed By:**

Distributed By:

Trifecta Pharmaceuticals USA®

Ft. Lauderdale, FL. 33301 USA

1-888-296-9067

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

Reorder No. 2022

Made in the USA



INNER PACKET



# IBUPROFEN

ibuprofen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-145
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	200 mg	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
TALC (UNII: 7SEV7J4R1U)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
Color	brown	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	B106	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-145-01	50 in 1 BOX	08/08/2023	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA207095	08/08/2023		

**Labeler** - Trifecta Pharmaceuticals USA LLC (079424163)