

**IBUPROFEN- ibuprofen tablet**  
**TOPCO ASSOCIATES LLC**

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**Ibuprofen Tablets USP, 200 mg**

**PAIN RELIEVER / FEVER REDUCER (NSAID)\***

**Contains no ingredient made from a gluten-containing grain (wheat, barley or rye)**

**Active ingredient (in each caplet)**

Ibuprofen 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purposes**

Pain reliever/ fever reducer

**Uses**

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

**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

### **Heart attack and 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.

### **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

### **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 this benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

### **When using this product**

- take with food or milk if stomach upset occurs

### **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 at 20 weeks or later in 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. (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 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 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]
- avoid excessive heat above 40°C (104°F)

### **Inactive ingredients**

colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

### **Questions or comments?**

call 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

Principal Display Panel

**TopCare** health  
NDC 36800-663-20  
**\*\*COMPARE TO THE ACTIVE INGREDIENT OF ADVIL®**

**Ibuprofen**  
Tablets USP, 200 mg  
**PAIN RELIEVER / FEVER REDUCER (NSAID)\***  
Contains no ingredient made from a gluten-containing grain (wheat, barley or rye)

**200** COATED CAPLETS\* CAPSULE-SHAPED TABLETS  
actual size

**IMPORTANT: READ THE DIRECTIONS AND WARNINGS BEFORE USE**  
**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Drug Facts**  
**Active ingredient (in each caplet)** Ibuprofen 200 mg (NSAID)\*  
\*nonsteroidal anti-inflammatory drug

**Purposes**  
Pain reliever/fever reducer

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

**Warnings**  
**Alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  
■ hives ■ facial swelling ■ rash ■ skin redness/itching ■ asthma (wheezing) ■ shock  
■ difficulty breathing ■ dizziness ■ blurred vision ■ ringing in ears ■ loss of consciousness

**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 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, heart failure, and stroke. These can be fatal. 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 ibuprofen or any other pain reliever/fever reducer ■ right before or after heart surgery

**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.

This product is not manufactured or distributed by HALLOW'S HOLDINGS, distributor of A&P.  
DISTRIBUTED BY: H&M PHARMACEUTICALS, LLC  
10001 W. 11th St., Overland Park, KS 66204  
TEL: 913-646-6541 FAX: 913-646-6542  
www.hallow.com www.hallow.com  
© 2008 H&M PHARMACEUTICALS, LLC  
NADA 141-3547  
IBUPROFEN TABLETS 200 MG  
36800-663-20  
Lot  
20000004628  
Exp.  
70000003628

Inside (adhesive side)

**Drug Facts (continued)**

such as heartburn ■ you have high blood pressure, heart disease, liver disease, kidney disease, asthma or had a stroke ■ you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**  
■ taking aspirin or 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

**When using this product** ■ take with food or milk if stomach upset occurs

**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  
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**If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.**

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children under 12 years  
■ ask a doctor

**Other information** ■ store between 20 to 25°C (68 to 77°F). (See USP Controlled Room Temperature) ■ avoid excessive heat above 40°C (104°F)

**Inactive ingredients** colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, polydioxane K-30, pregelatinized starch, sodium stearoyl glycolate, stearic acid, talc, titanium dioxide

**Questions or comments?**  
call 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

**IBUPROFEN**

ibuprofen tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-663
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HFI6D95)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	red ((Reddish Brown))	<b>Score</b>	no score
<b>Shape</b>	OVAL ((Capsule shaped tablet))	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	G;2
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-663-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	10/17/2024	

**Labeler** - TOPCO ASSOCIATES LLC (006935977)

Revised: 12/2025

TOPCO ASSOCIATES LLC