

**TOPCARE IBUPROFEN- ibuprofen tablet, film coated**  
**Topco Associates LLC**

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**Topco Associates LLC. Ibuprofen Tablets 200 mg 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**

**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 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**

- read all warnings and directions before use
- store between 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- see end panel for lot number and expiration date

### **Inactive ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

### **Questions or comments?**

**1-888-423-0139**

### **Principal Display Panel**

TopCare® health

COMPARE TO ADVIL® ACTIVE INGREDIENT

SEE REVISED WARNING

Ibuprofen Tablets, 200 mg

PAIN RELIEVER - FEVER REDUCER (NSAID)

24 CAPLETS†

†CAPSULE-SHAPED TABLETS

actual size

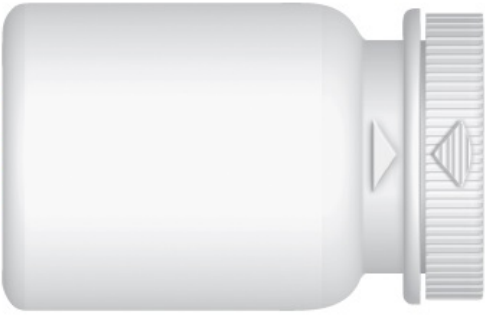
64762 88 C8



Important: Read all product information before using. Keep this box for important information.

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

actual size



GLUTEN FREE  
QUALITY GUARANTEED

**Drug Facts**

**Active ingredient (in each caplet)**  
Ibuprofen 200 mg (NSAID)..... Pain reliever/fever reducer  
hydrocortisone and inflammation drug

**Purposes**  
■ temporarily relieve minor aches and pains due to: ■ headache  
■ muscle aches ■ minor pain of arthritis ■ toothache ■ backache  
■ the common cold ■ menstrual cramps ■ 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 redness ■ rash ■ hives. 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, rofecoxib, 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 has bleeding warning applies to you ■ you have a history of stomach problems, such as

**Drug Facts (continued)**

as heartburn ■ you have high blood pressure, heart disease, heartburn, 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 its 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 or symptoms: ■ heartburn ■ 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 get worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present in the genital area ■ any new symptoms appear.

If pregnant or breast-feeding, ask a health professional before use. It is especially important 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** ■ read all warnings and directions before use ■ store below 20-25°C (68-77°F) ■ avoid high humidity and excessive heat above 40°C (104°F) ■ see separate box for lot number and expiration date

**Inactive ingredients** colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, hydroxypropyl cellulose, polyethylene glycol, polyoxona 80, stearic acid, titanium dioxide

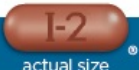
**Questions or comments?** 1-888-423-0139  
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topcare@topcare.com www.topcarebrand.com  
Visit here for more information:  
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COMPARE TO ADVIL®  
ACTIVE INGREDIENT\*\*  
SEE REVISED WARNING

TopCare health

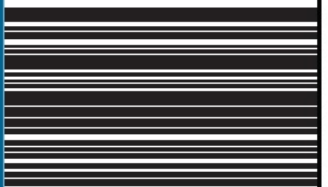
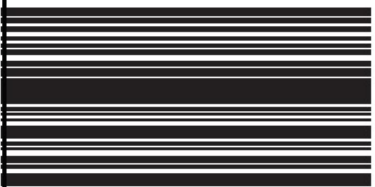
**Ibuprofen**  
Tablets, 200 mg  
PAIN RELIEVER • FEVER REDUCER (NSAID)

24 CAPLETS<sup>†</sup> CAPSULE-SHAPED TABLETS



actual size

NDC 36800-13309-62



ibuprofen tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-647
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BROWN	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	I2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-647-62	1 in 1 CARTON	04/28/2006	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-647-71	1 in 1 CARTON	11/15/1988	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:36800-647-78	1 in 1 CARTON	10/02/1991	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:36800-647-	500 in 1 BOTTLE; Type 0: Not a Combination	11/20/2003	

4	90	Product	11/20/2003	
5	NDC:36800-647-76	1 in 1 CARTON	09/27/1993	
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072096	11/15/1988	

**Labeler** - Topco Associates LLC (006935977)

Revised: 6/2023

Topco Associates LLC