

## **IBUPROFEN- ibuprofen tablet, film coated**

### **Major Pharmaceuticals**

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### **Major Pharmaceuticals Ibuprofen Tablets, 200mg 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 chances are 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**

- 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?**

**1-800-616-2471**

**Principal Display Panel**

MAJOR<sup>®</sup>

SEE REVISED WARNING

Ibuprofen Tablets, 200mg

PAIN RELIEVER / FEVER REDUCER (NSAID)

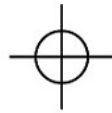
COMPARE TO the active ingredient of ADVIL<sup>®</sup>

50 COATED CAPLETS\*\*

\*\* Capsule-Shaped Tablets

Actual Size

64771 5C C10



ACTUAL SIZE



3 09047 91251 3



Rev. 08/22 M-05 Re-order No. 701028

**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**

**Drug Facts**

**Active ingredient (in each caplet)** **Purpose(s)**  
Ibuprofen 200 mg (NSAID) Pain reliever/fever reducer  
Nonsteroidal anti-inflammatory drug

**Uses** ■ Temporarily relieves minor aches and pains due to:  
■ muscular aches ■ minor pain of arthritis ■ toothache ■ headache  
■ 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 ■ 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) ■ take more or for a longer time than directed while using this product ■ have more or for a longer time than directed heart attack and stroke warnings: 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 or 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:

**Drug Facts (continued)**

as heartburn ■ you have high blood pressure, heart disease, liver, arthritis, 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

**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 goes worse or lasts more than 10 days ■ fever ■ gas 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 explicitly 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



**Drug Facts (continued)**  
**Other information** ■ read all warnings and directions before use ■ store between 20-25 °C (68-77 °F) ■ avoid light humidity and excessive moisture ■ see end panel for lot number and expiration date  
**Inactive ingredients** colorized silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polypropylene glycol, stearic acid, titanium dioxide  
**Questions or comments?** 1-800-616-2471  
Distributed by:  
MAJOR PHARMACEUTICALS  
Indianapolis, IN 46268  
www.majorpharmaceuticals.com

NDC 0904-7912-51

SEE REVISED WARNING

MAJOR®

**Ibuprofen**  
Tablets, 200mg

PAIN RELIEVER / FEVER REDUCER (NSAID)

COMPARE TO the active ingredient of ADVIL®\*\*\*

**50 COATED CAPLETS\*\***

\*\*Capsule-Shaped Tablets

Actual Size



IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7912
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BROWN	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	I2
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7912-51	1 in 1 CARTON	08/16/1994	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0904-7912-59	1 in 1 CARTON	08/30/1994	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0904-7912-24	1 in 1 CARTON	06/17/1998	09/07/2015
3		24 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	08/16/1994	

## Labeler - Major Pharmaceuticals (191427277)

Revised: 10/2023

Major Pharmaceuticals