

**IBUPROFEN- ibuprofen tablet, film coated**  
**CVS Pharmacy**

-----  
**CVS Pharmacy, Inc. Ibuprofen Tablets Drug Facts**

**Active ingredient (in each tablet)**

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 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 (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	<ul style="list-style-type: none"><li>• take 1 tablet every 4 to 6 hours while symptoms persist</li><li>• if pain or fever does not respond to 1 tablet, 2 tablets may be used</li><li>• do not exceed 6 tablets in 24 hours, unless directed by a doctor</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>• ask a doctor</li></ul>

**Other information**

- read all warnings and directions before use
- store at 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, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

**Questions or comments?**

**1-800-719-9260**

**Principal Display Panel**

Compare to the active ingredient in Motrin® IB

Coated Tablets

Ibuprofen TABLETS, 200 mg

SEE NEW WARNINGS

Pain reliever / Fever reducer (NSAID)

100 COATED TABLETS



Compare to the active ingredient in Motrin® IB†

**Coated Tablets**

NDC 59779-074-78

# Ibuprofen

TABLETS, 200 mg  
Pain reliever / Fever reducer (NSAID)

**100 COATED TABLETS**



Actual Size

**Drug Facts (continued)**

**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 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

ask a doctor

**Other information**

- read all warnings and directions before use
- store at 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:** coloidal silicon dioxide, corn starch, croscarmellose sodium, croscel, iron aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

**Questions or comments?** 1-800-719-2280

**Drug Facts (continued)**

**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 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:
  - belly pain
  - vomit blood
  - have bloody or black stools
  - 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
    - blurred speech
    - leg swelling
    - brain gets worse or lasts more than 10 days
    - fever gets worse or lasts more than 3 days
    - redness or swelling is present in the pain 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).

**Drug Facts (continued)**

**Active ingredient (in each tablet)** *Purposes*

Ibuprofen, 200 mg (NSAID)\*.....Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - 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 other drugs containing aspirin, ibuprofen, naproxen, or others
- take a blood thinning (anticoagulant) or steroid drug
- take 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.

#002808



0 50428129886 2

**CODE AREA**

07-478-17 C6

KEEP CARTON FOR REFERENCE

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

Distributed by: CVS Pharmacy, Inc.  
© 2016 CVS/pharmacy  
1-800-SHOP-CVS  
CVS Quality  
Money Back Guarantee

<b>IBUPROFEN</b>			
ibuprofen tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-074

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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	12
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-074-78	1 in 1 CARTON	02/17/2006	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59779-074-90	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/27/2006	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077349	02/17/2006	

Labeler - CVS Pharmacy (062312574)