

**IBUPROFEN- ibuprofen tablet, coated**  
**FSA STORE INC.**

-----  
**1109C-CRM-2025-0617**

***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 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 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 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
- children under 12 years: ask a doctor

## **Other information**

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

## **Inactive ingredients**

colloidal silicon dioxide, corn starch, iron oxide red, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

## **Questions or comments?**

1-844-705-4384

**PRINCIPAL DISPLAY PANEL**

Caring Mill™

NDC 81522-119-03

†Compare to the active ingredient of Advil®

Ibuprofen

Tablets, 200 mg

Pain Reliever/Fever Reducer (NSAID)

100 COATED TABLETS

Actual Size

INK AND COATING FREE  
FOR LOT AND  
EXPIRATION STAMPING



by patient use only  
SSK CH, USA  
This product is not manufactured or distributed by the manufacturer of Advil®

**DO NOT USE IF IMPRINTED SEAL  
UNDER CAP IS BROKEN OR MISSING**

**Drug Facts**

**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
  - minor pain of arthritis
  - backache
  - menstrual cramps
- temporarily reduces fever
- muscular aches
- toothache
- the common cold

**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) ■ 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

**Drug Facts (continued)**

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 ■ big 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

**Drug Facts (continued)**

**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 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
- 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 excessive heat above 40°C (104°F)

**Inactive ingredients**

colloidal silicon dioxide, corn starch, iron oxide red, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Questions or comments?** 1-844-705-4384

Manufactured for  
 FSA Store Inc.  
 5473 Blair Rd STE 100 PMB 24508  
 Dallas, Texas 75231  
 1-844-705-4384  
 Made in India

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

**ibuprofen**  
 caring mill™  
 Tablets, 200 mg

NDC 81522-119-03

caring mill™  
 \*Compare to the active ingredient of Advil®

# Ibuprofen

Tablets, 200 mg  
 Pain Reliever/Fever Reducer (NSAID)

**100 COATED TABLETS**



Actual Size

COATING FREE AREA

<b>IBUPROFEN</b> ibuprofen tablet, coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81522-119
<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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G2
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81522-119-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/2023	
2	NDC:81522-119-03	1 in 1 CARTON	05/03/2023	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/11/2023	

**Labeler** - FSA STORE INC. (049283340)