

**IBUPROFEN- ibuprofen capsule, liquid filled  
FSA STORE INC.**

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**1185A-CRM-2023-0111**

***Drug Facts***

**Active ingredient (in each capsule)**

Solubilized ibuprofen equal to

200 mg ibuprofen (NSAID)\*

\* nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever/fever reducer

**Uses**

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

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- 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**

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

### **When using this product**

- take with food or milk if stomach upset occurs

### **Stop use and ask a doctor if**

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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 over:
  - take 1 capsule every 4 to 6 hours while symptoms persist
  - if pain or fever does not respond to 1 capsule, 2 capsules may be used
  - do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

## Other information

- each capsule contains: **potassium 20 mg**
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- read all warnings and directions before use
- retain carton for complete product information and warnings

## Inactive ingredients

ammonium hydroxide, FD&C green #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, propylene glycol, potassium hydroxide, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

**Questions or comments?**

1-844-705-4384

**PRINCIPAL DISPLAY PANEL**

caring mill™

NDC 81522-185-03

†Compare to the active ingredient or Advil® Liqui-Gels®

Ibuprofen Capsules

200 mg

Pain Reliever/Fever Reducer (NSAID)

Actual Size

80 SOFTGELS\*\* \*(Liquid Filled Capsules)

INK AND COATING FREE  
FOR LOT AND  
EXPIRATION STAMPING



F1185A003CRM\_R0  
This product is not manufactured or distributed  
by Pfizer Consumer Healthcare, distributor of  
Advil® Light-Gels®



**Drug Facts**

**Active ingredient  
(in each capsule)**

Sulbuzitab ibuprofen equal to  
200 mg ibuprofen (NSAID)\*  
\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever/  
fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
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  - menstrual cramps
  - toothache
  - the common cold
  - minor pain of arthritis
- 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 peeling ■ 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

**Drug Facts (continued)**

**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**  
■ stomach bleeding warning applies to you  
■ you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are**  
■ under a doctor's care for any serious condition  
■ taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin  
■ 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  
■ you 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

**Drug Facts (continued)**

■ 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.

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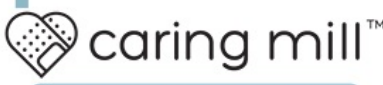
**Inactive ingredients** ammonium hydroxide, FD&C green #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, polyethylene glycol, potassium hydroxide, purified water, shellac, sorbitan monoleate, sorbitol sorbitan

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

Drug Facts (continued)  
Questions or comments?  
1-844-705-4384

Manufactured for: FSA Store Inc.  
601 W 26th St, 3rd Floor  
STE 357 / DPT# 24075  
New York, NY 10001  
Customer Care Help Line  
1-844-705-4384  
Made in India

NDC 81522-185-03



**Ibuprofen Capsules**

200 mg

Pain Reliever/Fever Reducer (NSAID)



80 SOFTGELS\*\* (Liquid Filled Capsules)

**IBUPROFEN**  
ibuprofen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81522-185
Route of Administration	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>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR601S)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>FERROUS OXIDE</b> (UNII: G7036X8B5H)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

**Product Characteristics**

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	133
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81522-185-03	1 in 1 CARTON	01/11/2023	
1		80 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	ANDA079205	01/11/2023	

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