

IBUPROFEN- ibuprofen tablet, coated
FSA STORE INC.

1109C-2023-0111

Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (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 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

- 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

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

NDC 81522-119-05

caring mill™

†Compare to the active ingredient of Advil®

Ibuprofen

Tablets 200 mg

Pain Reliever/Fever Reducer (NSAID)

Actual Size

500 COATED TABLETS

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

NDC 81522-119-05

caring mill™
Compare to the active ingredient of Advil®

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

Actual Size

500 COATED TABLETS

Drug Facts

Active Ingredient (in each tablet)
Ibuprofen 200 mg (NSAID)..... Pain reliever/fever reducer
* nonsteroidal anti-inflammatory drug

Uses
temporarily relieves minor aches and pains due to:
headache, toothache, minor pain of arthritis, menstrual cramps, the common cold, muscular aches, 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, 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 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
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:
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
sturred 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
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Other information
store at 20°-25°C (68°-77°F)
avoid excessive heat above 40°C (104°F)
read all warnings and directions before use

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

Questions or comments? 1-844-765-4384

Manufactured for:
FSA Store Inc., 3rd Floor
100 West 31st Street
New York, NY 10001
Customer Service Help Line
1-844-765-4384
Made in India
L1110000696L10

IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81522-119
Route of Administration	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)

Revised: 5/2023

FSA STORE INC.