

IBUPROFEN- ibuprofen tablet, coated
VALU MERCHANDISERS COMPANY

1109C-AWS-2023-1031

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?

1-844-292-1112

PRINCIPAL DISPLAY PANEL

Akways Save®

IBUPROFEN

TABLETS, 200 mg

PAIN RELIEVER/FEVER REDUCER

(NSAID)

ACTUAL SIZE

500 COATED TABLETS

Always Save
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

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Active ingredient (in each tablet)
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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 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 ■ take a blood thinning (anticoagulant) or steroid drug
 ■ have had stomach ulcers or bleeding problems ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
 ■ take 3 or more alcoholic drinks every day while using this product
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 are taking a diuretic
 ■ 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 ■ slurred speech ■ foggy thinking
 ■ 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).
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Other information ■ store at 20°-25°C (68°-77°F) ■ read all warnings and directions before use
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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

ALWAYS SAVE
 66836-0823-AAA
 0 17 0038 66836 17
 Questions or comments? 1-844-292-1112
 Scan here for more product information.
 Call 1-844-292-1112 for product information.
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IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-209
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)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

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:63941-209-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/29/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	10/29/2023	

Labeler - VALU MERCHANDISERS COMPANY (868703513)

Revised: 10/2023

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