

IBUPROFEN 200 MG- ibuprofen 200 mg tablet, coated
Farmacias De Similares TX LLC

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

. Temporarily relieves minor aches and pains due to:

- Headache - Backache - Muscular aches - Minor pain of arthritis - Menstrual cramps - Toothache - The common cold - 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 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 - Slurred speech - Weakness in one part or side of body

- 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

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 caplet every 4 to 6 hours while symptoms persist -If pain or fever does not respond to 1 caplet, 2 caplets may be used
- Do not exceed 6 caplets in 24 hours, unless directed by a doctor
- Children under 12 years: - Ask a doctor

Other information

Store between 20-25 °C (68-77°F)

Inactive ingredients

Colloidal silicon dioxide, Corn starch, FD&C Yellow No. 6 Aluminum Lake, Hypromellose, Magnesium stearate, Microcrystalline cellulose, Pregelatinized starch, Sodium starch glycolate, Talc, Titanium dioxide, Triacetin.

Questions or comments?

(855)-280-1079

t This product is not manufactured or distributed by GSK CH, owner of the registered trademark Advil®

Distributed in USA by:
FARMACIAS DE SIMILARES TXLLC
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 customerservice@drsimi.com

<p>Drug Facts</p> <p>Active ingredient (in each caplet).....Purpose Ibuprofen 200 mg (NSAID)*.....Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> Temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> Headache Backache Muscular aches Minor pain of arthritis Menstrual cramps Toothache The common cold Temporarily reduces fever <p>Warnings</p> <p>Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> hives facial swelling asthma (wheezing) shock skin reddening rash blisters <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> 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. <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p> <p>When using this product</p> <ul style="list-style-type: none"> Take with food or milk if stomach upset occurs <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> You experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Chest pain Trouble breathing Slurred speech Weakness in one part or side of body 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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 <p>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.</p> <p>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).</p> <p>Directions</p> <ul style="list-style-type: none"> Do not take more than directed The smallest effective dose should be used <p>Adults and children 12 years and over: • Take 1 caplet every 4 to 6 hours while symptoms persist • If pain or fever does not respond to 1 caplet, 2 caplets may be used • Do not exceed 6 caplets in 24 hours, unless directed by a doctor</p> <p>Children under 12 years: • Ask a doctor</p> <p>Other information</p> <ul style="list-style-type: none"> Store between 20-25 °C (68-77 °F) <p>Inactive ingredients Colloidal silicon dioxide, Corn starch, FD&C Yellow No. 6 Aluminum Lake, Hypromellose, Magnesium stearate, Microcrystalline cellulose, Pregelatinized starch, Sodium starch glycolate, Talc, Titanium dioxide, Triacetin.</p> <p>Questions or comments? (855)-280-1079</p> <p>† This product is not manufactured or distributed by GSK CH, owner of the registered trademark Advil®</p> <p>Distributed in USA by: FARMACIAS DE SIMILARES TXLLC 800 Brazos St Ste 260, Austin, TX, 78701, USA customerservice@drsimi.com www.drsimi.com</p>	 <p>DR. SIMI #</p>	<p>NDC: 85786-107-30</p> <p>Ibuprofen 200 mg</p> <p>Pain Reliever / Fever Reducer (NSAID)</p>	 <p>DR. SIMI #</p>	<p>30 caplets</p>
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Dr. Simi

Compare to the active ingredient in Advil®

NDC: 85786-107-30

Ibuprofen 200 mg

Pain Reliever / Fever Reducer (NSAID)

30 caplets

IBUPROFEN 200 MG

ibuprofen 200 mg tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85786-107
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	

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:85786-107-30	30 in 1 CARTON; Type 0: Not a Combination Product	01/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/01/2026	

Labeler - Farmacias De Similares TX LLC (119489934)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India		918609236	manufacture(85786-107)

Establishment

Name	Address	ID/FEI	Business Operations
Green Star Labs, Inc.		118673251	pack(85786-107)

Revised: 1/2026

Farmacias De Similares TX LLC