IBUPROFEN- ibuprofen tablet Granules USA, Inc.

SEE NEW WARNINGS
Ibuprofen
Tablets USP, 200 mg
Pain Reliever/Fever Reducer (NSAID)**

Active ingredient (For Tablet)

(in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Active ingredient (For Caplet)

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

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,

■ 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 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 the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions (For Tablets)

- 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

Directions (For Caplets)

- do not take more than directed
- the smallest effective dose should be used

adults and children 12 years and older

- 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

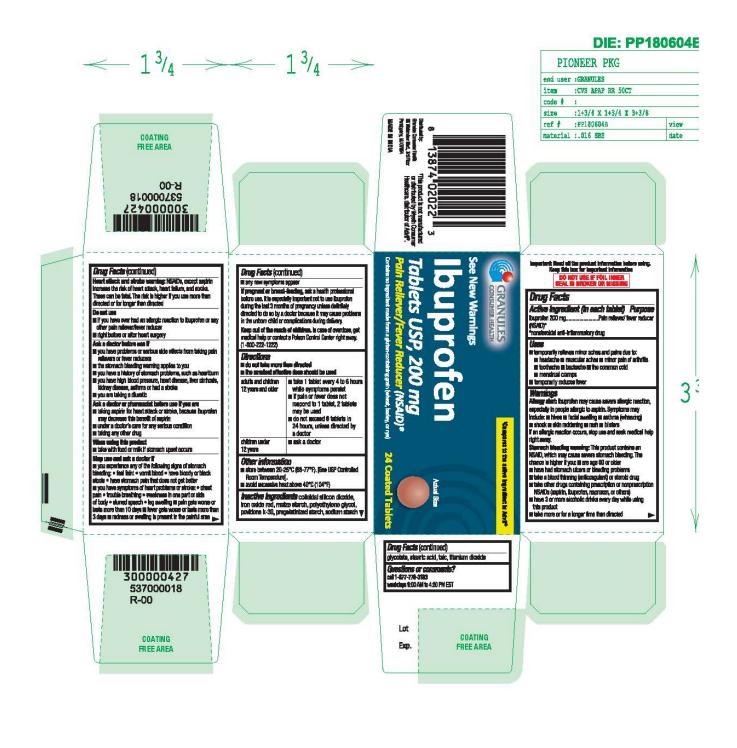
- store between 20-25°C (68-77°F). [See USP Controlled Temperature]
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide.

Questions or comments?

call **1-877-770-3183** weekdays 9:00 AM to 4:30PM EST.





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Tablets USP, 200 mg
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Quantiforms or community? call 1-877-778-9183 weekings 2:00 AM to 4:30 PM EST

lbuprofen GRANULES CONSUMER HEALTH

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Important: Hand all the product information before using.

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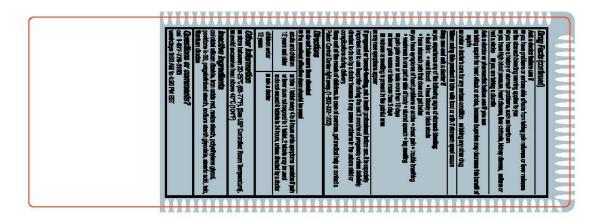
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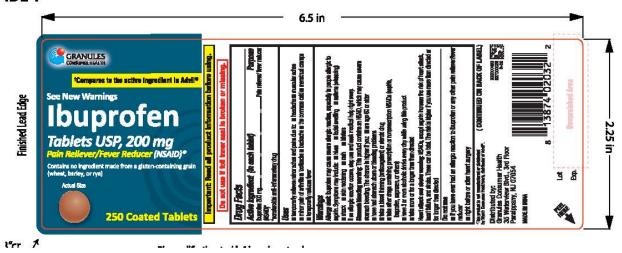
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IDE 1



Caplets



IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-012
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
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ 989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	brown (Reddish Brown color Tablets)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G2
Contains			

P	Packaging Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-012- 24	24 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
2	NDC:69848-012- 10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
3	NDC:69848-012- 25	250 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing Category Citation Date Date				
ANDA	ANDA079174	07/01/2019		

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ibuprofen tablet

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Route of Administration	ORAL			

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Ingredient Name	Basis of Strength	Strength
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Inactive Ingredients

Ingredient Name	Strength
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TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	brown (Reddish Brown tablets)	Score	no score
Shape	OVAL (Caplet shaped Tablets)	Size	14mm
Flavor		Imprint Code	G2
Contains			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:69848-011-	24 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	07/01/2019	

Labeler - Granules USA, Inc. (137098864)

Revised: 12/2024 Granules USA, Inc.