AMAZON BASIC CARE IBUPROFEN - ibuprofen tablet Amazon.com Services LLC

Ibuprofen Tablets

Drug Facts

Active ingredient (in each tablet)

Ibuprofen USP 200 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

Purposes

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

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
- 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 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.

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 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

Other information

- store between 20° to 25°C (68° to 77°F)
- do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing
- see bottom panel for lot number and expiration date

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, polyethylene glycol, red iron oxide, stearic acid, titanium dioxide and yellow iron oxide

Questions or comments?

Call **1-855-274-4122**

DISTRIBUTED BY:

AMAZON.COM SERVICES LLC 410 TERRY AVENUE N., SEATTLE, WA 98109

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (100 Tablets Bottle)

amazon basic+care

For Aches & Pains NDC 72288-513-10

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

100 COATED TABLETS

amazon

basic (care

NDC 72288-513-10

buprofen

Tablets USP 200 mg

Pain Reliever/ Fever Reducer (NSAID)

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Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is

Important: Read all product information before using. Keep the box for important information.

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LM-5707 P1434065

Unvarnished Zone (dotted line not for printing) 30 x 14 mm

Drug Facts (continued)

■ 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

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Do not use imit you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer imight 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 **u**you are taking a diuretic **Ask a doctor or pharmacist before use if you are u**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 at 20 weeks or later in

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Drug Facts (continued)

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For Aches & Pains NDC 72288-513-10

Compare to the active ingredinet in Advil®**

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

100 COATED TABLETS

actual size



AMAZON BASIC CARE IBUPROFEN

ibuprofen tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72288-513

Route of Administration ORAL

Active Ingredient/Active Moiety

l	Ingredient Name	Basis of Strength	Strength
ı	IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: 08232NY3SJ)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FERRIC OXIDE YELLOW (UNII: EX43802MRT)				

Product Characteristics			
Color	BROWN (Light Brown to Brown)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	N;II
Contains			

tem Code DC:72288- 13-10	Package Description 1 in 1 CARTON	Marketing Start Date	Marketing End Date
	1 in 1 CAPTON		
	I III I CARTON	05/15/2024	
	100 in 1 BOTTLE; Type 0: Not a Combination Product		
DC:72288- 13-20	1 in 1 CARTON	05/15/2024	
	200 in 1 BOTTLE; Type 0: Not a Combination Product		
DC:72288- 13-49	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2024	
	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2024	
		05/15/2024	
1 C 1	DC:72288- 3-20 DC:72288- 3-49 DC:72288- 3-50 DC:72288-	200 in 1 BOTTLE; Type 0: Not a Combination Product 0C:72288-3-49 500 in 1 BOTTLE; Type 0: Not a Combination Product 50C:72288-500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 50C:72288-1000 in 1 BOTTLE, PLASTIC; Type 0: Not a 50C:72288-1000 in 1 BOTT	1 in 1 CARTON 200 in 1 BOTTLE; Type 0: Not a Combination Product 0C:72288- 3-49 500 in 1 BOTTLE; Type 0: Not a Combination Product 0C:72288- 3-50 500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 05/15/2024 05/15/2024 05/15/2024

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208865	05/15/2024	

Labeler - Amazon.com Services LLC (128990418)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(72288-513), MANUFACTURE(72288-513)

Establishment			
Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(72288-513), MANUFACTURE(72288-513)

Revised: 5/2024 Amazon.com Services LLC