

IBUPROFEN- ibuprofen tablet
Rugby Laboratories

Ibuprofen Tablets, USP 200mg

Pain Reliever/Fever Reducer (NSAID)

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

Active ingredient (in each tablet)

Ibuprofen 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). [See USP Controlled Room Temperature]. ■ avoid excessive heat above 40°C (104°F)
■ tamper evident sealed packets ■ do not use any opened or torn packets

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** Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP

Cavalier
 Oneup:Cavalier26
 Size:4+1/4" x 2+1/2" x 3+7/16"



IBUPROFEN
 ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1390
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	red ((Reddish Brown))	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1390-48	100 in 1 CARTON; Type 0: Not a Combination Product	12/31/2024	
2	NDC:0536-1390-47	2 in 1 PACKET; Type 0: Not a Combination Product	08/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	08/25/2023	

Labeler - Rugby Laboratories (079246066)

Revised: 11/2024

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