

IBUPROFEN- ibuprofen tablet, coated
Spirit Pharmaceuticals LLC

Ibuprofen

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 a nonsteroidal anti-inflammatory drug (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: NSAID's except aspirin increases 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 • the 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 • 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

- read all warnings and directions before use. Keep carton. • store between 20°-25°C (68°-77°F) • avoid excessive heat above 40°C (104°F)

Inactive ingredients

Colloidal silicon dioxide, corn starch, croscarmellose sodium*, hypromellose, iron oxide red, magnesium stearate*, microcrystalline cellulose*, polyethylene glycol, polyvinyl alcohol, povidone K-30*, pregelatinized starch, sodium starch glycolate*, stearic acid*, talc, titanium dioxide, triacetin.

*contains one or more of these ingredients

Questions or comments?

1-888-333-9792

Display Panel

Compare to Motrin® IB Caplets active ingredientt

ibuprofen

Ibuprofen Tablets, USP 200 mg -

Pain Reliever / Fever Reducer

40 Caplet

Drug Facts (continued)

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chances are 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 and nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 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.

Ask a doctor before use if

- the 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

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)

Questions or comments? 1-888-333-9792

VALUHEALTH
BY SPIRIT

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

40 caplets

DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Active ingredient
(in each caplet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Uses

- temporarily relieves minor aches and pains due to:
 - headache ■ toothache ■ backache
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 - 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.

Drug Facts (continued under label)

Distributed By: Spirit Pharmaceuticals, LLC
Ronkonkoma, NY 11779
REV 02/23

88812-3

Made in India

LOT:
EXP:



IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4200
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

SODIUM STARCH GLYCOLATE TYPE B CORN (UNII: 2LI18Q1ZCG)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TRIACETIN (UNII: XHX3C3X673)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	IBU;200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4200-3	1 in 1 CARTON	06/15/2022	
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091355	06/15/2022	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2024

Spirit Pharmaceuticals LLC