

IBUPROFEN- ibuprofen tablet, film 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, croscarmellose sodium*, iron oxide red, magnesium stearate*, microcrystalline cellulose*, polyethylene glycol, polyvinyl alcohol, povidone K-30*, pregelatinized starch, sodium starch glycolate*, stearic acid*, talc, titanium dioxide.

*contains one or more of these ingredients

Questions or comments?

1-888-333-9792

Distributed By:

Spirit Pharmaceuticals, LLC
Ronkonkoma, NY 11779

Carton

LOT:
EXP:



DO NOT USE IF CARTON HAS OPENED OR SAFETY SEAL UNDERCAP IS BREAKENOR MISSING



Ibuprofen

Ibuprofen tablets, 200 mg
Pain Reliever / Fever Reducer (NSAID)

25 tablets

Actual Size

Compare to Advil®
Active ingredient†

Drug Facts (continued)

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- rashness or swelling is present in the painful area
- any new symptoms appear
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Directions

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Other information

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

Inactive ingredients: Colloidal silicon dioxide, croscarmellose sodium*, iron oxide red, magnesium stearate*, hydroxyethylcellulose*, polyethylene glycol, polyvinyl alcohol, polyvinyl k-30*, polydimethyl siloxane*

Drug Facts (continued)

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 disease, 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 pain reliever 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 of face or body
 - slurred speech
 - leg swelling

Drug Facts (continued)

†not in starch/glycerol*, stearic acid*, t.c., item in d box

* contains one or more of these ingredients

Questions or comments? 1-888-338-9762

†this product is not manufactured or distributed by Wyeth Consumer Healthcare, under other registered trademarks.

Distributed By: Spirit Pharmaceuticals, LLC
Rensselaer, NY 11779 CRG1021
Made in India 888-493-7

READ AND KEEP FOR YOUR COMPLETE WARNING INFORMATION

Drug Facts

Active ingredient (in each tablet): Purpose

Ibuprofen 200 mg (NSAID)*...Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

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)
- dizziness
- skin rash
- fast
- nausea

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 thinner (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.

Drug Facts (continued)

These can be fatal. The risk is higher if you use more than directed or for longer than directed.

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 - slurred speech
 - leg swelling

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	200 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE K30 (UNII: U725QWY32X)				
STARCH, POTATO (UNII: 8I089SAH3T)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
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:68210-4192-2	25 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA079174		12/08/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)