

IBUPROFEN- ibuprofen tablet, film coated
Spirit Pharmaceutical LLC

Ibuprofen Tablets

Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)*

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 stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- 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**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- 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

PRINCIPAL DISPLAY PANEL

COMPARE TO ACTIVE INGREDIENT OF
ADVIL® TABLETS*

Ibuprofen

- Ibuprofen Tablets USP, 200 mg
Pain reliever / Fever reducer (NSAID)

VALUMEDS™ NDC 682 10 8100 5
Compare to the active ingredient in Advil® Tablets

IBUPROFEN

Ibuprofen tablets
USP, 200 mg

pain reliever /
fever reducer (NSAID)

50 tablets



Actual Size

LOT: 910569779
EXP: 09/16

0 977 979 956 16 9

0-98-19

DO NOT REUSE THIS CAP OR SEAL. IF THE SEAL IS BROKEN OR MISSING, DO NOT USE. PRINTED IN INDIA.

30 tablets

pain reliever /
fever reducer (NSAID)



Actual Size

VALUMEDS™

Compare to Advil® Active Ingredient

IBUPROFEN

Ibuprofen tablets,
200 mg

76506A

Drug Facts (continued)

- weakness in one part or side of body
- sturred 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

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READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each tablet) Purpose
Ibuprofen 200 mg (NSAID)** ... Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

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 - headache
 - toothache
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- 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.

Do not use

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- right before or after heart surgery

Ask a doctor before use if

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- 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

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- under a doctor's care for any serious condition
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When using this product

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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

Drug Facts (continued)

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? 1-800-333-6792

This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Advil®.

Distributed By: Spirit Pharmaceuticals, LLC
Rionkonkoma, NY 11779 ORIG 07/19
Made in India

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68210-8100

Route of Administration	ORAL
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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)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
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:68210-8100-5	1 in 1 CARTON	03/10/2020	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210-8100-3	1 in 1 CARTON	03/10/2020	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68210-8100-2	1 in 1 CARTON	09/22/2020	
3		25 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	ANDA079174	03/10/2020	

Labeler - Spirit Pharmaceutical LLC (179621011)

Revised: 12/2024

Spirit Pharmaceutical LLC