

IBUPROFEN- ibuprofen tablet, coated
Geritrex LLC

Ibuprofen

Drug Facts

Active ingredient (in each brown tablet)

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- toothache
- the common cold
- menstrual cramps
- backache
- headache
- 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:

- facial swelling
- hives
- asthma (wheezing)
- rash
- shock
- skin reddening
- 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

- take more or for a longer time than directed
- are age 60 or older
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems

- 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.

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

- 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
- you have problems or serious side effects from taking pain relievers or fever reducers

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:
 - have bloody or black stools
 - vomit blood
 - feel faint
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - slurred speech
 - leg swelling
 - trouble breathing
 - weakness in one part or side of body
- 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 (1-800-222-1222) right away.

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

- use by expiration date on package
- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)

Inactive ingredients

carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

Call 1-800-736-3437 8:30 AM-5:00 PM ET, Monday-Friday

9.125"

3.750"

NDC 54162-941-90
Compare to the active ingredient in Advil® Tablets

Geritrex®

Ibuprofen
Ibuprofen Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)

1000 Tablets

Actual Size

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temporarily relieves minor aches and pains due to:
toothache, the common cold, menstrual cramps, backache, headache, muscular aches, minor pain of arthritis, temporarily reduces fever

Warnings
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Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you take more or for a longer time than directed, are age 60 or older, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others), have had stomach ulcers or bleeding problems, 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.

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
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, you have problems or serious side effects from taking pain relievers or fever reducers.

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

Drug Facts (continued)

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: have bloody or black stools, vomit blood, feel faint, have stomach pain that does not get better, you have symptoms of heart problems or stroke: chest pain, slurred speech, leg swelling, trouble breathing, weakness in one part or side of body, 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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Other information use by expiration date on package, store between 20°-25°C (68°-77°F), avoid excessive heat 40°C (104°F)

Inactive ingredients: carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

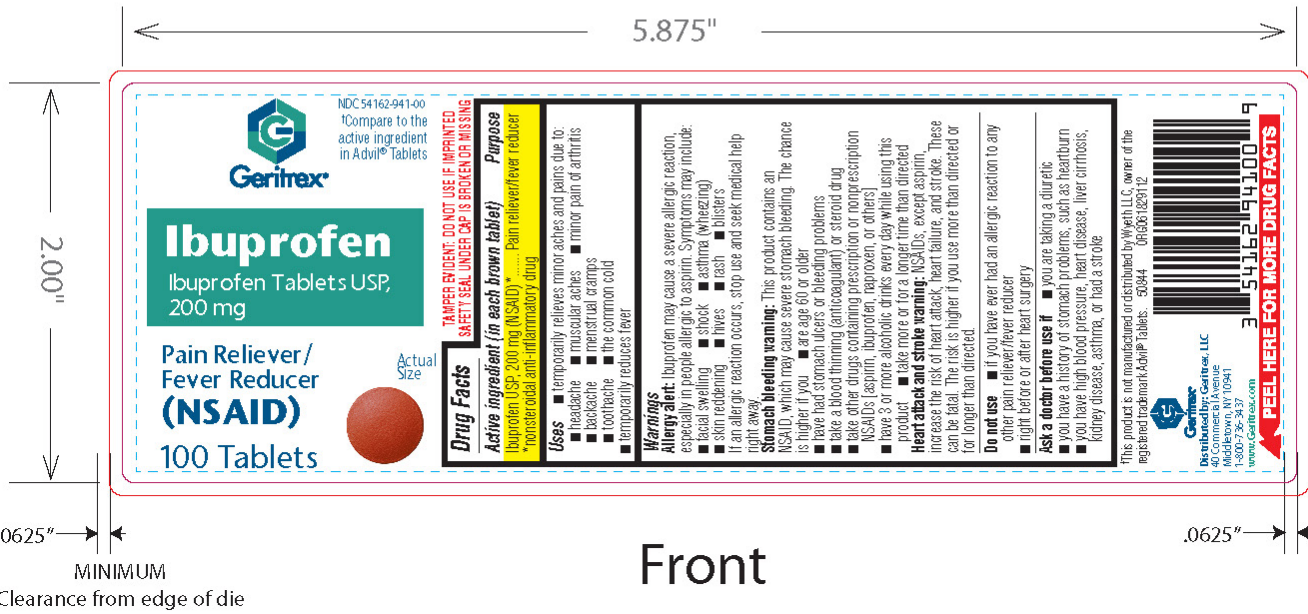
Questions or comments?
Call 1-800-736-3437 8:30 AM-5:00 PM ET, Monday-Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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1 This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Advil® Tablets. 30844 UN060123116

Distributed by: Geritrex, LLC
40 Commercial Avenue
Middletown, NY 10941
1-800-736-3437
www.Geritrex.com



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Front

IBUPROFEN			
ibuprofen tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-941
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
CARNAUBA WAX (UNII: R12CBM0EIZ)			

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STARCH, CORN (UNII: O8232NY3SJ)
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYDEXTROSE (UNII: VH2XOU12IE)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
FERRIC OXIDE RED (UNII: 1K09F3G675)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics			
Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;291
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-941-90	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/15/2018	
2	NDC:54162-941-00	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/15/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	10/15/2018	

Labeler - Geritrex LLC (112796248)