

HELP I HAVE AN ACHING BODY - ibuprofen tablet

Help Remedies, Inc.

Drug Facts

Active Ingredient.....Purpose
(in each tablet)

Ibuprofen 200 mg (NSAID)*.....Pain reliever/ Fever reducer

*nonsteroidal anti-inflammatory drug

Use

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

Warnings

Allergy Alert Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin
Symptoms may include:

• shock • hives • facial swelling • asthma (wheezing) • rash • skin reddening • 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 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 an NSAID (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.

Stop use and ask a doctor if you feel faint, vomit blood, or have bloody or black stools. These are the
signs of stomach bleeding

• 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
more than 10 days • stomach pain or upset gets worse or lasts • redness or swelling is present in the
painful area • any new symptoms appear.

Ask a doctor before use if you have • problems or serious side effects from taking pain relievers or
fever reducers • stomach

problems that last or come back, such as heartburn, upset stomach, or stomach pain • bleeding problems
• ulcers • high blood
pressure • taken a diuretic • heart or kidney disease • reached age 60 or older.

Ask a doctor or pharmacist before use if you are • taking any other drug containing an NSAID
(prescription or non prescription)

• taking a blood thinning agent (anticoagulant) or steroid drug • taking any other drug • under a doctor's
care for any serious condition.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

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)

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.

When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of a heart attack or stroke.

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
- do not take more than directed
- the smallest effective dose should be used

Directions

- do not take longer than 10 days, unless directed by a doctor (see Warnings)

Other information

- do not use if packet is torn, cut or opened
- store at controlled room temperature 15-30°C (59-86°F)
- avoid excessive heat and humidity
- keep carton. They contain important information.

Distributed by Help Remedies,
57 W. 28th St. Fl. 4
New York, NY 10001

www.helpneedhelp.com

Drug Facts (continued)
Stop use and ask a doctor if you feel faint, vomit blood, or have bloody or black stools. These are the signs of stomach bleeding
 • 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 more than 10 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 longer than 10 days, unless directed by a doctor (see Warnings)

Help I have an aching body is a drug, not a sweet candy treat. We wouldn't try to trick you by coating it with sugar.
 NDC number: 49260-615-40 LOT:
 8 3765411661514 4 EXP:
 SEE NEW STOMACH BLEEDING WARNING IN DRUG FACTS.

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 ibuprofen Pain reliever/
 200 mg (NSAID)* fever reducer
 *nonsteroidal anti-inflammatory drug
Use Temporarily relieves minor aches and pains due to • common cold • headache
 PEEL HERE FOR MORE DRUG FACTS →

page 2
typ 1.9375"

page 3
typ 1.8125"

Base Web
2.25" X 2.25" label size

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 • minor pain of arthritis • menstrual cramps
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 • shock • hives • facial swelling • asthma (wheezing) • rash • skin reddening • blisters
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Stomach bleeding warning This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 an NSAID (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 →

Drug Facts (continued)
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 you have
 • problems or serious side effects from taking pain relievers or fever reducers • stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain • bleeding problems • ulcers • high blood pressure • taken a diuretic • heart or kidney disease • reached age 60 or older
Ask a doctor or pharmacist before use if you are • taking any other drug containing an NSAID (prescription or non prescription) • taking a blood thinning agent (anticoagulant) or steroid drug • taking any other drug • under a doctor's care for any serious condition
When using this product • take with food or milk if stomach upset occurs • long term continuous use may increase the risk of a heart attack or stroke →

Black



10-31843
DO NOT USE IF SEAL IS BROKEN OR TAMPERED WITH

Drug Facts (continued)
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Other information
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 • store at controlled room temperature 15-30°C (59-86°F) • avoid excessive heat and humidity
 • keep carton. They contain important information.
Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, hypromellose, micro-crystalline cellulose, pregelatinized starch, stearic acid, titanium dioxide.
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HELP I HAVE AN ACHING BODY			
ibuprofen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49260-615
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	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white (white)	Score	no score	
Shape	ROUND (round)	Size	10mm	
Flavor		Imprint Code	44352	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49260-615-50	50 in 1 BOTTLE		
2	NDC:49260-615-16	16 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075139	07/01/2009		

Labeler - Help Remedies, Inc. (050359682)

Revised: 3/2013

Help Remedies, Inc.