IBUPROFEN - ibuprofen tablet Genuine First Aid LLC

Ibuprofen, 200 mg

Active Ingredient (in each tablet)

Ibuprofen USP (NSAID*) 200mg *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

the 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, facial swelling, asthma (wheezing) rash, skin reddening, blisters, hives 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 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

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 a high blood pressure, heart disease, liver cirrhosis, or kidney

disease; you are taking a diuretic

Ask a doctor before use if you are:

taking any other drug containing NSAID (prescription or nonprescription); 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 get better; 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.

Directions

do not use more than directed; the smallest effective dose should be used; do not take longer than 10 days, unless directed by a doctor.

Adults and Children (12 years and older): 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: Do not give to children under 12 years of age.

Other information

Store at controlled room temperature; avoid excessive heat 40 degree Celsius (104 degree Fahrenheit); tamper evident sealed packets; do not use any opened or torn packets

Inactive Ingredients

cellulose, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, silica, sodium starch glycolate, stearic acid, titanium dioxide, triacetin.

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IBUPROFEN 2 Tablets

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2 Tablets BUPROFEN

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

Uses temporarily relieves minor aches and pains due to: ■ the 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 ■ facial swelling ■ asthma (wheezing) ■ rash ■ skin reddening ■ blisters ■ hives 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 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

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, or kidney disease you are taking a diuretic

Ask a doctor or pharmacist before use if you are ■ taking any other drug containing an NSAID (prescription or nonprescription) Warnings (continued)

■ 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 ■ 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

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Inactive ingredients cellulose, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, silica, sodium starch glycolate, stearic acid, titanium

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IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52124-0009
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
IBUPRO FEN (UNII: WK2XYI10 OM) (IBUPRO FEN - UNII: WK2XYI10 OM)	IBUPROFEN	200 mg

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH94E)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
TRIACETIN (UNII: XHX3C3X673)		
PO WDERED CELLULOSE (UNII: SMD1X3XO9M)		
STARCH, CORN (UNII: O8232NY3SJ)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
LACTOSE (UNII: J2B2A4N98G)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

POLYDEXTROSE (UNII: VH2XOU12IE)

Product Characteristics			
Color	white (White)	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	44;352
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:52124-0009-1	2 in 1 PACKET; Type 0: Not a Combination Product	02/17/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	0 2/17/20 10	

Labeler - Genuine First Aid LLC (619609857)

Revised: 12/2017 Genuine First Aid LLC