

CAREALL IBUPROFEN- ibuprofen tablet
New World Imports

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Ibuprofen 200mg (NSAID)**

**nonsteroidal anti-inflammatory drug

Pain reliever / fever reducer

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Temporarily relieves minor aches and pains due to:

Headache, muscular aches, minor pain of arthritis, toothache, backache, common cold and menstrual cramps

Temporarily reduces fever

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, 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 60 years or older, have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing a NSAID [aspirin, ibuprofen, naproxen, or others], have 3 or more alcoholic drinks every day while using this product, or take more / for a longer time than directed.

Heart attack and stroke warning: NSAID's, 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 or right before / after heart surgery.

Ask a doctor before use if: 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: taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin. Under a doctor's

care for any serious condition, 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, or 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.

Pregnant or breast-feeding: ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Do not take more than directed. The smallest effective dose should be used.

Adult and children 12 years and older: Take 1 tablets every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablets, 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

colloidal silicon dioxide, pregelatinized starch, titanium dioxide, corn starch, croscarmellose sodium, FDandC yellow 6, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polyvinyl alcohol, povidone, purified water, sodium starch glycolate, stearic acid, talc, triacetin

Store between 20-25 degrees celcius (68-77 degrees farhenheit).

Read all warnings and directions before use

Do not use if seal under bottle cap is broken or missing

Questions or Comments: Call 1-888-952-0050 Monday through Friday 9 AM - 5 PM EST

NDC 51824-064-01



Compare to the active ingredient in ADVIL[®]**

Ibuprofen

Pain Relief

(NSAID)

- ▶ Pain Reliever
- ▶ Fever Reducer

SEE NEW WARNINGS INFORMATION



100 Ibuprofen Tablets
200mg each

Drug Facts

Purpose
Active ingredient (in each tablet)
Ibuprofen USP, 200mg (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) ■ 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: 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 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

Drug Facts (continued on inside)
**This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil[®].

Distributed By: NWI, Inc., 160 Athens Way, Nashville, TN 37228



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Lot No.

Exp. Date:



Drug Facts (continued)

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 the 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 at 20 weeks or later in 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 ■ store between 20-25 °C (68-77 °F) ■ read all warnings and directions before use ■ do not use if seal under bottle cap is broken or missing

Inactive ingredients

colloidal silicon dioxide, pregelatinized starch, titanium dioxide, May contain: corn starch, croscarmellose sodium, FD&C yellow #6, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polyvinyl alcohol, povidone, purified water, sodium starch glycolate, stearic acid, talc, inactin

Questions or Comments?

Call 1-888-952-0050 Monday through Friday 9AM - 5PM EST

CAREALL IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-064
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
Starch, Corn (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
Ferric Oxide Red (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown (Rusty brown color)	Score	no score
Shape	ROUND (Round)	Size	10mm
Flavor		Imprint Code	IBU200;114;G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-064-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/11/2017	

Labeler - New World Imports (075372276)

Registrant - New World Imports (075372276)