

IBUPROFEN- ibuprofen tablet
Pharbest Pharmaceuticals, Inc.

Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti- inflammatory drug

Purpose

Pain Reliever/ Fever Reducer

Uses

temporarily relieves minor aches and pain 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 an 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 non prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks everyday 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 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 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 last for more than 10 days
- fever gets worse or last 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 (1-800-222-1222). **This Package for Households Without Young Children.**

Directions

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

adults and children 12 years and older	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• consult a doctor

Other information

- **Tamper Evident: do not use if safety seal under cap is broken or missing**
- store at room temperature (20°- 25°C)
- avoid excessive heat above 40°C (104°F)

Inactive Ingredients:

colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, red iron oxide, talc & titanium dioxide

Questions? Adverse drug event call: (866)562-2756 Mon-Fri: 8 AM to 4 PM

*This product is not manufactured or distributed by Pfizer Consumer Products, owner of the registered trademark ADVIL®.

Manufactured for:

Pharbest Pharmaceuticals, Inc.,

Farmingdale, NY 11735

LRev 02/16

NDC 16103-0396-11

PHARBEST

***Compare to the active ingredient in Advil®**

Pain Reliever / Fever Reducer (NSAID)

IBUPROFEN

Tablets

200mg

1000 Tablets

NDC 16103-0396-11

PHARBEST

Compare to the active ingredient in ADVIL

Pain Reliever/Fever Reducer (NSAID)

Ibuprofen Tablets

200 mg

1000 Tablets

100% SATISFACTION GUARANTEE

This Package for Households Without Young Children

Drug Facts	Purpose	Drug Facts (continued)
Active ingredient (in each tablet) Ibuprofen 200mg (NSAID) (nonsteroidal anti-inflammatory drug)	Pain Reliever/ Fever Reducer	Drug Facts (continued) • 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 • 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).
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		Directions • Do not take more than directed • The smallest effective dose should be used adults and children 12 years of age 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 consult a doctor
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 an 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 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, 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		Other information • Tamper Evident: do not use if safety seal under cap is broken or missing • store at room temperature (20°-25°C) • avoid excessive heat above 40°C (104°F) Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, red iron oxide, talc & titanium dioxide Questions? Adverse drug event call: (866) 562-2756 Mon-Fri: 8 AM to 4 PM

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IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-396
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16 103-396-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2016	
2	NDC:16 103-396-08	1 in 1 CARTON	03/01/2016	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:16 103-396-06	1 in 1 CARTON	03/01/2016	
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:16 103-396-04	1 in 1 CARTON	03/01/2016	
4		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	03/01/2016	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	repack(16 103-396) , relabel(16 103-396)

Revised: 5/2018

Pharbest Pharmaceuticals, Inc.