

IBUPROFEN - ibuprofen tablet

Kinray

Drug Facts

Active ingredient (in each caplet)

Ibuprofen USP 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 nonprescription 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

- the 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 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)

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 caplet every 4 to 6 hours while symptoms persist • if pain or fever does not respond to 1 caplet, 2 caplets may be used • do not exceed 6 caplets in 24 hours, unless directed by a doctor
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Children under 12 years

- ask a doctor

Other Information

- store between 20°- 25°C (68°- 77°F)
- see end panel for lot number and expiration date

Inactive Ingredients:

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

Questions or comments? 1-877-586-7979

PRINCIPAL DISPLAY PANEL - 200 mg TABLET CARTON

Preferred Plus Pharmacy

NDC 61715-061-51

SEE NEW WARNINGS INFORMATION

*Compare to the Active Ingredient in ADVIL®

Ibuprofen TABLETS, USP 200 mg

Pain Reliever/Fever Reducer (NSAID)

200 COATED CAPLETS†

†CAPSULE-SHAPED TABLETS

Distributed By:

Kinray, Inc., Whitestone, NY 11357

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Exp. Date: _____

Lot No.: _____

3 45738 41110 1

KIN# 412510

NDC 61715-061-51

SEE NEW WARNINGS INFORMATION

Preferred plus Pharmacy

Compare to the Active Ingredient in ADVIL

Ibuprofen

TABLETS, USP 200 mg

Pain Reliever / Fever Reducer (NSAID)

100 COATED CAPLETS*

*CAPSULE-SHAPED TABLETS

100% SATISFACTION GUARANTEE

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

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

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Made in India

Rev. 05/13

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

- the 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 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

Important: Read all product information before using. Keep this box for important information.

Do not use if seal under bottle cap imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.

Drug Facts

Active ingredient (in each caplet)

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

* nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - the common cold
 - 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
- shock
- skin redness
- asthma (wheezing)
- rash
- hiccups

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 thinner (anticoagulant) or steroid drug

Take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) this product

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Drug Facts (continued)

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 more than directed
- the smallest effective dose should be used

Adults and children 12 years and older

- take 1 caplet every 4 to 6 hours while symptoms persist
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Children under 12 years

- ask a doctor

Other information

- store between 20°-25°C (68°-77°F)
- see end panel for lot number and expiration date

Inactive ingredients croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide.

Questions or comments? 1-877-586-7979

IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61715-061
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
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	Score	no score
Shape	OVAL (Capsule-Shaped)	Size	15mm
Flavor		Imprint Code	117
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-061-51	1 in 1 CARTON		
1		100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	07/25/2011	

Labeler - Kinray (012574513)**Registrant** - Aphenia Pharma Solutions - Kentucky, LLC (557054835)**Establishment**

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Kentucky, LLC		557054835	repack(61715-061)

Establishment

Name	Address	ID/FEI	Business Operations
Marksans Pharma Limited		925822975	manufacture(61715-061)

