

**PREFERRED PLUS IBUPROFEN - ibuprofen tablet, film coated**  
**Kinray, Inc.**

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**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
  - minor pain of arthritis
  - headache
  - toothache
  - backache
  - the common cold
  - menstrual cramps
  - muscular aches
- 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 an NSAID [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 to prevent heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

**when using this product**

- take 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 or pregnancy unless 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 take more than directed**
- **the smallest effective dose should be used**

	<ul style="list-style-type: none"> <li>• take one tablet every 4 to 6 hours while symptoms persist</li> </ul>
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Adults and children 12 years and older	<ul style="list-style-type: none"> <li>• if pain or fever does not respond to 1 tablet, 2 tablets may be used</li> <li>• do not exceed 6 tablets in 24 hours, unless directed by a doctor</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>• ask a doctor</li> </ul>

**other information**

- store between 20°- 25°C (68°- 77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- **Tamper Evident:** do not use if imprinted seal under the cap is broken or missing

**Inactive ingredients**

colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, red iron oxide, sodium starch glycolate, titanium dioxide and triacetin.

**Questions?**

**Adverse drug event call:** (866) 562-2756

**Principal Display Panel**

Ibuprofen Tablets 200 mg

\*Compare to the active ingredient in ADVIL®.

See New Warnings Information

Pain Reliever/Fever Reducer (NSAID)

KEEP OUTER CARTON FOR COMPLETE WARNING AND PRODUCT INFORMATION

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

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

**Distributed By: Kinray, Inc.**

**Whitestone, NY 11357**

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**Product Label**

**Drug Facts (continued)**

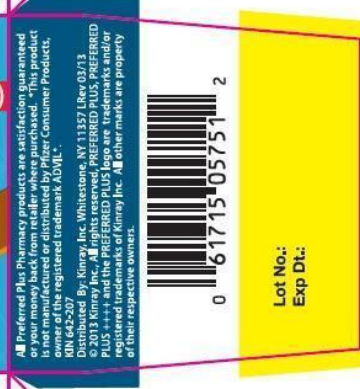
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 ■ headache ■ muscular aches ■ minor pain of arthritis ■ toothache ■ backache ■ the common cold ■ menstrual cramps  
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**Warnings**  
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 • hives • facial swelling • asthma (wheezing) • shock • skin reddening • rash • blisters  
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**Stomach bleeding warning:** This product contains an 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

**Do not use** • if you have ever had an allergic reaction to any other pain reliever/fever reducers • right before or after heart surgery

**Drug Facts (continued)**

**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 to prevent 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.

**PREFERRED PLUS IBUPROFEN**

ibuprofen tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61715-057
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
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### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TRIACETIN (UNII: XHX3C3X673)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	IBU200
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-057-50	1 in 1 CARTON		
1		50 in 1 BOTTLE, PLASTIC		
2	NDC:61715-057-51	1 in 1 CARTON		
2		100 in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	05/11/2013	

**Labeler** - Kinray, Inc. (012574513)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	repack(61715-057) , relabel(61715-057)