IBUPROFEN - ibuprofen tablet Kinray

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 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 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.

Directions

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

• take one tablet every 4 to 6 hours while symptoms persists

- 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
- Adults and children 12 years and older

Children under 12 years	ask a doctor

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 the imprinted seal under the cap is broken or missing

Inactive Ingredients:

colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, FD&C yellow #6 Al. lake, sodium starch glycolate, talc, titanium dioxide and triacetin.

Questions? Adverse drug event call: (866) 562-2756



IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:61715-018
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPROFEN (IBUPROFEN)	IBUPROFEN	200 mg	

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIO XIDE				
FD&C YELLOW NO. 6				
HYPROMELLOSES				
MAGNESIUM STEARATE				
CELLULO SE, MICRO CRYSTALLINE				
TITANIUM DIO XIDE				
STARCH, CORN				
TRIACETIN				
SODIUM STARCH GLYCOLATE TYPE A POTATO				
TALC				

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	IBU200
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61715-018-50	1 in 1 CARTON			
1		50 in 1 BOTTLE, PLASTIC			
2	NDC:61715-018-51	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	ANDA091355	11/22/2011	

Labeler - Kinray (012574513)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharbest Pharmaceuticals, Inc.		557054835	repack(61715-018), relabel(61715-018)	

Revised: 3/2013 Kinray