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

Adults and children 12 years and older	• 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

Children under 12 years	• ask a doctor

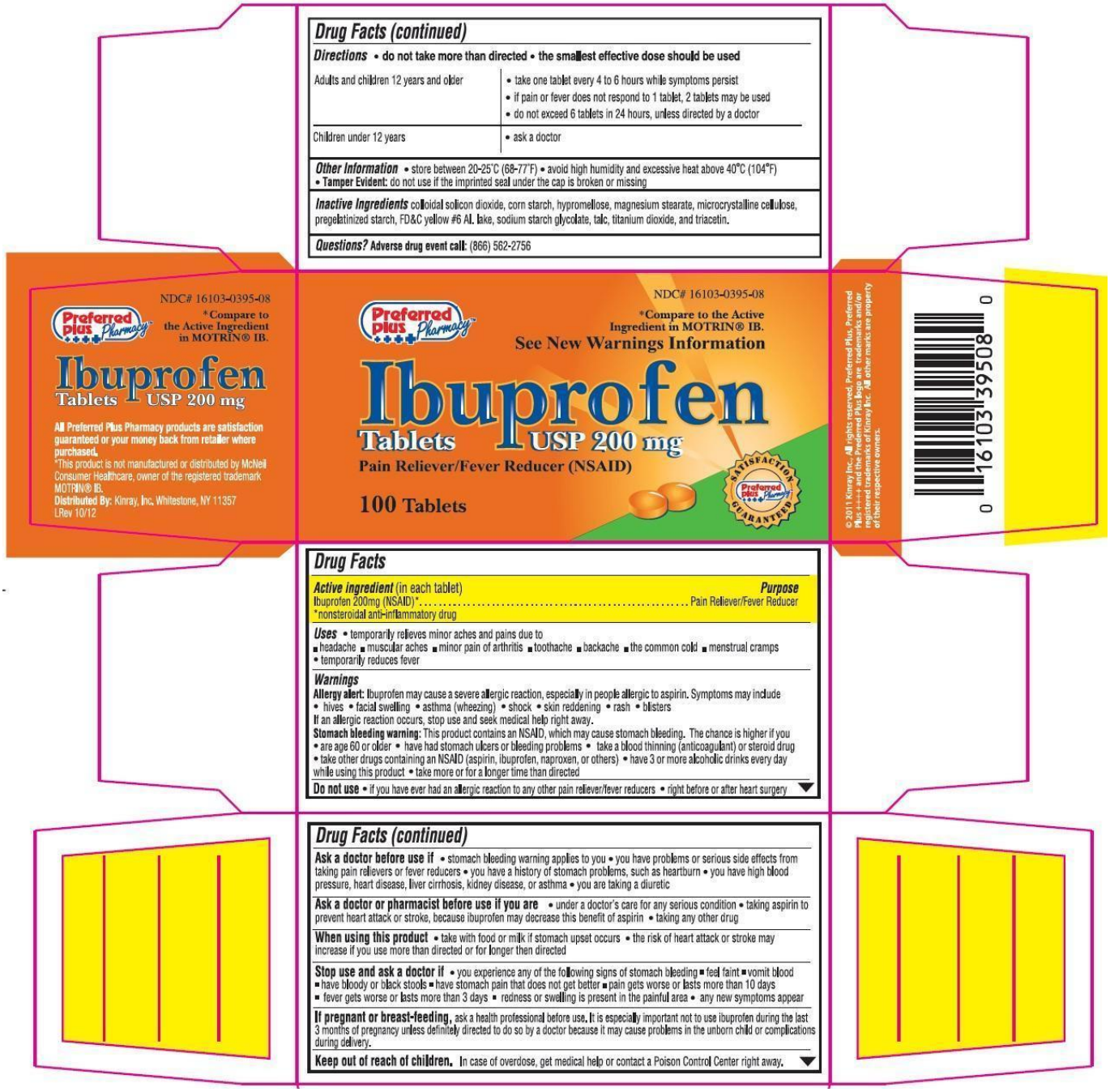
Other Information

- 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	**Item Code (Source)**	NDC:61715-018
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TRIACETIN (UNII: XHX3C3X673)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	orange	**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:61715-018-50	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)