IBUPROFEN- ibuprofen tablet
SDA Laboratories, 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	• take 1 tablet every4 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

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: (800)687-0176 Mon-Fri: 8 AM to 4 PM

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

NDC 66424-396-10

*Compare to the active ingredient in Advil®

IBUPROFEN

Tablets 200mg

Pain Reliever / Fever Reducer (NSAID)

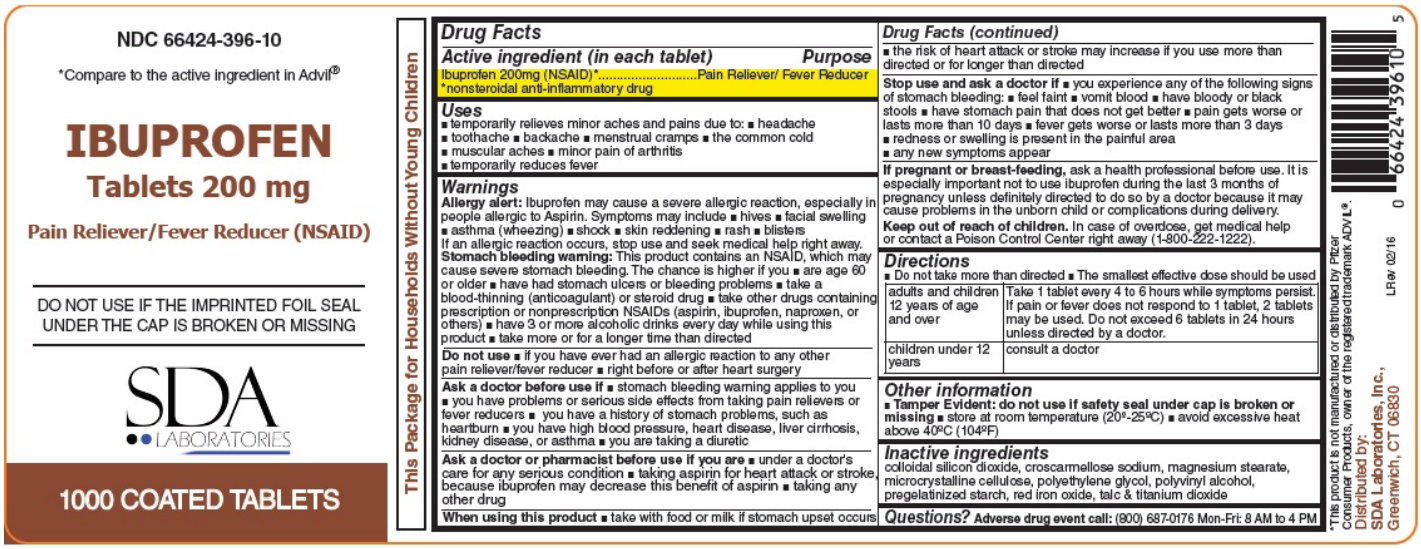
DO NOT USE IF THE IMPRINTED FOIL SEAL

UNDER THE CAP IS BROKEN OR MISSING

SDA

LABORATORIES

1000 COATED TABLETS



IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66424-396
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, PREGELATINIZED 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**	10mm
Flavor		**Imprint Code**	114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66424-396-10	1000 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 - SDA Laboratories, Inc. (948067889)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	repack(66424-396) , relabel(66424-396)

Revised: 3/2016 SDA Laboratories, Inc.