IBUPROFEN- ibuprofen 200mg tablet, film coated
ADVANCED FIRST AID, INC.

ACTIVE INGREDIENT IN EACH TABLET- Ibuprofen 200 mg (NSAID)

pain reliever/fever reducer

Uses:

temporarily relieves minor aches and pains due to: • headache • muscular aches • backache • minor pain of arthritis • toothache • menstrual cramps • common cold • 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 • blisters If an allergic reaction occurs, stop use and seek medical help right away.

Stomach Bleeding Warning: This product contains a nonsteroidal anti-inflammatory drug (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 reducer • right before or after heart surgery

Ask a doctor use if you have: • problems or serious side effects from taking pain relievers or fever reducers • stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain •

ulcers • bleeding problems • high blood pressure • heart disease, liver cirrhosis, or kidney disease • taken a diuretic • reached age 60 or older

Ask a doctor or pharmacist before use if you are: • taking any other drug containing an NSAID (prescription or nonprescription) • taking a blood thinning (anticoagulant) or steroid drug • under a doctor’s care for any serious condition • taking any other drug

When using this product: • take with food or milk if stomach upset occurs • long term continuous use may increase the risk of heart attack or stroke

Stop use and ask a doctor if: • you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding. • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • stomach pain or upset gets worse or lasts • 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 specifically 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:

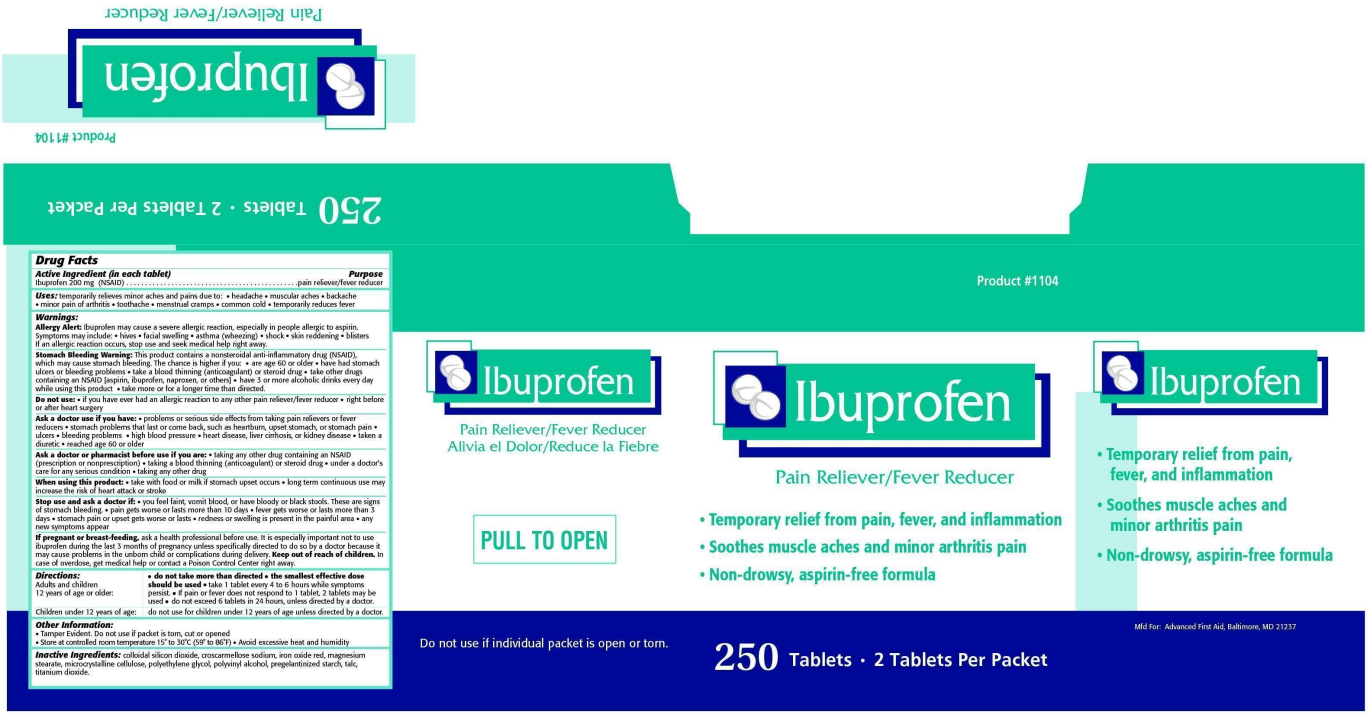
Adults and children 12 years of age and older:

• do not take more than directed • the smallest effective dose should be used • take 1 tablet every 4 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 of age: do not use for children under 12 years of age unless directed by a doctor.

Inactive Ingredients: colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelantinized starch, talc, titanium dioxide.



IBUPROFEN

ibuprofen 200mg tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67060-750
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	IBU;200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67060-750-68	100 in 1 CARTON	04/09/2015	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67060-750-67	250 in 1 CARTON	04/09/2015	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	04/09/2015	

Labeler - ADVANCED FIRST AID, INC. (114477180)

Registrant - ADVANCED FIRST AID, INC. (114477180)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(67060-750)

Establishment

Name	Address	ID/FEI	Business Operations
SHAUN PHARMACEUTICALS LIMITED		915786829	manufacture(67060-750)

Revised: 10/2019 ADVANCED FIRST AID, INC.