

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

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

\*nonsteroidal anti-inflammatory drug

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 prescription or non prescription NSAIDs [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.

**Heart Attack and Stroke Warning:** NSAIDS, except aspirin, increase the risk of heart attack, heart failure and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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 heart burn • high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma or had a stroke • you are taking a diuretic

**Ask a doctor or pharmacist before use if you are:** • taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin • 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

**Stop use and ask a doctor if:** • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • or if redness or swelling is present in the painful area • any new symptoms appear • You experience any of the following signs of stomach bleeding: • feel faint • vomit blood • or have bloody or black stools • have stomach pain that does not get better • You have symptoms of heart problems or stroke: • chest pain • trouble breathing • weakness in one part or side of the body • slurred speech • leg swelling

**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:

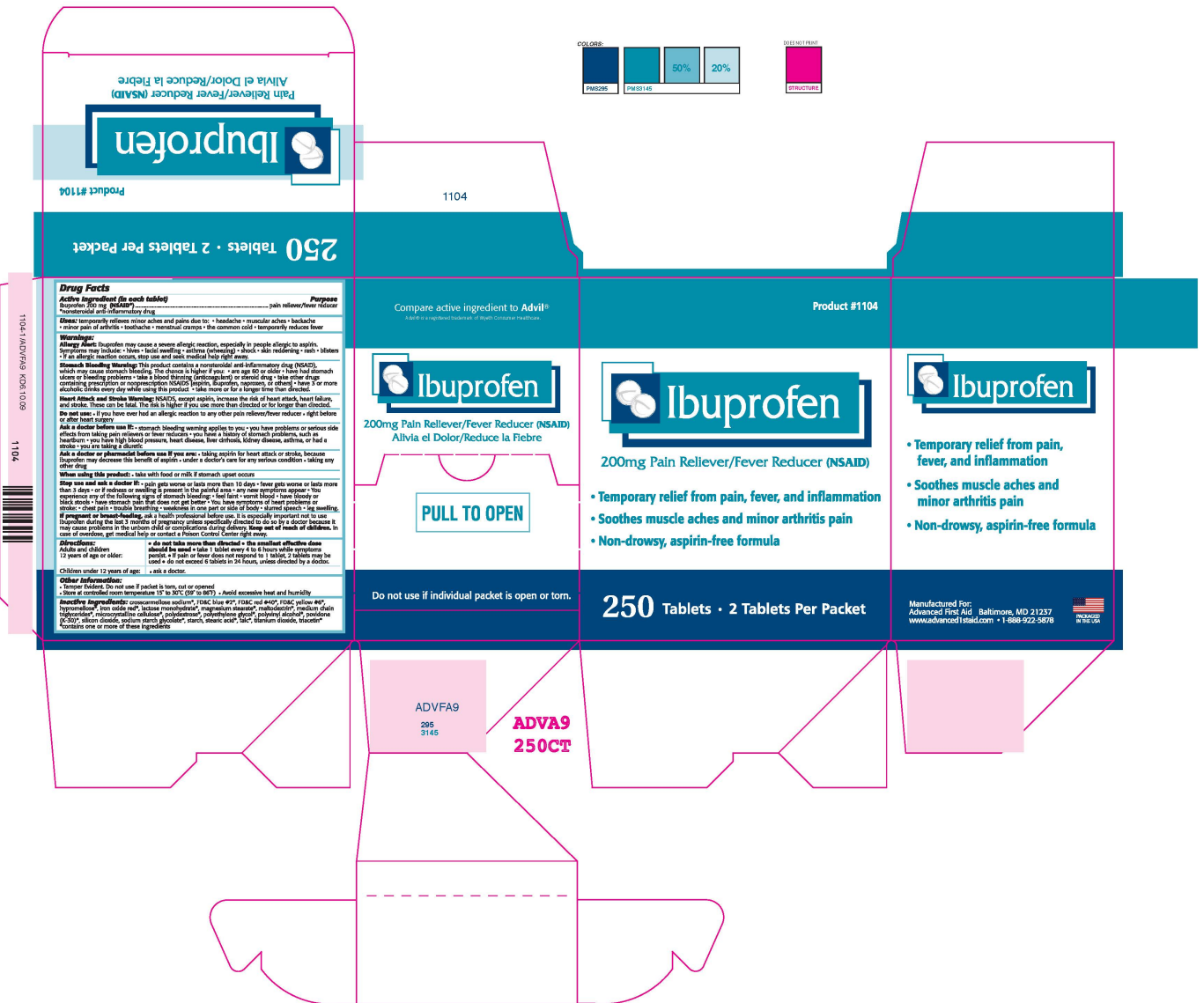
• **do not take more than directed** • **the smallest effective dose should be used** • take 1 tablet every 4 to 6 hours while symptoms

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: ask a doctor

Inactive Ingredients: croscarmellose sodium\*, FD& C Blue #2\*, FD& C Red #40\*, FD& C Yellow #6\*, hypromellose\*, iron oxide red\*, lactose monohydrate\*, magnesium stearate\*, maltodextrin\*, medium chain triglycerides\*, microcrystalline cellulose\*, polydextrose\*, polyethylene glycol\*, polyvinyl alcohol\*, Povidone (K-30)\*, silicon dioxide, sodium starch glycolate\*, starch, stearic acid\*, talc\*, titanium dioxide, triacetin\*.

**\*contains one or more of these ingredients**



ibuprofen 200mg tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67060-002
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	114
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67060-002-68	100 in 1 CARTON	03/20/2019	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67060-002-67	250 in 1 CARTON	03/20/2019	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA091239	03/20/2019	

**Labeler** - ADVANCED FIRST AID, INC. (114477180)

**Registrant** - ADVANCED FIRST AID, INC. (114477180)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ULTRA SEAL CORPORATION		085752004	pack(67060-002)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Marksans Pharma		925822975	manufacture(67060-002)

Revised: 3/2019

ADVANCED FIRST AID, INC.