## PAIN RELIEF ANTI INFLAMMATORY - ibuprofen tablet Select Corporation

-----

## **Drug Facts**

Active Ingredients Ibuprofen USP 200 mg

Pain reliever/fever reducer nonsteroidal anti-inflammatory drug

Directions: • do not take more than directed • the smallest effective dose should be used • adults and children 12 years and over: • 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: • ask a doctor

Uses • temporarily relieves minor aches and pains due to: • headache • muscular aches • minor pain of arthritis • toothache • backache • the common cold • menstrual cramps • 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 nonprescription NSAID's (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 before use if • you have problems or serious side effects from taking pain relievers or fever reducers • the stomach bleeding warning applies to you • you have a history of stomach problems such as heartburn• you have high blood pressure, heart disease, liver cirrhosis, or kidney disease you have asthma • 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 • 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 • vou have stomach pain that does not get better • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • redness or swelling is present in the painful area • any new symptoms appear

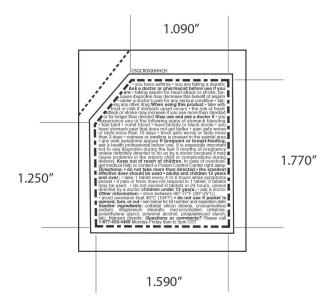
If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

## KEEP OUT OF REACH OF CHILDREN.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide.

MM1





ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52904-486
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg	

Inactive Ingredients		
Ingredient Name	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
TALC (UNII: 7SEV7J4R1U)		
STARCH, CORN (UNII: O8232NY3SJ)		
POLYVINYL ALCOHOL (UNII: 532B59J990)		
POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8 AQ)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

Product Characteristics			
Color	white (snow white)	Score	no score
Shape	ROUND (115)	Size	10 mm
Flavor		Imprint Code	115
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-486-02	2 in 1 PACKET		

Marketing Info	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091239	10/15/2012		

## Labeler - Select Corporation (053805599)

Revised: 10/2012 Select Corporation