

PAIN RELIEF - 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 • you 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

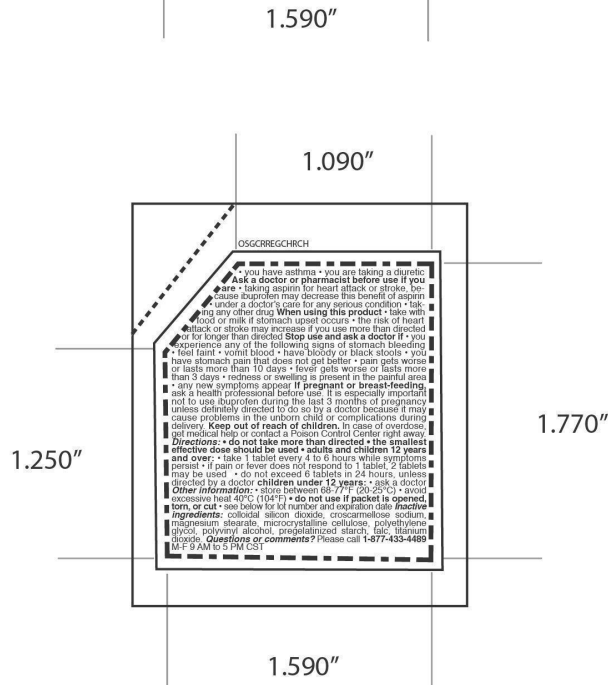
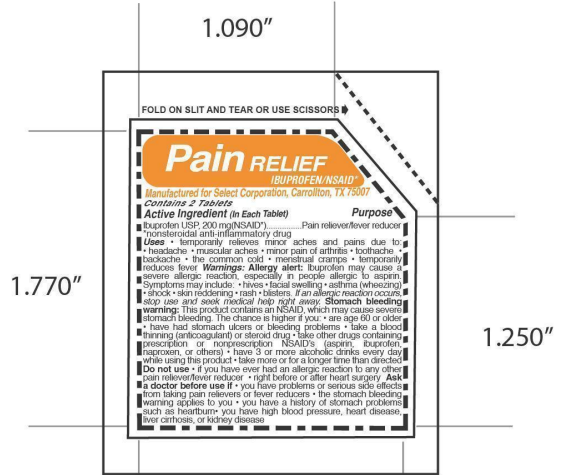
If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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

Pain Relief - Ibuprofen



ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52904-447
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-447-02	2 in 1 PACKET		

Marketing Information

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

Labeler - Select Corporation (053805599)

Registrant - Select Corporation (053805599)

