REDICARE IBUPROFEN- ibuprofen 200mg tablet, film coated
Redicare LLC

Ibuprofen 200mg

Active Ingredient (in each tablet) Purpose

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 non-steroidal 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 as NSAID (prescription or non-prescription) ■ taking a blood thinning (anti-coagulated) 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 specially 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 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 take a 2nd tablet - do not exceed 6 tablets in 24 hours unless directed by a doctor

Children under 12 years of age do not use unless directed by a doctor

Other Information:

■ Tamper Evident. Do not use if packet is torn, cut or opened ■ Store at controlled room temperature 15˚ to 30˚C (59˚ to 86˚F) ■ Avoid excessive heat and humidity

Inactive Ingredients:

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

REDICARE IBUPROFEN

ibuprofen 200mg tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71105-750
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

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:71105-750-68	1 in 1 BOX; Type 0: Not a Combination Product	02/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA079129	02/01/2017	

Labeler - Redicare LLC (800149346)

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