FIRST AID ONLY IBUPROFEN- ibuprofen tablet, coated
Acme United Corporation

First Aid Only Ibuprofen

Active ingredient

Ibuprofen 200 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Drug Facts

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains associated with

■ headache ■ toothache ■ backache ■ menstrual cramps

■ common cold ■ muscular aches ■ minor arthritis pain

Temporarily reduces fever.

Warnings

Allergy Alert:

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

■ hives ■ skin reddening ■ asthma (wheezing) ■ facial swelling ■ rash ■ shock ■ 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 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

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

■ 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 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

■ have stomach pain that does not get better

■ pain gets worse or lasts for more than 10 days

■ fever gets worse or lasts for more than 3 days

■ redness or swelling is present in the painful area

■ any new or unexpected symptoms occur

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

■ **do not use more than directed**

■ **the smallest effective dose should be used**

■ do not take longer than 10 days, unless directed by a doctor (see Warnings)

Adults and children:(12 years and older)

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:

Do not give to children under 12 years of age.

Other information

■ read all product information before using

■ store at 68-77°F (20-25°C)

■ avoid excessive heat 40°C (above 104°F)

■ tamper evident sealed packets

■ do not use any opened or torn packets

Inactive ingredients

carnauba wax*, corn starch, hypromellose*, iron oxide red, lactose*, magnesium stearate*, microcrystalline cellulose*, polydextrose*, polyethylene glycol, polyvinyl alcohol*, povidone K30*, silicon dioxide, sodium starch glycolate, stearic acid, talc*, titanium dioxide

***may contain**

Questions or comments?

1-800-835-2263

First Aid Only Ibuprofen Label

FIRST AID ONLY IBUPROFEN

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-0275(NDC:47682-600)
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;291
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0275-01	20 in 1 BOX, UNIT-DOSE	01/26/2017	
1		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	ANDA075010	02/01/2016	

Labeler - Acme United Corporation (001180207)

Registrant - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-0275) , repack(0924-0275)

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Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-0275) , repack(0924-0275)

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