# FIRST AID ONLY ASPIRIN- as pirin tablet, film coated Acme United Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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### First Aid Only Aspirin Tablets

**Drug Facts** 

### **Active ingredient (in each tablet)**

Aspirin (NSAID\*) 325 mg

\*nonsteroidal anti-inflammatory drug

### Purpose

Pain reliever/fever reducer

### Uses

### Temporarily relieves minor aches and pains associated with

- headache
- minor arthritis
- common cold
- menstrual cramps
- muscular aches
- backache
- toothache

### Temporarily reduces fever.

### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy Alert:** aspirin may cause a severe allergic reaction which may include:

•hives •facial swelling •shock •asthma (wheezing)

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 alcohol drinks every day while using this product

• take more or for a longer time than directed

### Do not use

• If you are allergic to aspirinor any other pain reliever/fever reducer

### Ask a doctor before use if

- 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 are taking a diuretic
- you have asthma

### Ask a doctor or pharmacist before use if you are

• taking prescription drugs for gout, diabetes or arthritis

### When using this product

• take with food or milk if stomach upset occurs

### 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 more than 10 days
- fever gets worse or lasts more than 3 days
- if ringing in the ears or loss of hearing occurs
- redness or swelling is present in the painful area
- any new symptoms appear
- an allergic reaction occurs. Seek medical help right away.

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use aspirin 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.** In case of overdose, get medical help or contact a Poison Control Center right away.

### **Directions**

- do not take more than directed
- the smallest effective dose should be used
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- drink a full glass of water with each dose

### Adults and children: (12 years and older)

Take 1 or 2 tablets with water every 4 hours as needed. Do not take more than 12 tablets in 24 hours, or as 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 room temperature 59°-86°F (15°-30°C)
- avoid excessive heat and humidity
- tamper evident sealed packets
- do not use any opened or torn packets

### **Inactive ingredients**

corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

### Questions or comments?

1-800-835-2263

### First Aid Only Aspirin Label

First Aid Only Label



# FIRST AID ONLY ASPIRIN aspirin tablet, film coated Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0924-0204(NDC:47682-097) Route of Administration ORAL Active Ingredient/Active Moiety

**Basis of Strength** 

Strength

**Ingredient Name** 

ASPIRIN

325 mg

Inactive Ingredients			
Ingredient Name	Strength		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
MINERAL OIL (UNII: T5L8T28FGP)			
STARCH, CORN (UNII: O8232NY3SJ)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics			
Color	white (white)	Score	no score
Shape	ROUND (ROUND)	Size	10 mm
Flavor		Imprint Code	TCL;011
Contains			

	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>	
ı	1 NDC:0924-0204-01	20 in 1 BOX, UNIT-DOSE	03/27/2018		
ı	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
OTC monograph final	part343	12/30/2008	

# Labeler - Acme United Corporation (001180207)

## **Registrant -** Acme United Corporation (001180207)

Establishment			
Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-0204), repack(0924-0204)

Establishment			
Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-0204), repack(0924-0204)

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