FIRST AID ONLY EXTRA-STRENGTH NON-ASPIRIN- acetaminophen 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.

First Aid Only Extra-Strength Non-Aspirin

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

For the temporary relief of minor aches and pains associated with

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

temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert:

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug
  contains acetaminophen, ask a doctor or pharmacist.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

Ask a doctor before use if you have

- liver disease

Ask a doctor or pharmacist before use if

- you are taking the blood thinning drug warfarin

Stop using and ask a doctor if

- symptoms do not improve
- pain or fever persists or gets worse
- new symptoms occur
- redness or swelling is present

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed**

Adults and children: (12 years and older)

Take 2 tablets every 4 to 6 hours as needed. Do not take more than 8 tablets in 24 hours.

Children under 12 years:

Do not give this adult strength product to children under 12 years of age;

this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- store at room temperature 59º-86ºF (15º-30ºC)
- tamper-evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

corn starch, hypromellose, maltodextrin*, microcrystalline cellulose*, polyethylene glycol, povidone*, pregelatinized corn starch*, sodium starch glycolate*, stearic acid, titanium dioxide*

* *May contain*

Questions? 1-800-835-2263

First Aid Only Extra-Strength Non-Aspirin Label

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FIRST AID ONLY EXTRA-STRENGTH NON-ASPIRIN

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-0223(NDC:47682-175)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white (white)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	12mm

Flavor		**Imprint Code**	AZ;235
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0223-01	20 in 1 BOX, UNIT-DOSE	12/30/2008	
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 not 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(0924-0223) , repack(0924-0223)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-0223) , repack(0924-0223)

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