# ACETAMINOPHEN- acetaminophen tablet, coated AAA Pharmaceutical, Inc.

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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## **Acetaminophen Tablets**

**Drug Facts** 

## Active ingredient (in each tablet)

Acetaminophen 500 mg

## Purpose

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - the common cold
  - headache
  - backache
  - minor pain of arthritis
  - toothache
  - muscular aches
  - premenstrual and menstrual cramps
- temporarily reduces fever

#### Warnings

#### Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

#### 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.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

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 use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur

redness or swelling is present

These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use.

## Keep out of reach of children.

## Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul> <li>take 2 tablets every 6 hours while symptoms last</li> <li>swallow whole – do not crush, chew, or dissolve</li> <li>do not take more than 6 tablets in 24 hours, unless directed by a doctor</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	■ ask a doctor

### Other information

- store between 20-25°C (68-77°F)
- retain carton for complete product information

## **Inactive ingredients**

acesulfame potassium, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

## Distributed by:

AAA Pharmaceutical, Inc. 681 Main Street Lumberton, NJ 08048

#### PRINCIPAL DISPLAY PANEL - 50 Tablet Bottle Carton

#### RESTORE u

NDC 57344-092-03

†COMPARE TO THE ACTIVE INGREDIENT IN TYLENOL®

## EXTRA STRENGTH EZ TABS

EXTRA STRENGTH CONTAINS NO ASPIRIN

EASY TABS

Easy To Swallow Sweet Coated

Pain Relief Pain Reliever, Fever Reducer Contains Acetaminophen

**50** TABLETS - 500 mg each



## **ACETAMINOPHEN**

acetaminophen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:57344-092
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Acetaminophen (Acetaminophen)	Acetaminophen	500 mg		

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM	
FD&C RED NO. 40	
ALUMINUM O XIDE	
FD&C YELLOW NO. 6	
HYPROMELLOSES	
POLYETHYLENE GLYCOLS	
POLYSORBATE 80	
POVIDONES	
STARCH, CORN	
SODIUM STARCH GLYCOLATE TYPE A CORN	
STEARIC ACID	
TITANIUM DIO XIDE	

Product Characteristics					
Color	RED	Score	no score		
Shape	ROUND	Size	11mm		
Flavor		Imprint Code	A92		
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:57344-092-02	1 in 1 CARTON				
1		24 in 1 BOTTLE, PLASTIC				
2	NDC:57344-092-03	1 in 1 CARTON				
2		50 in 1 BOTTLE, PLASTIC				
3	NDC:57344-092-01	1 in 1 CARTON				
3		100 in 1 BOTTLE, PLASTIC				
4	NDC:57344-092-05	1 in 1 CARTON				
4		250 in 1 BOTTLE, PLASTIC				
5	NDC:57344-092-04	150 in 1 BOTTLE, PLASTIC				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part343	12/13/2012			

## Labeler - AAA Pharmaceutical, Inc. (181192162)

Establishment				
Name	Address	ID/FEI	Business Operations	
AAA Pharmaceutical, Inc.		18 119 216 2	MANUFACTURE(57344-092)	

Establishment				
Name	Address	ID/FEI	Business Operations	
AAA Pharmaceutical, Inc.		010411533	PACK(57344-092)	

Revised: 12/2012 AAA Pharmaceutical, Inc.