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.

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	■ take 2 tablets every 6 hours while symptoms last ■ swallow whole – do not crush, chew, or dissolve ■ do not take more than 6 tablets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
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	**Item Code (Source)**	NDC:57344-092
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

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.		181192162	MANUFACTURE(57344-092)

Establishment

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

Revised: 12/2012 AAA Pharmaceutical, Inc.