

ACETAMINOPHEN- acetaminophen tablet
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	<ul style="list-style-type: none">▪ take 2 tablets every 6 hours while symptoms last▪ 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	<ul style="list-style-type: none">▪ ask a doctor

Other information

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

Inactive ingredients

povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Distributed by:

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

PRINCIPAL DISPLAY PANEL - 60 Tablet Bottle Carton

RESTORE *u*

NDC 57344-003-02

†COMPARE TO THE ACTIVE
INGREDIENT IN TYLENOL®
EXTRA STRENGTH

**EXTRA
STRENGTH
CONTAINS NO ASPIRIN**

**Pain Relief
Pain Reliever, Fever Reducer
Contains Acetaminophen**

60 TABLETS - 500 mg each



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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

RESTORE U NDC 57344-003-02
 100% COMPARE TO THE ACTIVE INGREDIENT IN TYLENOL® EXTRA STRENGTH
EXTRA STRENGTH
 CONTAINS NO ASPIRIN

Pain Relief
 Pain Reliever, Fever Reducer
 Contains Acetaminophen

60 TABLETS - 500 mg each

INK AND COATING FREE FOR LOT AND EXPIRATION STAMPING

0 99581 91108 6

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not to be refilled or distributed by McKesson or HealthCare, distributor of Tylenol Extra Strength tablets.

RESTORE U NDC 57344-003-02
 100% COMPARE TO THE ACTIVE INGREDIENT IN TYLENOL® EXTRA STRENGTH
EXTRA STRENGTH
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Pain Relief
 Pain Reliever, Fever Reducer
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60 TABLETS - 500 mg each

RESTORE U EXTRA STRENGTH
 CONTAINS NO ASPIRIN

Pain Relief
 Pain Reliever, Fever Reducer
 Contains Acetaminophen

Distributed by:
 AAA Pharmaceutical, Inc.
 981 Main Street
 Lumberton, NJ 08048

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Drug Facts (continued)

- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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ACETAMINOPHEN
 acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-003
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
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	M2A4;57344
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-003-01	1 in 1 CARTON		
1		30 in 1 BOTTLE, PLASTIC		
2	NDC:57344-003-02	1 in 1 CARTON		
2		60 in 1 BOTTLE, PLASTIC		
3	NDC:57344-003-03	100 in 1 BOTTLE, PLASTIC		
4	NDC:57344-003-04	1 in 1 CARTON		
4		100 in 1 BOTTLE, PLASTIC		
5	NDC:57344-003-05	1000 in 1 BOTTLE, PLASTIC		
6	NDC:57344-003-06	100 in 1 BOTTLE, PLASTIC		
7	NDC:57344-003-07	500 in 1 BOTTLE, PLASTIC		
8	NDC:57344-003-11	1000 in 1 BOTTLE, PLASTIC		
9	NDC:57344-003-99	39604 in 1 CONTAINER		

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(57344-003)

Establishment

Name	Address	ID/FEI	Business Operations
AAA Pharmaceutical, Inc.		0 10 411 53 3	PACK(57344-003)

Revised: 12/2012

AAA Pharmaceutical, Inc.