

**APAP- acetaminophen tablet**  
**Richmond Pharmaceuticals, 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 USP 500 mg**

**Active Ingredient**

**(in each caplet)**

Acetaminophen 500 mg

**Purpose**

Pain Reliever / Fever Reducer

**Uses**

temporarily relieves minor aches and pains due to:

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

**Warnings**

**Liver warning:** this product contains acetaminophen. The maximum daily dose of this product is 6 caplets (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 non prescription). 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 the 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
- redness or swelling is present
- new symptoms occur

- 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:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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 over dose warning) adults & children 12 years and over :**
- take 2 caplets every 6 hours while symptoms last
- do not take more than 6 caplets in 24 hours, unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor
- **children under 12 years : ask a doctor**

#### **Other Information**

- store at 15-30 °C (59-86 °F)

#### **Inactive Ingredients**

hypromellose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized corn starch, sodium starch glycolate, stearic acid, TITANIUM DIOXIDE

#### **Questions or Comments**

**call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**NDC: 54738-040-01 ..100 APAP 500mg tabs**

NDC 54738-040-01  
\*Compare to active ingredient in Extra Strength TYLENOL®

See New Warnings Information

# EXTRA STRENGTH APAP

Acetaminophen USP, 500 mg  
Pain Reliever / Fever Reducer  
100 CAPLETS

Richmond Pharmaceuticals, Inc.

**Drug Facts**

**Active ingredient (in each caplet)** Purpose  
Acetaminophen 500 mg..... Pain reliever/fever reducer

**Uses**

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

**Warnings**

**Liver warnings:** This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (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

**Drug Facts** continued on back of label

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

\*Richmond Pharmaceuticals, Inc. is not affiliated with the owner of the trademark Extra Strength TYLENOL®.

Distributed by: Richmond Pharmaceuticals, Inc.  
Richmond, VA 23233, USA

LR0015  
0 54738 04001 2

Lot No.:  
Exp. Date:

FEEL HERE FOR MORE DRUG FACTS

**Drug Facts (continued)**

**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 above warning drug warnings**

**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:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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 & children 12 years and over:

- take 2 caplets every 6 hours with symptoms but
- do not take more than 6 caplets in 24 hours, unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor

children under 12 years: ■ ask a doctor

**Other information**

- store at 15° to 30° C (59° to 86° F)

**Inactive ingredients** hypromellose, polyethylene glycol, polyvinylpyrrolidone, polybutylacrylate, croscarmellose sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?** call 866-278-4491, 8:30 am - 4:30 pm ET, Monday - Friday

NDC: 54738-040-03 ..1000 APAP 500mg tabs

## APAP

acetaminophen tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54738-040
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
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<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	AP;014
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-040-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2015	
2	NDC:54738-040-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2015	

**Labeler** - Richmond Pharmaceuticals, Inc. (043569607)

**Registrant** - Advance Pharmaceutical Inc. (078301063)

### Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-040)

Revised: 10/2017

Richmond Pharmaceuticals, Inc.