APAP- acetaminophen tablet
Advance 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 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)

For Bulk package: This is a bulk package, dispense contents with a child-resistant closure in a tight, light resistant container as defined in the USP.

Inactive Ingredients

polyvinylpyrrolidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

Questions or Comments

Call 631-981-4600 8.30 am- 4.30 pm ET, Monday-Friday

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

Manufactured by: Advance Pharmaceutical, Inc. Holtsville, NY 11742

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Advance Pharmaceutical Inc.

NDC 17714-014-01

*Compare to active ingredient in Extra Strength TYLENOL®

EXTRA STRENGTH

APAP

Acetaminophen USP, 500 mg

Pain Reliever / Fever Reducer

100 CAPLETS

See New Warnings Information

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

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- 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

*Advance Pharmaceutical, Inc. is not affiliated with the owner of the trademark Extra Strength Tylenol®.

Manufactured by: **Advance Pharmaceutical Inc.**
Holtsville, NY 11742

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LA1112

PEEL HERE FOR MORE DRUG FACTS

Lot No.:

Exp. Date:

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 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: 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. (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 & 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°to 30°C(59° to 86°F)

Inactive ingredients

hypromellose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized corn starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

call **631-981-4600**, 8:30 am - 4:30 pm ET, Monday - Friday

NDC: 17714-014-01 – 100 COUNT

NDC: 17714-014-10 – 1000 COUNT

APAP

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17714-014
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**
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	AP;014
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17714-014-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/14/1990	
2	NDC:17714-014-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/14/1990	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/14/1990	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-014)

Revised: 12/2017 Advance Pharmaceutical Inc.