ACETAMINOPHEN- 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 325 mg

Active Ingredient

(in each tablet)

Acetaminophen 325 mg

Purpose

Pain Reliever / Fever Reducer

Uses

temporarily reduces fever and relieves minor aches and pains caused by

- common cold
- headache
- toothache
- muscular aches
- premenstrual and menstrual cramps

Warnings

Liver warning: this product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- child takes more than 5 tablets in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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.

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- adult's pain gets worse or lasts more than 10 days
- child's pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical

attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

adults and children 12 years and over	1-2 tablets every 4 hours or 2-3 tablets every 6 hours while symptoms last, not more than 12 tablets in 24 hours
children 6 to 11 years	1 tablet every 4 hours while symptoms last, not more than 5 tablets in 24 hours
children under 6 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

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.

REGULAR STRENGTH

APAP

Acetaminophen USP, 325 mg

Pain Reliever/Fever Reducer

100 TABLETS

*Compare to Active Ingredient in Regular Strength TYLENOL®

See New Warnings Information

NDC 17714-012-01

Drug Facts

Active ingredient (in each tablet)	Purpose
Acetaminophen 325 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 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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

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 regular strenth TYLENOL®.

Manufactured by: Advance Pharmaceutical Inc.
Holtsville, NY 11742

0 17714 01201 4

LA1112

PEEL HERE FOR MORE DRUG FACTS

Lot No.:

Exp. Date:

Drug Facts (continued)

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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 tablets every 4 to 6 hours while symptoms last
- do not take more than 10 tablets in 24 hours
- do not use for more than 10 days unless directed by a doctor

children 6-11 years:

- take 1 tablet every 4 to 6 hours while symptoms last
- do not take more than 5 tablets in 24 hours
- do not use for more than 5 days unless directed by a doctor

children under 6 years: ■ ask a doctor

Other information

- store at 15° to 30°C (59° to 86°F)

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

Advance Pharmaceutical Inc.

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

1000 TABLETS

Acetaminophen USP, 325 mg

Pain Reliever/Fever Reducer

REGULAR STRENGTH

APAP

*Compare to Active Ingredient in Regular Strength TYLENOL®

See New Warnings Information

NDC 17714-012-10

Drug Facts

Active ingredient (in each tablet) — **Purpose**

Acetaminophen 325 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
  - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if ■ pain gets worse or lasts more than 10 days in adults

- pain gets worse or lasts more than 5 days in children under 12 years
- 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.

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- do not use for more than 10 days unless directed by a doctor

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- do not take more than 5 tablets in 24 hours
- do not use for more than 5 days unless directed by a doctor

children under 6 years: ■ ask a doctor

Other information

■ store at 15° to 30°C (59° to 86°F)

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Inactive ingredients

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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

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

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

LA1112

Lot No.:

Exp. Date:

0 17714 01210 6

NDC: 17714-012-01 – 100 COUNT

NDC: 17714-012-10 – 1000 COUNT

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17714-012
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 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	ROUND	**Size**	8mm
Flavor		**Imprint Code**	AP;012
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17714-012-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/05/1989	
2	NDC:17714-012-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/05/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/05/1989	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-012)

Revised: 12/2017 Advance Pharmaceutical Inc.