ACETAMINOPHEN PM- acetaminophen pm 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-PM

Active Ingredient

(in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain Reliever / Night time sleep aid

Uses

temporarily relief of occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

Liver warning: This product contains acetaminophen. 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.
- with any other drug containing diphenhydramine, even one used on skin
- in children under 12 years of age

Ask a doctor before use if the you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedative or tranquilizers

when using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks, insomnia may be a symptom of serious underlying medical illness.
- Any new symptoms appear
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

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
- **adults and children 12 years and over:** take 2 caplets at bedtime if needed or as directed by a doctor
- **children under 12 years :** do not use this adult product in children under 12 years of age; this will provide more than the recommended dose(overdose) and may cause liver damage

Other Information

- store at 15-30 °C (59-86 °F)

Inactive Ingredients

crosscarmellose sodium, FD&C blue # 1, hypromellose, microcrystalline cellulose, polyethylene glycol 400, povidone, silicon dioxide, starch, stearic acid, titanium dioxide

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

Drug Facts

Active ingredients (in each caplet)	Purposes
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	Night time sleep aid

Uses temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

Liver warning: This product contains acetaminophen. 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.
- with any other drug containing diphenhydramine, even one used on skin
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers ▶

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

†Advance Pharmaceutical Inc. is not affiliated with the owner of the trademark Tylenol®-PM.

Manufactured and distributed by: Advance Pharmaceutical Inc.
Holtsville, NY 11742, USA

LA0413

Lot No.:

Exp. Date:

PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- any new symptoms appear
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

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
- **adults and children 12 years and over:** take 2 caplets at bedtime if needed or as directed by a doctor
- **children under 12 years:** do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

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

Inactive ingredients

croscarmellose sodium, FD&C blue #1, hypromellose, microcrystalline cellulose, polyethylene glycol 400, povidone, silicon dioxide, starch, stearic acid, titanium dioxide

Questions or comments?

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

NDC: 17714-133-50 – 50 COUNT CAPLETS

ACETAMINOPHEN PM

acetaminophen pm tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17714-133
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	AP;133
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17714-133-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	01/09/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/09/2002	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-133)

Revised: 12/2017 Advance Pharmaceutical Inc.