ACETAMINOPHEN PM- acetaminophen 500mg / diphenhydramine hcl 25mg tablet, film coated
Ulai Health LLC

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.

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime 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

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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 a pharmacist.
- with any other product containing diphenhydramine, even one used on skin

- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

When using this product
- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operating machinery

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

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.
- 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
- **do not take more than directed (see overdose warning)**

adults and children 12 years and over	• take 2 caplets at bedtime • do not take more than 2 caplets of this product in 24 hours
children under 12 years	do not use

Other information
- store at 20-25 ^{0}C (68-77 ^{0}F)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, FD&C Blue #1, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized corn starch, purified water, stearic acid, titanium dioxide

Questions or comments?

(866) 562-2756 (Mon - Fri 8 AM to 4 PM EST)

PHARBEST

NDC 73057-352-03

Manufactured in the USA

Extra Strength

***COMPARE TO the active ingredients in TYLENOL ® PM**

ACETAMINOPHEN

PM

Pain Reliever

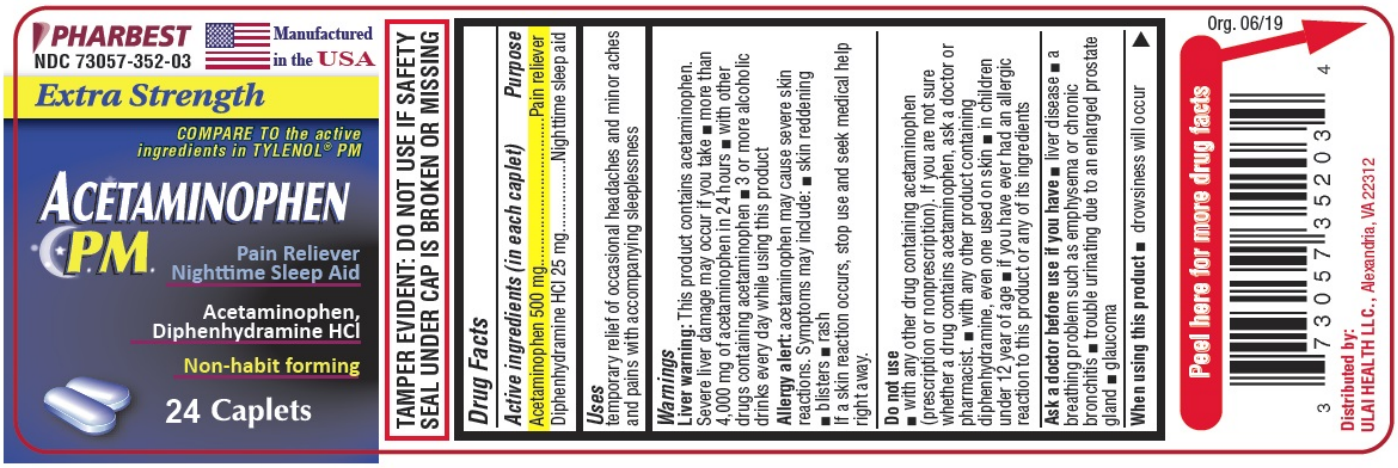
Nighttime Sleep Aid

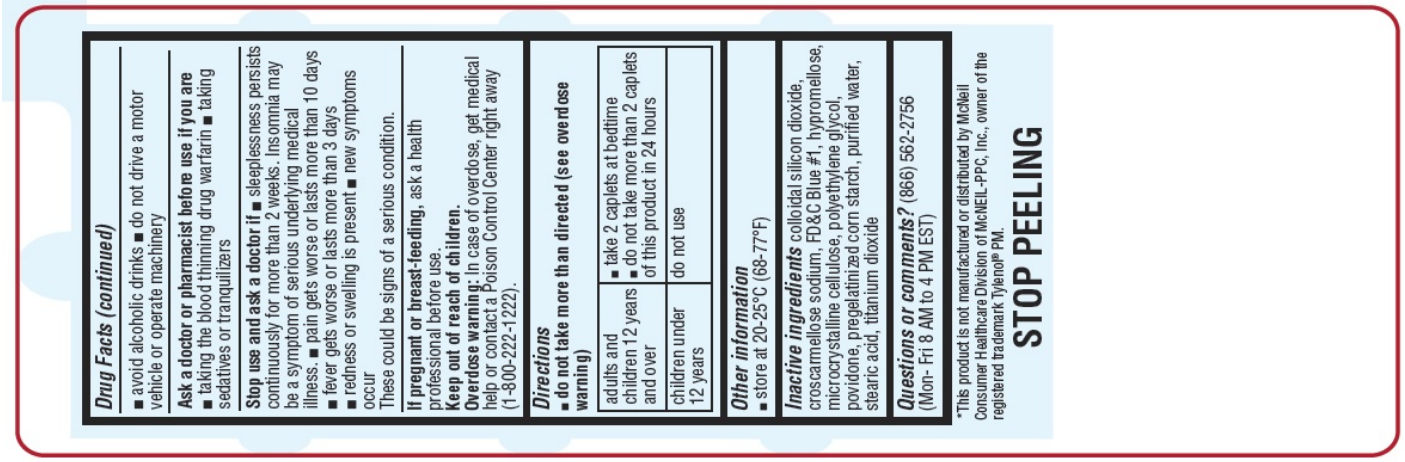
Acetaminophen,

Diphenhydramine HCl

Non-habit forming

24 Caplets





ACETAMINOPHEN PM

acetaminophen 500mg / diphenhydramine hcl 25mg tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73057-352
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (Light Blue color tablet)	**Score**	no score
Shape	CAPSULE (Capsule Shaped tablet)	**Size**	18mm
Flavor		**Imprint Code**	PH019
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73057-352-03	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/08/2019	

Labeler - Ulai Health LLC (081181535)

Revised: 1/2022 Ulai Health LLC