

**EXTRA STRENGTH ACETAMINOPHEN PM- acetaminophen 500mg/
diphenhydramine hcl 25mg tablet
TIME CAP LABS INC**

430_Timely_Extra Strength_APAP PM Caplets

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 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

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives 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.
- 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). 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 and children 12 years and over	<ul style="list-style-type: none">• 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 between 20-25°C (68-77°F)

Inactive ingredients carnauba wax, colloidal silicon dioxide, FD&C blue#1 aluminum lake, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium starch glycolate**, stearic acid, talc, titanium dioxide

**may contain this ingredient

Questions or comments?

Call **1-877-290-4008**

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

NDC 49483-430-40

timely™

Compare to the active ingredients in Extra Strength Tylenol® PM

Extra Strength

Acetaminophen PM

Acetaminophen 500 mg, Diphenhydramine HCl 25 mg

**Pain Reliever
Nighttime Sleep-Aid**

Non-habit forming

400 CAPLETS*
(*Capsule-Shaped Tablets)



Actual Size

<p>Drug Facts</p> <p>Active ingredients (in each caplet) Purpose Acetaminophen 500 mg Pain reliever Diphenhydramine HCl 25 mg Nighttime sleep aid</p> <p>Uses ■ temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness</p> <p>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 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</p>	<p>Drug Facts (continued)</p> <p>product or any of its ingredients</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers</p> <p>When using this product ■ drowsiness will occur ■ avoid alcoholic drinks ■ do not drive a motor vehicle or operate machinery</p> <p>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.</p> <p>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 ▶</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions Do not take more than directed. See overdose warning</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years and over</td> <td style="width: 50%;">■ take 2 caplets at bedtime ■ do not take more than 2 caplets of this product in 24 hours</td> </tr> <tr> <td>children under 12 years</td> <td>■ do not use</td> </tr> </table> <p>Other information ■ store between 20-25°C (68-77°F)</p> <p>Inactive ingredients carnauba wax, colloidal silicon dioxide, FD&C blue#1 aluminum lake, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium starch glycolate**, stearic acid, talc, titanium dioxide **may contain this ingredient</p> <p>Questions or comments? Call 1-877-290-4008</p>	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
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This product is not manufactured or distributed by Kenne Inc., owner of the registered trademark Extra Strength Tylenol® PM
Distributed by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735
430R 0225
Made in India

Varnish Omit Area

LOT: 49483143040110
EXP: 3

EXTRA STRENGTH ACETAMINOPHEN PM			
acetaminophen 500mg/ diphenhydramine hcl 25mg tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-430
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg	
Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
TALC (UNII: 7SEV7J4R1U)			
POVIDONE (UNII: FZ989GH94E)			
STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics			
Color	blue	Score	no score

Shape	CAPSULE (Capsule shaped tablet)	Size	18mm
Flavor		Imprint Code	TCL430
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-430-40	400 in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/22/2023	

Labeler - TIME CAP LABS INC (037052099)

Registrant - TIME CAP LABS INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABS INC		037052099	manufacture(49483-430)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		677604129	manufacture(49483-430)

Revised: 7/2025

TIME CAP LABS INC