

**EXTRA STRENGTH NITETIME PAIN RELIEF- acetaminophen 500 mg,diphenhydramine hydrochloride 25 mg tablet tablet
WALGREENS**

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.

430R Walgreens Acetaminophen Diphenhydramine 500 mg/25 mg Caplets-24 counts

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 a 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:

- 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**

NDC 0363-0714-42

Walgreens

Pain Reliever PM

ACETAMINOPHEN 500 mg /
PAIN RELIEVER
DIPHENHYDRAMINE HCl 25 mg /
NIGHTTIME SLEEP AID

24 CAPLETS**
(**capsule-shaped tablets)

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

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

Warnings (See carton for complete warnings)

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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 **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING** ■ store between 20-25°C (68-77°F)

Questions or comments? call 1-877-290-4008

Walgreens Pharmacist Recommended.

Our pharmacists recommend the Walgreens brand.

We invite you to compare to national brands.

DISTRIBUTED BY: WALGREEN CO.,

200 WILMOT RD., DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED

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ITEM 823581 W00000-0000-0 430R 1021 W30RG0122-F



Varnish Omit Area

Lot No.:

Exp. Date:

Coating/Print
Omit Area

EXP. DATE:
LOT No.:



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RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg. Pain reliever
Diphenhydramine HCl 25 mg. Nighttime sleep aid

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■ with any other product containing diphenhydramine, even one used on skin
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Drug Facts (continued)

■ if you have ever had an allergic reaction to this product or any of its ingredients

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Drug Facts (continued)

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■ children under 12 years:
■ do not use

Other information

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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

Coating
Omit

REV-0322
W30RG0122-F

NDC 0363-0714-42



Pain Reliever PM

ACETAMINOPHEN 500 mg / PAIN RELIEVER
DIPHENHYDRAMINE HCl 25 mg / NIGHTTIME SLEEP AID

Extra Strength

Nighttime

24 CAPLETS**
(**capsule-shaped tablets)

ACTUAL SIZE

E826R1 Coating/Print Omit Area



Coating
Omit

EXTRA STRENGTH NIGHTTIME PAIN RELIEF

acetaminophen 500 mg, diphenhydramine hydrochloride 25 mg tablet tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0714	
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	
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE (UNII: FZ989GH94E)				
TALC (UNII: 7SEV7J4R1U)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	TCL430	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0714-42	1 in 1 CARTON	10/12/2021	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part343		10/12/2021	

Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(0363-0714)

Revised: 7/2022

WALGREENS