EXTRA STRENGTH NITE-TIME PAIN RELIEF- 430r walgreens acetaminophen 500 mg,diphenhydramine hcl 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 0363-0715 Acetaminophen 500mg Diphenhydramine HCl 25mg 100ct

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

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**



W30RG0122-

Varnish Omit Area

Walgreens

Reliever PM

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

100 CAPLETS**

(**capsule-shaped tablets)

NDC 0363-0715-01

temporary relief of occasional headaches and minor pains with accompanying sleeplessness

Severe liver **iver warning:** This product contains acetaminophen. damage may occur if you take ■ more than 4,000 mg of acetaminophen in 24 hours

Symptoms may include: skin reddening blisters rash 3 or more alcoholic drinks every day while using this product
 Allergy alert: a cetaminophen may cause severe skin reactions. with other drugs containing acetaminophen

prescription or nonprescription). If you are not sure whether a

drug contains acetaminophen, ask a doctor or pharmacist

used on skin in thildren under 12 years of age if you have ever had an allergic reaction to this product or any of its ingredients 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 ■ with any other product containing diphenhydramine, even one

(see overdose

a Poison Control Center right away (1-800-222-1222).

Directions = do not take more than directed (see overdos 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 EVIDEN

AMPER EVIDENT: DO NOT USE THIS ED FOIL SEAL OVER THE MOUTH OF BROKEN OR MISSING ■ store Questions or comments? call 1-877-290-4008 oetween 20-25°C (68-77°F)

invite you to compare to national brands. Walgreens Pharmacist Recommended Our pharmacists recommend the Walgreens brand.
We invite you to compare to n

DISTRIBUTED BY: WALGREEN CO., 200 WILMOT RD., DEERFIELD, IL 60015 100% SATISFACTION GUARANTEED

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TEM 823754 W00000-0000-0 430R 1021

LOT No.:

EXP. DATE:

Coating/Print EXP. DATE: **Omit Area** :.ON TOJ **Coating Omit** TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING M30RG0122-F Drug Facts (continued) Drug Facts (continued) **Drug Facts** C6011AR3 Ask a doctor before use if you have Directions do not take more than directed (see overdose warning) adults and children 12 years and over: Active ingredients Purpose a breathing problem such as emphysema or (in each caplet) chronic bronchitis ■ trouble urinating due to an enlarged prostate gland ■ glaucoma ■ take 2 caplets at bedtime Diphenhydramine HCl 25 mg. Nighttime sleep aid do not take more than 2 caplets of this product in 24 hours. children under 12 years: Ask a doctor or pharmacist before use if you are **Uses** temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers Reliever PN When using this product Other information 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 — a or more alcoholic drinks every day while using this drowsiness will occur avoid alcoholic drinks ■ store between 20-25°C (68-77°F) Coating/Print Omit Area 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, 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 persymptoms occur ETAMINOPHEN 500 mg / PAIN RELIEVER Henhydramine HCI 25 mg / Nighttime Sleep Aid 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 talc, titanium dioxide *may contain this ingredient Questions or comments? call 1-877-290-4008 new symptoms occur help right away. These could be signs of a serious condition. Do not use If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a Neep au of readen to enlineren. 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. doctor or pharmacist. 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 Walgreens **ACETAMINOPHEN** 500 mg / PAIN RELIEVER DIPHENHYDRAMINE HCI 25 mg / NIGHTTIME SLEEP AID Reliever P 0 **Coating Omit**

EXTRA STRENGTH NITE-TIME PAIN RELIEF

430r walgreens acetaminophen 500 mg,diphenhydramine hcl 25 mg tablet tablet

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0715 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|---|----------------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) | ACETAMINOPHEN | 500 mg | |
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE (UNII: FZ989GH94E) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|-------------------------|---------|--------------|----------|
| Color | blue | Score | no score |
| Shape | CAPSULE | Size | 20mm |
| Flavor | | Imprint Code | TCL430 |
| Contains | | | |

| ı | Packaging | | | |
|---|----------------|--|-------------------------|-----------------------|
| 7 | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| : | NDC:0363-0715- | 1 in 1 CARTON | 10/12/2021 | |
| : | L | 100 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(0363-0715) | |

Revised: 7/2022 WALGREENS