ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE - acetaminophen and diphenhydramine hydrochloride tablet
KROGER COMPANY

Drug Facts

Active ingredients (in each gelcap)

Acetaminophen USP 500 mg
Diphenhydramine hydrochloride USP 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:

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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
- if you are allergic to acetaminophen or any of the inactive ingredients in this product
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the 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 beverages
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

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

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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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 gelcaps at bedtime
  - do not take more than 2 gelcaps of this product in 24 hours.
- children under 12 years: do not use

Other information

- avoid high humidity

- store at 20º to 25°C (68º to 77°F)
- use by expiration date on package

Inactive ingredients

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, FD&C red #3, gelatin, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch (maize), propylene glycol, shellac glaze, talc, and titanium dioxide.

Questions or comments?

Call **1-800-632-6900**

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202
MADE IN INDIA

Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg / 25 mg (50 Caplets Bottle)

NDC 30142-193-14
Kroger®
health

NON-HABIT
FORMING

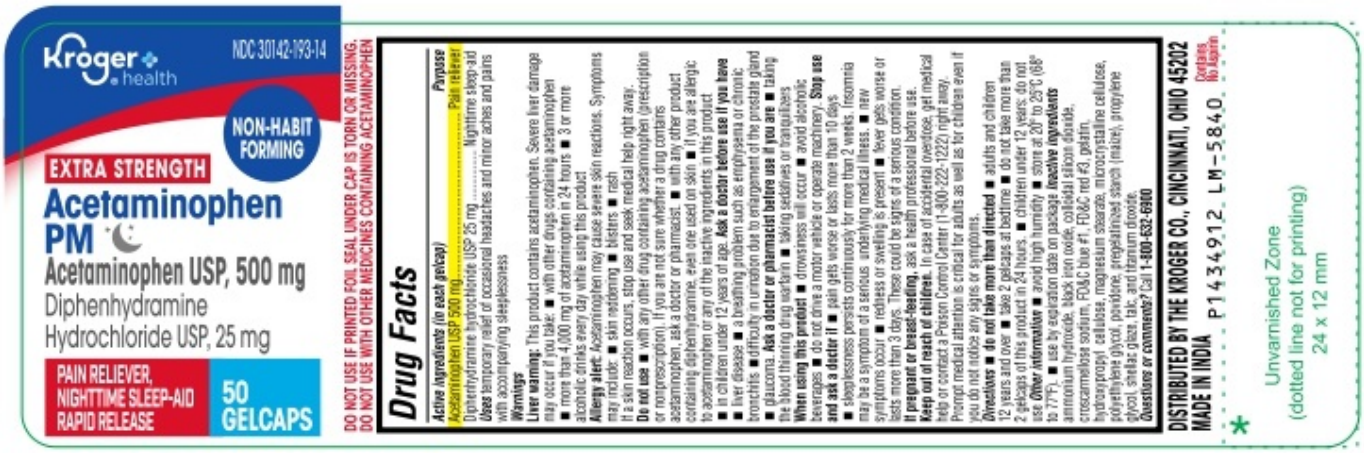
EXTRA STRENGTH

Acetaminophen
PM
Acetaminophen USP, 500 mg

Diphenhydramine
Hydrochloride USP, 25 mg

PAIN RELIEVER,
NIGHTTIME SLEEP-AID
RAPID RELEASE

50
GELCAPS



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg / 25 mg (50 Caplets Bottle Carton)

NDC 30142-193-14

Kroger®
health

COMPARE TO THE ACTIVE INGREDIENTS OF EXTRA STRENGTH TYLENOL® PM*

NON-HABIT FORMING

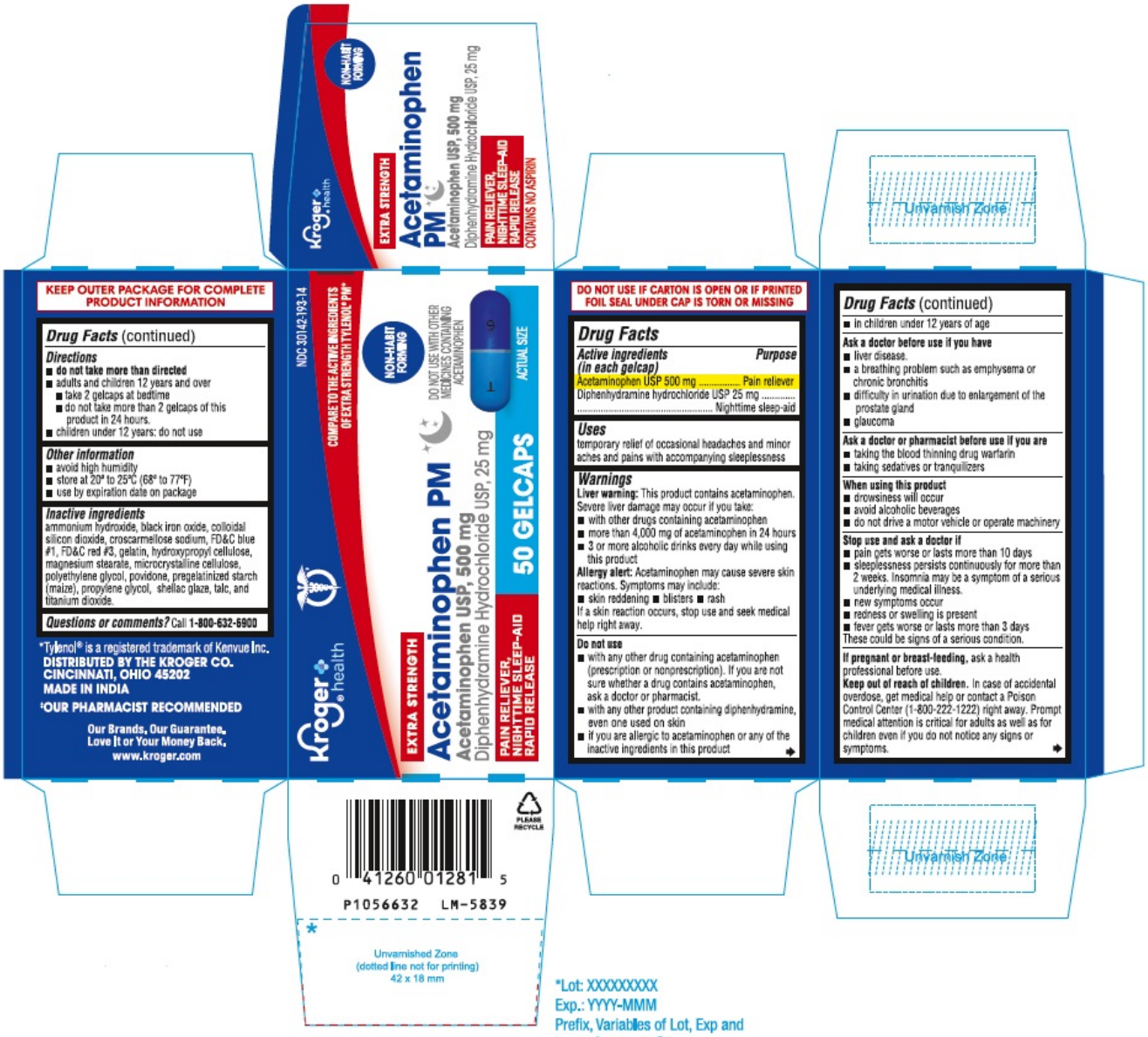
EXTRA STRENGTH

Acetaminophen PM
Acetaminophen USP, 500 mg
Diphenhydramine Hydrochloride USP, 25 mg

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

PAIN RELIEVER, NIGHTTIME SLEEP-AID RAPID RELEASE

50 GELCAPS ACTUAL SIZE



ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen and diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-193
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
AMMONIA (UNII: 5138Q19F1X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (Dark blue and Light blue with white band)	**Score**	no score
Shape	CAPSULE (Biconvex)	**Size**	20mm
Flavor		**Imprint Code**	T;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-193-14	1 in 1 CARTON	03/06/2021	
1		50 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 Drug	M013	03/06/2021	

Labeler - KROGER COMPANY (006999528)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(30142-193) , MANUFACTURE(30142-193)

Revised: 9/2024

KROGER COMPANY