

**ACETAMINOPHEN AND DIPHENHYDRAMINE HCL- acetaminophen and
diphenhydramine hcl tablet
PUBLIX SUPERMARKETS, INC**

**Extra Strength
Pain Relief PM**

ACETAMINOPHEN, 500 mg DIPHENHYDRAMINE HCl, 25 mg

- **Pain reliever/nighttime sleep-aid**
- **Non-habit forming**
- **Contains no aspirin**

Active ingredients (in each caplet)

Acetaminophen USP, 500 mg

Diphenhydramine HCl USP, 25 mg

Purpose

Pain reliever

Nighttime sleep aid

Uses

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

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

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). See USP Controlled Room Temperature.
- see end panel for lot number and expiration date

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone k-30, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

Principal display panel

COATING
FREE AREA

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READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION

TAMPER EVIDENT: DO NOT USE IF IMPROPER
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

Active Ingredients (in each caplet)

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Acetaminophen USP, 500 mg	Pain reliever
Diphenhydramine HCl USP, 25 mg	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 redness, 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 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

Drug Facts (continued)

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

sleepiness 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

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see end panel for lot number and expiration date

Inactive ingredients

croscarmellose, croscarmellose sodium, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, polyvinylpyrrolidone K-30, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

call 1-877-776-6183 Mon-Fri 8:00 AM EST to 6:00 PM PST

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Pain Relief PM**

ACETAMINOPHEN, 500 mg
DIPHENHYDRAMINE HCl, 25 mg

- Pain reliever/nighttime sleep-aid
- Non-habit forming
- Contains no aspirin

NDC 41415-661-10

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ACTUAL SIZE

Compare to the active ingredients in Extra Strength Tylenol® PM Caplets*

100 Caplets*
*Capsule-shaped tablets

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ACTUAL SIZE

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100 Caplets*
*Capsule-shaped tablets

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*This product is not manufactured or distributed by Vertex Inc., owner of the registered trademark Extra Strength Tylenol® PM Caplets.

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Lot:

Exp.:

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ACETAMINOPHEN AND DIPHENHYDRAMINE HCL

acetaminophen and diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41415-661
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE (UNII: 8GTS82S83M) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE	25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STARCH, CORN (UNII: O8232NY3SJ)
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)
STEARIC ACID (UNII: 4ELV7Z65AP)
POVIDONE K30 (UNII: U725QWY32X)
HYPROMELLOSES (UNII: 3NXW29V3WO)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	G651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41415-661-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2024	
2	NDC:41415-661-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/02/2024	

Labeler - PUBLIX SUPERMARKETS, INC (006922009)

Revised: 8/2024

PUBLIX SUPERMARKETS, INC