**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

700000003736
200000005002

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

## Drug Facts

**Active Ingredients (in each caplet)** — **Purpose**

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 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

►

## 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**

- 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 | ■ take 2 caplets at bedtime<br>■ 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 1-877-770-5183 Mon-Fri 8:00 AM EST to 6:00 PM EST

200000005002
700000003736

COATING
FREE AREA

# Extra Strength 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

ACTUAL SIZE

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

**100 Caplets†**

†Capsule-shaped tablets

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

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.
3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811
1-800-242-1227 publix.com
PUBLIX GUARANTEE:
COMPLETE SATISFACTION OR YOUR MONEY BACK

PAPER BOX — PLASTIC BOTTLE

Publix.

0 41415 55873 1

Lot

Exp.

COATING
FREE AREA


# Extra Strength Pain Relief PM

ACETAMINOPHEN, 500 mg
DIPHENHYDRAMINE HCl, 25 mg

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

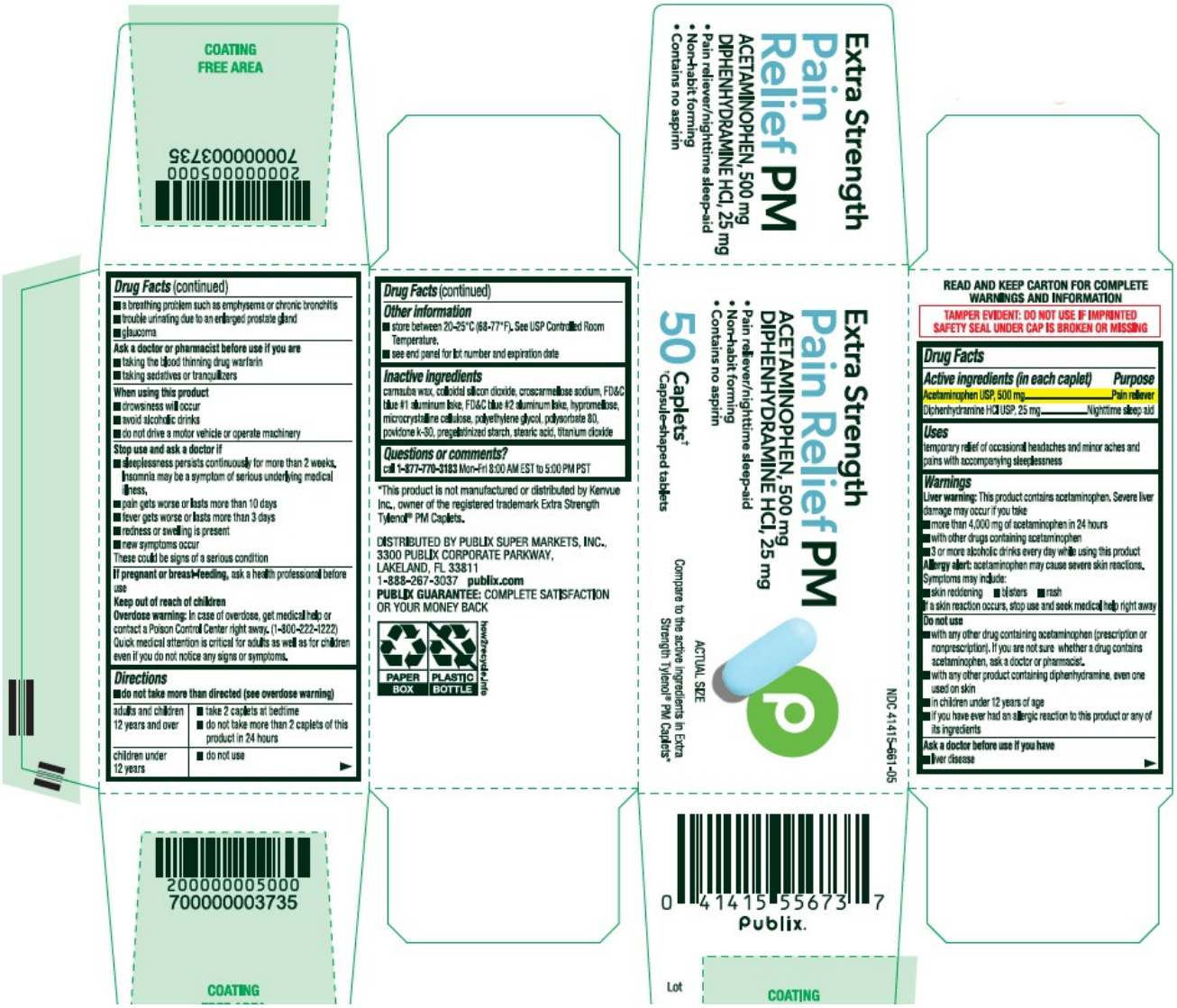
NDC 41415-661-10

ACTUAL SIZE

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

**100 Caplets†**

†Capsule-shaped tablets




# 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) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **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) | |

## 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: 12/2024 PUBLIX SUPERMARKETS, INC