

**ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated**  
**Family Dollar (FAMILY WELLNESS)**

*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.*

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**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 products 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 problems 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.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for 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.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 15-30°C (59-86°F)
- avoid high humidity and excessive heat

## **Inactive ingredients**

carnauba wax\*, croscarmellose sodium\*, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate\*, microcrystalline cellulose, polyethylene glycol, polysorbate 80\*, polyvinyl alcohol\*, povidone K30, pregelatinized starch, purified water\*, silicon dioxide\*, sodium starch glycolate\*, stearic acid\*, talc\*, titanium dioxide

\*contains one or more of these ingredients

## **Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

## **Principal Display Panel**

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

Acetaminophen 500 mg **PM**

with Diphenhydramine HCl 25 mg

Pain Reliever, Nighttime Sleep Aid

Non-Habit Forming

CAPLETS

\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare distributor of Extra Strength Tylenol® **PM**.

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

DISTRIBUTED BY: MIDWOOD BRANDS, LLC

10611 MONROE RD ,MATHEWS, NC 28105 USA

## **Package Label**

Exp. Date:  
Lot No.:  
PLD-D134H  
FC004295



SKU 0902381

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

NDC 55319-447-01

FAMILY wellness™

EXTRA STRENGTH

Acetaminophen 500 mg **PM**

With Diphenhydramine HCl 25 mg

Pain Reliever, Nighttime Sleep-Aid

Non Habit-Forming

100 CAPLETS



ACTUAL SIZE



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■ 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**

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**Drug Facts (continued)**

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 10611 MONROE RD., MATTHEWS, NC 28105

NOT 100% SATISFIED?

Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

**FAMILY WELLNESS Extra Strength Acetaminophen PM****ACETAMINOPHEN PM EXTRA STRENGTH**

acetaminophen, diphenhydramine hcl tablet, coated

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55319-447 |
| <b>Route of Administration</b> | ORAL           |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b>      | <b>Strength</b> |
|---|-------------------------------|-----------------|
| <b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                   | ACETAMINOPHEN                 | 500 mg          |
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg           |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                        |                 |
| <b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)               |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                 |                 |
| <b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)                 |                 |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)                       |                 |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                  |                 |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)         |                 |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)    |                 |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                      |                 |
| <b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)      |                 |
| <b>POVIDONE K30</b> (UNII: U725QWY32X)                        |                 |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                               |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                     |                 |
| <b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B) |                 |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                        |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                                |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                    |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)                      |                 |

**Product Characteristics**

|                 |         |                     |                |
|-----------------|---------|---------------------|----------------|
| <b>Color</b>    | blue    | <b>Score</b>        | no score       |
| <b>Shape</b>    | CAPSULE | <b>Size</b>         | 18mm           |
| <b>Flavor</b>   |         | <b>Imprint Code</b> | S525;P525;G651 |
| <b>Contains</b> |         |                     |                |

**Packaging**

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55319-447-01 | 1 in 1 BOX  | 11/30/2014           | 04/26/2024         |
| 1 |                  | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:55319-447-50 | 1 in 1 BOX  | 11/30/2014           | 04/26/2024         |
| 2 |                  | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  |                      |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 11/30/2014           | 04/26/2024         |

**Labeler** - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 10/2021

Family Dollar (FAMILY WELLNESS)