

**PAIN RELIEVER PM- acetaminophen, diphenhydramine hcl tablet, coated**  
**CVS PHARMACY, INC**

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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.
- pain gets worse or last 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 (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 of age 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)
- avoid high humidity and excessive heat

**Inactive ingredients**

croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatanized starch, purified water, silicon dioxide,

sodium starch glycolate, talc, titanium dioxide

### **Questions or comments?**

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

### **Principal Display Panel**

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

#### **EXTRA STRENGTH**

##### **Acetaminophen PM**

**ACETAMINOPHEN 500 mg**

DIPHENHYDRAMINE HCl 25 mg

**Pain reliever; nighttime sleep-aid**

non habit-forming

For ages 12 years and over

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: CVS Pharmacy, Inc.**

One CVS Drive, Woonsocket, RI 02895

### **Package Label**

**VALUE SIZE 500 CAPLETS**

**CVS Health.** Compare to the active ingredients in Extra Strength Tylenol® PM\* **Caplets**

**EXTRA STRENGTH** NDC 51316-863-50

**Acetaminophen PM**

**ACETAMINOPHEN 500 mg**  
**DIPHENHYDRAMINE HCl 25 mg**

**Pain reliever; nighttime sleep-aid**

Non habit-forming  
For ages 12 years and over



Actual Size

**500 CAPLETS**

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

**Drug Facts**

**Active Ingredients (in each caplet)**  
Acetaminophen 500 mg, Diphenhydramine HCl 25 mg, Inactive ingredients: Pain reliever, Nighttime sleep-aid

**Uses** Temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

**Warnings**  
Liver warnings: 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 ■ 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 ■ taking ■ taking  
**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 (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 of age and over: take 2 caplets at bedtime. Do not take more than 12 caplets of this product in 24 hours. ■ children under 12 years of age: do not use

**Other information** ■ store between 20-25°C (68-77°F) ■ avoid high humidity and excessive heat

**Inactive ingredients** croscarmellose sodium, FD&C blue #1, aluminum lake, FD&C blue #2, aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatinized starch, purified water, silicon dioxide, sodium starch glycolate, talc, titanium dioxide

**Questions or comments?** Call 1-877-755-3835 Monday-Friday 9AM-5PM EST


This product is not manufactured or distributed by McKell Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

**Distributed by: CVS Pharmacy, Inc.**  
One CVS Drive, Woonsocket, RI 02895  
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**CVS Quality**  
Money Back Guarantee

PLD-E596A  
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#713423



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Exp. Date:

**CVS HEALTH Extra Strength Acetaminophen PM**

**PAIN RELIEVER PM**

acetaminophen, diphenhydramine hcl tablet, coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-863
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<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**

Ingredient Name	Strength
<b>CROSCARMELOSE 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: 70097M6130)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WQ0SDWL1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STARCH, CORN</b> (UNII: O8232NY35J)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

### 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>	P525
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-863-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/15/2024	

**Labeler** - CVS PHARMACY, INC (062312574)

Revised: 9/2024

CVS PHARMACY, INC