

**ACETAMINOPHEN 500MG DIPHENHYDRAMINE HCL 25MG- acetaminophen 500mg  
diphenhydramine hcl 25mg tablet  
Strive Pharmaceuticals Inc**

*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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**Pain Relief PM - Extra Strength  
Body Pain - Dolor Corporal  
(Acetaminophen 500mg; Diphenhydramine Hydrochloride 25mg)**

Acetaminophen 500mg; Diphenhydramine 25mg

colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, hydroxypropyl methyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

- take with a full glass of water
- do not take more than directed
- do not take more than 2 caplets in 24 hours

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adults and children 12 years of age and over	<ul style="list-style-type: none"><li>• 2 caplets at bedtime</li><li>• do not take more than 2 caplets in 24 hours</li></ul>
children under 12 years of age	do not use

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\*temporarily relief of occasional heaches and minor aches and pains with accompanying sleeplessness

**Liver warning:**

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4000mg 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 non prescription). 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 a 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
- new symptoms occur
- redness or swelling is present

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 accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Pain reliever

Nighttime sleep-aid

- store at room temperature between 20 °C - 25 °C (68 °F - 77 °F)

**Compare to active ingredients in**  
**TYLENOL<sup>®</sup> PM Extra Strength**  
**RIGHT**  
**KNOWLEDGE**  
**Pain Relief<sup>PM</sup>**  
**EXTRA STRENGTH**  
**pain reliever**  
 acetaminophen **500 mg**  
 diphenhydramine HCl **25 mg**  
 each caplet  
**50**  
 caplets  
 NDC 70692-119-05

**RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.**  
 Most important: Do not use if important safety seal under cap is broken or missing.

<b>Drug Facts</b>	<b>Active Ingredient (in each tablet)</b> Acetaminophen 500mg Diphenhydramine HCl 25 mg	<b>Purpose</b> Pain reliever Nighttime sleep aid
<b>Uses:</b>	Temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.	
<b>Warnings:</b>	Liver warning: This product contains acetaminophen severe liver damage may occur. Allergy alert: Acetaminophen may cause severe skin reactions.	
<b>Do not use</b>	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 have ever had an allergic reaction to this product or any of its ingredients.	
<b>Stop use and ask a doctor if</b>	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.	
<b>If pregnant or breast-feeding,</b>	ask a health professional before use. Keep out of reach of children.	
<b>OVERDOSE WARNING:</b>	In case of accidental overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b>	Do not take more than directed. adults & children 12 years of age and over take 2 caplets at bedtime do not take more than 2 caplets in 24 hours. children under 12 years of age do not use	
<b>Other information:</b>	store at room temperature between 20-25°C (68-77°F) avoid excessive heat, cold and humidity.	
<b>Questions or comments?</b>	Call 1 (888) 577-8033.	
Distributed by: STORME PHARMACEUTICALS, INC. East Brunswick, NJ 08816   1.B1.1905   REV. 00-072019		
Lot No.	Exp. Date	



†compare to active ingredients in  
**TYLENOL®** PM Extra Strength

NDC 70692-119-05

# Pain Relief PM

**+** EXTRA STRENGTH  
pain reliever

acetaminophen **500 mg**  
diphenhydramine HCl **25 mg**  
each caplet

**50**  
caplets



**Pain Relief PM**  
EXTRA STRENGTH  
pain reliever  
acetaminophen 500mg  
diphenhydramine HCl 25mg

**READ AND KEEP OUTER PACKAGE FOR  
COMPLETE PRODUCT INFORMATION**

†This product is not manufactured or distributed by  
Johnson & Johnson Consumer, Inc., McNeil Consumer  
Healthcare Division, owner of the registered  
trademark Tylenol® PM Extra Strength.



†compare to active ingredients in  
**TYLENOL®** PM Extra Strength

NDC 70692-119-05

# Pain Relief PM

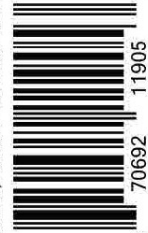
**+** EXTRA STRENGTH  
pain reliever

acetaminophen **500 mg**  
diphenhydramine HCl **25 mg**  
each caplet

**50**  
caplets



Distributed by: STRIVE PHARMACEUTICALS INC.  
East Brunswick, NJ 08816 - CT11905 - REV.00-072019



3 70692 11905 3

Lot. No.:  
Exp. Date:

**COATING  
FREE AREA**

**Drug Facts (continued)**

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 accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

**Directions**

■ take with a full glass of water ■ Do not take more than directed. **SEE OVERDOSE WARNING.** ■ do not take more than 2 caplets in 24 hours

adults & children 12 years of age and over	■ take 2 caplets at bedtime
children under 12 years of age	■ do not take more than 2 caplets of this product in 24 hours
	■ do not use

**Other information**

■ store at room temperature between 20° - 25° C (68° - 77° F) ■ avoid moisture, cold and humidity. ■ close cap tightly after use.

**Inactive ingredients**

cellulose, silicon dioxide, croscarmellose sodium, EPOC, blue #1, hydroxypropyl methyl cellulose, magnesium stearate, starch, starch, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide.

**Questions or comments?**  
Call 1 (888) 577-8033

**Drug Facts**

**Active ingredient (in each caplet)**

Acetaminophen 500mg	Pain reliever
Diphenhydramine HCl 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

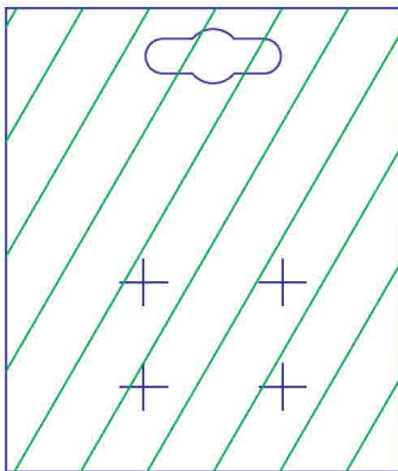
■ in children under 12 years of age ■ if you have ever had an allergic reaction to this product or any of its ingredients.


**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



		LOT: EXP:
<b>DRUG FACTS</b> Active ingredients (in each caplet)		
Acetaminophen 500mg	Pain reliever	
Diphenhydramine HCl 25 mg	Nighttime sleep aid	
<b>Uses:</b> • temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness		
<b>Warnings:</b> <b>Liver warning:</b> 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		
<b>Allergy Alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: • skin redness • hives • rash If a skin reaction occurs, stop use and seek medical help right away.		
<b>Do not use</b> • 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		
<b>Ask a doctor before use if you have</b> • liver disease • a breathing problem such as emphysema or chronic bronchitis • trouble urinating due to an enlarged prostate gland • glaucoma		
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LIFT PANEL FOR CONTINUED DRUG FACTS ▶		

<b>DRUG FACTS (Continued)</b>	
<b>When using this product</b> • drowsiness will occur • avoid alcoholic drinks • do not drive a motor vehicle or operate machinery	
<b>Stop use and ask a doctor if</b> • 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.	
<b>If pregnant or breast-feeding</b> ask a health professional before use.	
<b>Keep out of reach of children</b> <b>Overdose Warning:</b> In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	
<b>Directions:</b> • take with a full glass of water • do not take more than directed (see Overdose Warning) • do not take more than 2 caplets in 24 hours	
adults and children 12 years of age & over	• 2 caplets at bedtime • do not take more than 2 caplets in 24 hours
children under 12 years of age	do not use
<b>Other Information:</b> • Store at room temperature between 20-25°C (68-77°F).	
<b>Inactive Ingredients:</b> Colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, hydroxypropyl methyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide.	

<b>DRUG FACTS (Continued)</b>	
<b>QUESTIONS OR COMMENTS ?</b> 1-833-865-9444	
<b>READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION.</b> Distributed By: O4 GLOBAL TRADING USA LLC, 2241 S Watson Rd, Suite 121 Arlington, TX 76010. www.onlyfor.com Packaged By: Srinve Pharmaceuticals Inc., East Brunswick, NJ 08816.	
<b>TAMPER EVIDENT, DO NOT USE IF PACKAGE IS OPENED OR IF A BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING.</b>	
 Tear at arrows push through foil	
www.onlyfor.com	CT2DCN4-REV.102013

**ACETAMINOPHEN 500MG DIPHENHYDRAMINE HCL 25MG**

acetaminophen 500mg diphenhydramine hcl 25mg tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70692-119
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue (LIGHT BLUE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	AD01
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-119-41	4 in 1 PACKAGE; Type 0: Not a Combination Product	12/20/2018	
2	NDC:70692-119-05	50 in 1 PACKAGE; Type 0: Not a Combination Product	09/23/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/20/2018	

