

**PM GET RELIEF- acetaminophen and diphenhydramine hydrochloride tablet**  
**Eagle Distributors, 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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**PM Get Relief**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purposes</i></b>
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	Nighttime sleep aid

**Uses**

temporarily relieves 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

**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 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.**

**Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. 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**

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 of age	Do not use this adult strength product. This will provide more than the recommended dose (overdose) and could cause serious health problems

**Other information**

- store between 20-25 C (68-77 F)
- **do not use if pouch is torn or open**

**Inactive ingredients**

croscarmellose sodium, FD&C blue #1, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, starch, stearic acid, titanium dioxide. May contain polyvinyl alcohol, silicon dioxide, sodium starch glycolate, talc.

**Questions or comments?**

Call **1-800-570-8650 (M-F 9am to 5pm PST)**

Product manufactured for:

*Eagle Distributors, Inc.*

Los Angeles, CA 90011

**PRINCIPAL DISPLAY PANEL - 50 Pouch Carton**

**See New Warnings Information & Directions**

**Compare to the Active Ingredients in**

***Tylenol PM<sup>®</sup>\****

**Extra Strength**

***PM***

***Get Relief***

**Pain Reliever**

**Nighttime Sleep Aid**

*Acetaminophen, Diphenhydramine HCl*

See New Warnings Information & Directions  
Compare to the Active Ingredients in

**Tylenol PM<sup>®</sup>**

Extra Strength  
**PM** Pain Reliever  
Nighttime Sleep Aid  
Get Relief

*Acetaminophen, Diphenhydramine HCl*

TO OPEN  
PUSH IN TAB AND PULL OUT

*50 Pouches of 2 Caplets Each*

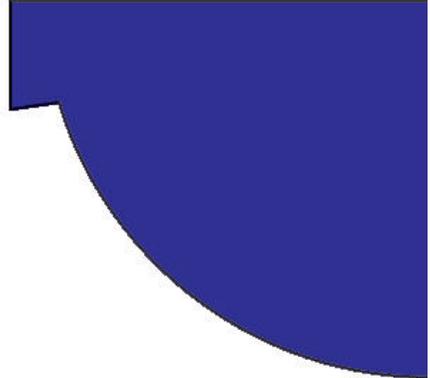
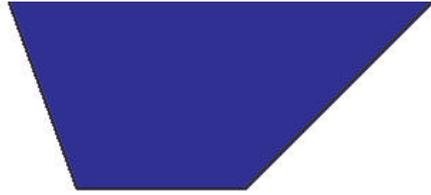
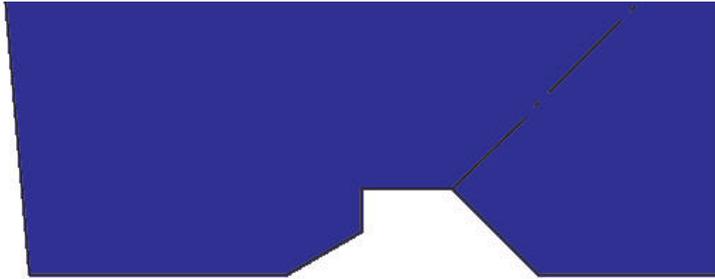
See New Warnings Information & Directions  
Compare to the Active Ingredients in

**Tylenol PM<sup>®</sup>**

Extra Strength  
**PM** Pain Reliever  
Nighttime Sleep Aid  
Get Relief

*Acetaminophen, Diphenhydramine HCl*





*50 Pouches of 2 Caplets Each*

*Acetaminophen, Diphenhydramine HCl*

*Get Relief*

**PM**

Extra Strength  
Pain Reliever  
Nighttime Sleep Aid

★ ★ ★ ★ ★

**Tylenol PM**®

★ ★ ★ ★ ★

See New Warnings Information & Directions  
Compare to the Active Ingredients in

<b>Drug Facts</b>	
<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 500 mg.....	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 <input type="checkbox"/> more than 4,000 mg of acetaminophen in 24 hours <input type="checkbox"/> with other drugs containing acetaminophen <input type="checkbox"/> 3 or more alcoholic drinks every day while using this product	
<b>Do not use</b> <input type="checkbox"/> with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. <input type="checkbox"/> with any product containing diphenhydramine, even one used on skin <input type="checkbox"/> in children under 12 years of age <input type="checkbox"/> 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> <input type="checkbox"/> liver disease <input type="checkbox"/> a breathing problem such as emphysema or chronic bronchitis <input type="checkbox"/> trouble urinating due to an enlarged prostate gland <input type="checkbox"/> glaucoma	
<b>Ask a doctor or pharmacist before use if you are</b> <input type="checkbox"/> taking the blood thinning drug warfarin <input type="checkbox"/> taking sedatives or tranquilizers	
<b>When using this product</b> <input type="checkbox"/> drowsiness will occur <input type="checkbox"/> avoid alcoholic drinks <input type="checkbox"/> do not drive a motor vehicle or operate machinery	
<b>Stop use and ask a doctor if</b> <input type="checkbox"/> sleeplessness persists continuously for more than 2 weeks, insomnia may be a symptom of serious underlying medical illness, <input type="checkbox"/> pain gets worse or lasts more than 10 days <input type="checkbox"/> fever gets worse or lasts more than 3 days <input type="checkbox"/> redness or swelling is present <input type="checkbox"/> 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> Taking more than the recommended dose (overdose) may cause liver damage. 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.	
<b>Directions</b>	
<input type="checkbox"/> do not take more than directed (see overdose warning)	
adults and children 12 years and over	<input type="checkbox"/> take 2 caplets at bedtime <input type="checkbox"/> do not take more than 2 caplets of this product in 24 hours
children under 12 years	do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage
<b>Other information</b> <input type="checkbox"/> store between 20-25°C (68-77°F) <input type="checkbox"/> do not use if card or pouch is torn or open <input type="checkbox"/> see side panel for lot number and expiration date	

See New Warnings Information & Directions  
Compare to the Active Ingredients in

★ ★ ★ ★ ★

**Tylenol PM**®

★ ★ ★ ★ ★

Extra Strength ★

**PM**

Pain Reliever  
Nighttime Sleep Aid

*Acetaminophen, Diphenhydramine HCl*

\*This product is not manufactured or distributed by:  
McNeil Consumer Specialty Pharmaceuticals Division of McNeil PPC, Inc.  
Eagle Distributors, Inc., does not own the Tylenol® PM trademark.

**Inactive ingredients**  
 carnauba wax, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, polyethylene glycol, polysorbate 80, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium citrate, sodium starch glycolate, titanium dioxide

**Questions or comments?** call 1-800-570-8650 (M-F 9 am to 5 pm PST)

**Contains No Aspirin**



Product manufactured for:  
**Eagle Distributors, Inc.**  
 Los Angeles, CA 90011

## PM GET RELIEF

acetaminophen and diphenhydramine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68737-224
<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>croscarmellose sodium</b> (UNII: M28OL1HH48)	
<b>FD&amp;C blue no. 1</b> (UNII: H3R47K3TBD)	
<b>hypromelloses</b> (UNII: 3NXW29V3WO)	
<b>cellulose, microcrystalline</b> (UNII: OP1R32D61U)	
<b>polyethylene glycols</b> (UNII: 3WJQ0SDW1A)	
<b>povidone</b> (UNII: FZ989GH94E)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>polyvinyl alcohol</b> (UNII: 532B59J990)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>talc</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	2 pieces
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<b>Shape</b>	OVAL (Capsule shape)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	AZ;020
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68737-224-08	50 in 1 BOX		
1		2 in 1 POUCH		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/30/2012	

**Labeler** - Eagle Distributors, Inc. (929837425)

Revised: 6/2012

Eagle Distributors, Inc.