

**PAIN RELIEF PM- acetaminophen, diphenhydramine tablet**  
**Pioneer Life Sciences, LLC**

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**Pain Relief PM**

**Active Ingredients (in each caplet)**

Acetaminophen 500 mg

Diphenhydramine 25 mg

**Purpose**

Acetaminophen 500 mg

.....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 hrs ■ 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

■ glaucoma

- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland.

**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:** In case of overdose, get medical help or contact Poison Control (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 in 24 hours unless directed by a doctor
- children under 12 years do not use

## Other Information:

- store at 20°-25°C (68°-77°F)
- do not use if foil or inner seal is broken or missing

## Inactive Ingredients:

FD & C Blue # 1, FD & C Blue # 2, Hypromellose, Microcrystalline Cellulose, Magnesium Stearate, Polyethylene glycol 400, Pregelatinized Starch, Polyvinyl Pyrrolidone, Stearic Acid Powder, Titanium Dioxide.

## Questions or Comments?

Call **1-732-698-5070** Monday through Friday 9am to 5pm EST or visit [www.pioneerlifesciences.com](http://www.pioneerlifesciences.com)

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

**Distributed by:** GenCare Consumer Products, LLC 40E Cotters Ln Suite A, East Brunswick, NJ 08816

TAMPER EVIDENT Do not use if safety seal under cap is broken or missing.

**Drug Facts**

**Active Ingredients (in each caplet)**  
 Acetaminophen 500 mg  
 Diphenhydramine HCl 25 mg

**Use:** ■ temporary relief of occasional headaches and minor aches and pains with accompanying sleepiness

**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: acetaminophen may cause allergic reactions (rash, hives, itching, trouble breathing, swelling of the face or throat) ■ If you have ever had an allergic reaction to this product or any of its ingredients

**Do Not Use:** ■ with any other drug containing acetaminophen (prescription or nonprescription) ■ 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 ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland

**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:** ■ sleepiness 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**

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Lot No.  
Exp. Dt.

## PAIN RELIEF PM

acetaminophen, diphenhydramine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC: 72090-006
<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	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
Magnesium Stearate (UNII: 70097M6I30)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
STARCH, CORN (UNII: O8232NY3SJ)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Titanium Dioxide (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	27mm	
Flavor		Imprint Code	None	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-006-25	375 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	05/08/2024		

**Labeler** - Pioneer Life Sciences, LLC (014092742)

**Registrant** - Pioneer Life Sciences, LLC (014092742)