

**PAIN RELIEVER PM- acetaminophen and diphenhydramine hydrochloride tablet**  
**Health Pharma USA LLC**

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**Pain Relief PM - Acetaminophen and Diphenhydramine HCl**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
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 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**

- **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 this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

### **Other information**

- store between 20-25°C (68-77°F)
- **do not use if pouch is torn or open**
- see side panel for lot number and expiration date

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, fdc blue #1 aluminum lake, fdc blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, purified water, sodium metabisulfite, sodium starch glycolate, stearic acid, titanium dioxide

### **Questions or comments?**

Call toll free 1-844-832-1138 Monday through Fri day 9am-5pm EST

# PRINCIPAL DISPLAY PANEL

## See New Warnings Information & Directions

### Compare to the Active Ingredients in


Tylenol PM®\*

**PAIN RELIEVER PM**

★Pain Reliever★Nighttime Sleep Aid

**Acetaminophen, Diphenhydramine HCl**

NDC 71679-113-03



Compare to EXTRA STRENGTH Tylenol® PM active ingredients\*

Extra Strength


## Pain Reliever PM

Acetaminophen  
500 mg / Pain Reliever

Diphenhydramine HCl  
25 mg / Nighttime Sleep Aid

Aspirin Free • Non-Habit Forming  
For Adults

300 CAPLETS



**Drug Facts**

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

**Purpose**  
Pain Reliever, Fever Reducer, Nighttime Sleep Aid

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

**Warnings**  
This product contains acetaminophen. Severe liver damage may occur if you take more than 4000 mg of acetaminophen in 24 hours. Do not take other drugs containing acetaminophen. Do not drink alcohol while using this product. Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, hives, rash.

**Do not use** with any other drug containing acetaminophen (prescription or not prescribed). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. Do not use with any other product containing diphenhydramine, even one used on skin. In children under 12 years of age.

**ask a doctor before use if you have:** liver disease, asthma, a breathing problem such as emphysema or chronic bronchitis, trouble urinating due to an enlarged prostate gland, glaucoma

**ask your doctor or pharmacist before use if you are:** taking the blood thinning drug warfarin

**When using this product:** avoid alcoholic drinks; do not drive a motor vehicle or operate machinery, this product will cause drowsiness

**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.

**Keep out of reach of children.** Overuse or misuse of this product may cause liver damage, breathing problems, or other serious effects of 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.

**Directions**  
do not exceed recommended dose. 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 this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

**Other information** store at 25° (77°) excursions permitted between 15°-30°C (59°-86°F); read all product information before using. **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Inactive ingredients** colloidal silicon dioxide, croscarmellose sodium, 14Kc blue #1 aluminum lake, 14Kc blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polydioxane, pregelatinized starch, purified water, sodium metabisulfite, sodium starch glycolate, stearic acid, titanium dioxide


**Questions or comments?** Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM EST

**Mfg / Dist by:**  
Health Pharma  
Rahway, NJ 07065  
www.healthpharma.us

MADE IN THE USA

Lot No.:

Exp. Date:



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## PAIN RELIEVER PM

acetaminophen and diphenhydramine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71679-113
<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</b> (UNII: 8GTS82S83M) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
<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>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY35J)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>POVIDONE</b> (UNII: FZ989GH94E)
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)

**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>	APM
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-113-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2022	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/27/2022	

**Labeler - Health Pharma USA LLC (080804485)**

**Establishment**

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-113)