

**CAREALL NON-ASPIRIN PM EXTRA STRENGTH- acetaminophen,  
diphenhydramine hcl tablet  
New World Imports, Inc**

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## **Drug Facts**

### **Active Ingredients**

Acetaminophen 500mg

Diphenhydramine HCl 25mg

### **Purpose**

Pain reliever

Nighttime sleep aid

### **Keep Out of reach of Children**

**Keep out of reach of children.** In case of accidental overdose, contact a doctor or 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.

### **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 4000 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 product containing diphenhydramine, even one used on skin
- in children under 12 years of age
- if you have even 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
- do not drive a motor vehicle or operate machinery
- avoid alcoholic drinks

**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 last for more than 10 days.
- fever gets worse or last for more than 3 days
- redness or swelling are present
- new symptoms occur. These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use.

**Directions**

**Do not use more than directed. (see overdose warning)**

**Adults and children 12 years of age and older:**Take 2 caplets at bedtime. Do not take more than 2 caplets in 24 hours

**Children under 12 years:**do not use

**Inactive Ingredients**

Croscarmellose sodium, FD and C blue #1, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, starch, stearic acid, titanium dioxide, Copovidone K25-31, Lactose, and Magnesium Sterate

CAREALL

Compare to the active ingredients of **TYLENOL® PM Caplets**

# Non-Aspirin PM

Extra Strength

Acetaminophen/  
Diphenhydramine HCl

- ▶ Pain Reliever
- ▶ Nighttime Sleep Aid



50 CAPLETS

DO NOT USE IF IMPRINTED SEAL UNDER CAPLET IS BROKEN OR MISSING

### Drug Facts

**Active ingredients (in each caplet)** 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 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**  

- in children under 12 years of age
- 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

PEEL BACK HERE FOR MORE DRUG FACTS

Distributed by: NWI, Inc.  
160 Athens Way  
Nashville, TN 37228



\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® PM Caplets.

COATING FREE AREA FOR LOT/EXP

STOP PEEING

Questions or comments? 1-844-705-4394

**Inactive ingredients** colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

**Other information**  

- store between 20-25°C (68-77°F) in a dry place
- children under 12 years: do not use

**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

**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 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. These could be signs of a serious condition.

**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

**Ask a doctor before use if you have**  

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

**Ask a doctor or pharmacist before use if you are**  

- taking sedatives or tranquilizers

## CAREALL NON-ASPIRIN PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-069
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY35J)	

<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>COPOVIDONE K25-31</b> (UNII: D9C330MD8B)	
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	AAA;1031
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-069-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/30/2018	

### Labeler - New World Imports, Inc (075372276)