

**ACETAMINOPHEN DIPHENHYDRAMINE HCL- acetaminophen diphenhydramine hcl tablet Granules USA, 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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**EXTRA STRENGTH**

**Pain Relief PM**

**Acetaminophen, USP 500 mg/ Diphenhydramine HCl, USP 25 mg  
Pain Reliever/ Nighttime Sleep-Aid**

**Non-Habit Forming**

**Active ingredients**

(in each caplet)

Acetaminophen, USP 500mg

Diphenhydramine HCl. 25mg

**Purposes**

Pain reliever

Nighttime sleep-aid

**Uses**

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

**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**

- 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 have**

- 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 a 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 the reach of children.**

### **Overdose warning**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 take more than directed (see overdose warning)

adults and children 12 years and over

- take 2 caplets at bedtime do not use
- do not take more than 2 caplets of this product in 24 hours

children under 12 years

- do not use

### **Other information**

- store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.
- see end panel for expiration date and lot number

### Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate, povidone, pregelatinized starch, stearic acid, titanium dioxide

### Questions or comments?

item	: CVS APAP PR 50CT
code #	:
size	: 1+3/4 X 1+3/4 X 3+3/8
ref #	: PPI:00604B
material	: .016 SBS
view	: PRINT
date	: 06/21

**COATING FREE AREA**

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**Drug Facts (continued)**  
 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 or 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.  
 Stop use and ask a doctor if:  
 ■ sleepiness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness  
 ■ rash 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 the reach of children.  
 Overdose warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 take more than directed (see enclosed warning)

**Drug Facts (continued)**  
 adults and children 12 years and over take 2 caplets at bedtime and over do not take more than 2 caplets of this product in 24 hours  
 children under 12 years do not use  
**Other Information**  
 ■ store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.  
 ■ see end panel for expiration date and lot number  
**Active Ingredients**  
 acetaminophen, croscarmellose sodium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate, povidone, pregelatinized starch, stearic acid, titanium dioxide  
**Questions or comments?**  
 call 1-877-776-3183 Mon-Fri 9:00 AM to 4:30 PM EST  
 This product is not affiliated with the makers/owners of Extra Strength Tylenol® PM Caplets.  
 \*All trademarks are property of their respective owners.  
 This product is not affiliated with the makers/owners of Extra Strength Tylenol® PM Caplets.  
 Distributed by:  
 Granules Consumer Health  
 36 Waterview Blvd., 3rd Floor  
 Parsippany, NJ 07054  
 MADE IN INDIA

**EXTRA STRENGTH Pain Relief PM**  
 Acetaminophen, USP 500 mg/  
 Diphenhydramine HCl, USP 25 mg  
 Pain Relief or Sleep-Aid  
 Nighttime Sleep-Aid  
 Non-Habit Forming  
 20 Caplets\*  
 (Contains Diphenhydramine)  
 \*Compare to the active ingredients in Extra Strength Tylenol® PM Caplets

**EXTRA STRENGTH Pain Relief PM**  
 Acetaminophen, USP 500 mg/  
 Diphenhydramine HCl, USP 25 mg  
 Pain Relief or Sleep-Aid  
 Nighttime Sleep-Aid  
 Non-Habit Forming  
 20 Caplets\*  
 (Contains Diphenhydramine)  
 Lot:  
 Exp.:

**Drug Facts**  
**Active Ingredients**  
 For each caplet:  
 Acetaminophen, USP 500 mg.....Pain reliever  
 Diphenhydramine HCl, 25 mg.....Nighttime sleep-aid  
**Purposes**  
 ■ temporary relief of occasional headache 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  
 ■ 5 or more alcoholic drinks every day while using this product.  
 Always 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

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**COATING FREE AREA**

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<p><b>Drug Facts (continued)</b></p> <p>Ask a doctor or pharmacist before use if you are taking any other drugs (including OTC products) or supplements.</p> <p><b>When using this product:</b></p> <ul style="list-style-type: none"> <li>Do not take more than 2 capsules at one time.</li> <li>Do not take more than 2 capsules in 24 hours.</li> <li>Do not take more than 2 capsules in 12 hours.</li> <li>Do not use if you do not have any signs or symptoms.</li> </ul> <p><b>Warnings:</b></p> <ul style="list-style-type: none"> <li>Do not use if you are taking any other drugs (including OTC products) or supplements.</li> <li>Do not use if you are taking any other drugs (including OTC products) or supplements.</li> <li>Do not use if you are taking any other drugs (including OTC products) or supplements.</li> </ul> <p><b>Directions:</b></p> <p>Take 1 or 2 capsules every 6 hours as needed for pain or sleep. Do not take more than 2 capsules in 24 hours.</p> <p><b>Other information:</b></p> <p>Keep out of the reach of children. Do not use if you are taking any other drugs (including OTC products) or supplements.</p> <p><b>Contains 150 Caplets (Capsule-Shaped Tablets).</b></p>
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Dim modifications to side 2 incoming artwork:  
 1) Adjusted size of bounding box so text does not extend into it

IGS



DE 1

Product packaging for Extra Strength Pain Relief PM capsules. The box is red and white with a blue caplet illustration. Dimensions are 6.5 inches by 2.25 inches. The packaging includes the following text:

**GRANULES CONSUMER HEALTH**

**EXTRA STRENGTH Pain Relief PM**

Acetaminophen, USP 500 mg/  
 Diphenhydramine HCl, USP 25 mg  
 Pain Reliever/ Nighttime Sleep-Aid  
 Non-Habit Forming

actual size **150 Caplets†**  
 (†Capsule-Shaped Tablets)

**Important:** Read all product information before using.

**WARNING: Do NOT USE IF IMPRINTED SAFETY SEAL LINDER CAP IS BROKEN OR MISSING**

**Drug Facts**

**Active Ingredients:**  
 Acetaminophen, USP 500 mg.....Pain reliever  
 Diphenhydramine HCl, USP 25 mg.....Nighttime sleep-aid

**Uses:**  
 Temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

**Warnings:**  
 Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours. Do not take more than 2 capsules every 6 hours with this product. Always seek acetaminophen may cause severe side reactions. Symptoms may include:  
 • nausea  
 • loss of appetite  
 • loss of weight  
 • loss of interest in food  
 • loss of interest in activities  
 • loss of interest in sex  
 • loss of interest in work  
 • loss of interest in school  
 • loss of interest in sports  
 • loss of interest in hobbies  
 • loss of interest in social activities  
 • loss of interest in family activities  
 • loss of interest in friends  
 • loss of interest in pets  
 • loss of interest in travel  
 • loss of interest in shopping  
 • loss of interest in eating  
 • loss of interest in drinking  
 • loss of interest in smoking  
 • loss of interest in drinking alcohol  
 • loss of interest in using tobacco  
 • loss of interest in using recreational drugs  
 • loss of interest in using prescription drugs  
 • loss of interest in using over-the-counter drugs  
 • loss of interest in using supplements  
 • loss of interest in using herbal products  
 • loss of interest in using essential oils  
 • loss of interest in using aromatherapy  
 • loss of interest in using massage  
 • loss of interest in using acupuncture  
 • loss of interest in using chiropractic  
 • loss of interest in using yoga  
 • loss of interest in using meditation  
 • loss of interest in using mindfulness  
 • loss of interest in using breathers  
 • loss of interest in using essential oils  
 • loss of interest in using aromatherapy  
 • loss of interest in using massage  
 • loss of interest in using acupuncture  
 • loss of interest in using chiropractic  
 • loss of interest in using yoga  
 • loss of interest in using meditation  
 • loss of interest in using mindfulness  
 • loss of interest in using breathers

**Directions:**  
 Take 1 or 2 capsules every 6 hours as needed for pain or sleep. Do not take more than 2 capsules in 24 hours.

**Other information:**  
 Keep out of the reach of children. Do not use if you are taking any other drugs (including OTC products) or supplements.

**Contains 150 Caplets (Capsule-Shaped Tablets).**

6.5 in

2.25 in

Finished Lead Edge



# ACETAMINOPHEN DIPHENHYDRAMINE HCL

acetaminophen diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-014
Route of Administration	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. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL (CAPLET SHAPED TABLET)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	G;651
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-014-02	20 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
2	NDC:69848-014-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
3	NDC:69848-014-15	150 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/01/2019	

**Labeler** - Granules USA, Inc. (137098864)

Revised: 12/2020

Granules USA, Inc.