

**EXTRA STRENGTH NIGHT TIME PAIN MEDICINE- acetaminophen,  
diphenhydramine hcl tablet  
Geri-Care Pharmaceutical Corp**

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**GC 224**

**Active Ingredients**

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

**Purposes**

Pain Reliever

Sleep aid

**Uses**

for the temporary relief of occasional headaches and minor aches and pains along 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** • 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 • glaucoma • difficulty urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are taking** • the blood thinning drug warfarin

- sedatives or tranquilizers

**When using this product** • drowsiness will occur • do not drive a motor vehicle or operate machinery after use • avoid alcoholic drinks

**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 for more than 10 days • fever gets worse or lasts more than 3 days • new symptoms occur • redness or swelling is present. These may 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 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.

### **Other information**

• store at controlled room temperature 20-25 °C (68-77° F)

### **Inactive ingredients**

croscarmellose sodium, FD&C blue #1 lake, hypromellose, microcrystalline cellulose, PEG, povidone, silica, starch, stearic acid, titanium dioxide

### **Questions or comments?**

**1-800-540-3765**

**package Label**

**EXTRA STRENGTH  
 NIGHT TIME  
 PAIN MEDICINE**  
 Acetaminophen 500 mg  
 Diphenhydramine HCl 25 mg  
**PAIN RELIEVER & SLEEP AID**

Compare to the active ingredients in **TYLENOL® PM\***  
**100 Caplets**

**TAMPER EVIDENT:** Do not use if imprinted seal under cap is missing or broken.

**Drug Facts**

**Active ingredients (in each caplet) Purposes**  
 Acetaminophen 500 mg.....Pain Reliever  
 Diphenhydramine HCl 25 mg.....Sleep-aid

**Uses** • for the temporary relief of occasional headaches and minor aches and pains along 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** • 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 →

\* This product is not manufactured or distributed by the owner of the registered trademark **TYLENOL® PM**.

Dist. By: Geri-Care Pharmaceuticals Corp.  
 1295 Towbin Ave, Lakewood, NJ 08701  
 REV 0524A1

3 57896 22401 1  
**PEEL HERE FOR MORE DRUG FACTS**

**Drug Facts (continued)**

**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 • 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 for more than 10 days • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur  
 These may 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 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

**Other information** • store at controlled room temperature 20-25 °C (68-77° F)

**Inactive ingredients:** croscarmellose sodium, FD&C blue #1 lake, hypromellose, microcrystalline cellulose, PEG, povidone, silica, starch, stearic acid, titanium dioxide.

**Questions or comments?** 1-800-540-3765

**STOP PEELING**

**EXTRA STRENGTH NIGHT TIME PAIN MEDICINE**

acetaminophen, diphenhydramine hcl tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57896-224
<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>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	

<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (caplet)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	AZ267
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-224-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2024	
2	NDC:57896-224-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/01/2024	

**Labeler** - Geri-Care Pharmaceutical Corp (611196254)

**Registrant** - Geri-Care Pharmaceutical Corp (611196254)