

**EXTRA STRENGTH NIGHT TIME PAIN MEDICINE- acetaminophen, diphenhydramine hcl tablet**

**Geri-Care Pharmaceutical Corp**

*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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**Active Ingredients**

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

**Purposes**

Pain Reliever

Sleep aid

**Uses**

for the temporary relief of occasional headaches and minor ache and pains along with accompanying sleeplessness

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

• more than directed • 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 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 • 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:** 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. Prompt medical attention is critical for adults / children even if you do not notice any signs / symptoms.

**Directions**

- do not exceed recommended dose

Adults and Children 12 years and over	Take 2 caplets at bedtime if needed, or as directed by a doctor.
Children under 12 years	Do not use.

**Other information**

- Tamper Evident: do not use if imprinted safety seal under cap is broken or missing.
- store at room temperature

**Inactive ingredients**

cellulose, croscarmellose sodium, FD and C blue no.1, hypromellose, PEG, stearic acid, titanium dioxide. May also contain silica, sodium starch glycolate.

**package Label**

57896-224-05

Health star the sensible choice for price and health

Extra Strength

pain relief and sleep aid

night time pain medicine

acetaminophen 500 mg

Diphenhydramine HCl 25mg

100 caplets

compare to the active ingredients in tylenol pm

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

Acetaminophen 500 mg	Pain Reliever
Diphenhydramine HCl 25 mg	Sleep-aid

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NDC 57896-224-01

THE SENSIBLE CHOICE FOR PRICE AND HEALTH

**EXTRA STRENGTH****NIGHT TIME****Pain Medicine****ACETAMINOPHEN 500 mg  
Diphenhydramine HCl 25 mg**COMPARE TO THE ACTIVE INGREDIENTS IN **TYLENOL® PM\***

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**Inactive ingredients:** cellulose, croscarmellose sodium, FD&C blue #1, hypromellose, PEG, stearic acid, titanium dioxide. May also contain silica, sodium starch glycolate.

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

Dist. By: **Geri-Care Pharmaceuticals Corp.**,  
1650 63<sup>rd</sup> Street,  
Brooklyn, NY 11204

REV 0612

**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
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

**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>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:57896-224-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2012	
2	NDC:57896-224-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2012	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part341	01/01/1996		

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

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Allegiant Health		079501930	manufacture(57896-224)

Revised: 12/2018

Geri-Care Pharmaceutical Corp