

**EXTRA STRENGTH NIGHT TIME PAIN RELIEF- acetaminophen, diphenhydramine
hcl tablet, coated
AMERISOURCE BERGEN**

GNP 224B (324)

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 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

cellulose, croscarmellose sodium, FD&C blue #1 lake, FD&C blue #2 lake, hypromellose, magnesium stearate, PEG, polyvinyl alcohol, povidone, purified water, silicon dioxide, sodium starch glycolate, starch, talc, titanium dioxide

Questions or comments?

1-800-540-3765

package Label

Drug Facts (continued)

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 of age	Do not use

Other information • store at controlled room temperature 20-25 °C (68-77° F)
• **Tamper Evident:** do not use if imprinted safety seal under cap is broken or missing.

Inactive ingredients cellulose, croscarmellose sodium, FD&C blue #1 lake, FD&C blue #2 lake, hypromellose, magnesium stearate, PEG, polyvinyl alcohol, povidone, purified water, silicon dioxide, sodium starch glycolate, starch, talc, titanium dioxide

Questions or comments? 1-800-540-3765



Compare to Tylenol® PM active ingredients*

NDC 46122-707-71

Extra Strength Night time
Pain Relief

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg



Distributed By
AmerisourceBergen
1 West First Avenue
Conshohocken, PA 19428
Questions or Concerns?
www.mygnp.com
Product of India

Extra Strength Night time

Pain Relief

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

PAIN RELIEVER & SLEEP AID

50 Caplets



Drug Facts

SAVE CARTON FOR COMPLETE DRUG FACTS

Active ingredients (in each caplet)

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

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Warnings

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- 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.

Drug Facts (continued)

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

Ask a doctor or pharmacist before use if you are taking • the blood thinning drug warfarin
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If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

REV 224-0622B

ABC# 10265695

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



EXTRA STRENGTH NIGHT TIME PAIN RELIEF

acetaminophen, diphenhydramine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-707
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
TALC (UNII: 7SEV7J4R1U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE (UNII: FZ989GH94E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	P525
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-707-78	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2022	
2	NDC:46122-707-71	1 in 1 CARTON	09/16/2022	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:46122-707-62	1 in 1 CARTON	10/05/2022	
3		24 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug	M013	06/01/2022	
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Labeler - AMERISOURCE BERGEN (007914906)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023

AMERISOURCE BERGEN