

EXTRA STRENGTH PM PAIN MEDICINE- acetaminophen, diphenhydramine hcl tablet

Amerisource Bergen

GNP 224AL

Active Ingredients

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purposes

Pain Reliever

Nighttime 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 of age	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

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: 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



Compare to Tylenol® PM active ingredients*

NDC 46122-799-69

Extra Strength Night time
PM Pain Relief
Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

Distributed By
AmerisourceBergen
1 West First Avenue
Conshohocken, PA 19128
Questions or Concerns?
www.mygnp.com

Extra Strength Night time
PM 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)	Purposes
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	Nighttime 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.

REV 08/24 224H

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 • sedatives or tranquilizers

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Keep out of reach of children.

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



EXTRA STRENGTH PM PAIN MEDICINE			
acetaminophen, diphenhydramine hcl tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-799
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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
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)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE (caplet)	Size	16mm
Flavor		Imprint Code	AZ267
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-799-70	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2024	
2	NDC:46122-799-69	1 in 1 CARTON	10/01/2024	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/01/2024	

Labeler - Amerisource Bergen (007914906)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

