PAIN RELIEF PM- acetaminophen, diphenhydramine tablet
NUVICARE LLC

Pain Relief PM

Active Ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine 25 mg

Purpose

Acetaminophen 500 mg .....Pain reliever
Diphenhydramine HCl 25 mg ....Nighttime sleep aid

Uses:

- temporary relief of occasional headaches 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 hrs ■ 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

■ 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
- 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 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 REACH OF CHILDREN

Overdose warning: In case of overdose, get medical help or contact Poison Control (1-800-222-1222) right away.
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 in 24 hours unless directed by a doctor

■ children under 12 years do not use

Other Information:

- store at 20°-25°C (68°-77°F)

Inactive Ingredients:

FD & C Blue # 1, FD & C Blue # 2, Hypromellose, Microcrystalline Cellulose, Magnesium Stearate, Polyethylene glycol 400, Pregelatinized Starch, Polyvinyl Pyrrolidone, Stearic Acid Powder, Titanium Dioxide.

Questions or Comments?

Call **1-718-337-8733** or visit support@nuvicare.com

PAIN RELIEF PM

acetaminophen, diphenhydramine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:84324-005
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. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
Magnesium Stearate (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	27mm
Flavor		**Imprint Code**	None
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84324-005-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/30/2024	

Labeler - NUVICARE LLC (119257565)

Registrant - NUVICARE LLC (119257565)

Revised: 9/2024 NUVICARE LLC