CAREONE ACETAMINOPHEN PM- acetaminophen, diphenhydramine hcl tablet, film coated
American Sales Company

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.

CareOne Acetaminophen PM Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

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 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
- 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 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 20-25˚C (68-77˚F)

Inactive ingredients

carnauba wax, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

CAREone®

Compare to the active ingredients in Tylenol® PM

Extra Strength

ACETAMINOPHEN PM

Acetaminophen, 500 mg

Diphenhydramine HCl, 25 mg

Pain Reliever/Nighttime Sleep-Aid

Actual Size

For Adults

Non-habit forming

Gluten Free

OUR PHARMACISTS RECOMMEND

100 CAPLETS

CAREONE ACETAMINOPHEN PM

acetaminophen, diphenhydramine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-514
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (Light blue)	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	L437;PM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-514-78	1 in 1 CARTON	09/02/2016	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41520-514-71	1 in 1 CARTON	09/02/2016	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41520-514-47	1 in 1 CARTON	04/12/2019	04/12/2019
3		150 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph not final	part343	09/02/2016	

Labeler - American Sales Company (809183973)

Revised: 6/2023 American Sales Company