

**CAREALL PAIN RELIEF PM EXTRA STRENGTH- acetaminophen,
diphenhydramine hcl tablet
New World Imports, Inc**

Drug Facts

Active Ingredients

Acetaminophen 500mg

Diphenhydramine HCl 25mg

Purpose

Pain reliever

Nighttime sleep aid

Keep Out of reach of Children

Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) right away. Prompt Medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Uses

Temporarily relieves 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 4000 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 even 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
- trouble urinating due to an enlarged prostate gland
- glaucoma

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
- do not drive a motor vehicle or operate machinery
- avoid alcoholic drinks

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 last for more than 10 days.
- fever gets worse or last for more than 3 days
- redness or swelling are present
- new symptoms occur. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Directions

Do not take more than directed. (see overdose warning)

Adults and children 12 years of age and older: Take 2 caplets at bedtime. Do not take more than 2 caplets in 24 hours

Children under 12 years: do not use

Inactive Ingredients

croscarmellose sodium, FD and C blue #1 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide.

NDC 51824-107-50

CAREALL®

Extra Strength

Pain Relief PM

ACETAMINOPHEN 500mg
Diphenhydramine HCl 25mg

- ▶ Pain Relief
- ▶ Sleep Aid

Compare to the active ingredients in Tylenol®PM Caplets*



50 Caplets

DO NOT USE IF IMPRINTED SEAL UNDER SAFETY CAP IS BROKEN OR MISSING

Drug Facts

Active ingredients (in each caplet) **Purposes**
Acetaminophen 500mg.....Pain reliever
Diphenhydramine HCl 25mg.....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 4000 mg of acetaminophen in 24 hours with other drugs containing acetaminophen or 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 trouble urinating due to an enlarged prostate gland glaucoma

Drug Facts (continued on inside)

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Tylenol®PM. Distributed By: CareAll Products, 160 Athens Way, Nashville, TN 37228 www.carealproducts.com



Lot No. Exp. Date: **PREP HERE**

Questions or Comments?
Call 1-888-952-0050
Monday through Friday 9AM – 5PM EST

Inactive ingredients croscarmellose sodium, FD&C blue #1 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide
May contain: carnauba wax, FD&C blue #2 aluminum lake, polysorbate 80

Other information store between 20-25 °C (68-77° F)

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

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 (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.

Drug Facts (continued)

CAREALL PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-107
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	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE (Capsual Shaped)	Size	16mm
Flavor		Imprint Code	AZ267;G651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-107-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2024	

Marketing Information

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

Labeler - New World Imports, Inc (075372276)