ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride tablet, coated WinCo Foods, LLC

WNC - 1095 - 2024-0709

Drug Facts

Active ingredients (in each caplet)	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 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
- 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
- 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 between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions?

Call 800-824-1706 Monday - Friday 0am - 4pm MST

PRINCIPAL DISPLAY PANEL

WinCo® Foods

*Compare to the active ingredients in TYLENOL® PM

EXTRA STRENGTH

Acetaminophen PM

ACETAMINOPHEN/ PAIN RELIEVER

DIPHENHYDRAMINE HCI/ NIGHTTIME SLEEP AID

For Adults

50 Caplets



ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen and diphenhydramine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-137
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
COPOVIDONE K25-31 (UNII: D9C330MD8B)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
LACTOSE (UNII: J2B2A4N98G)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	AAA;1031	
Contains				

ı	Packaging					
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:67091- 137-50	1 in 1 CARTON	12/15/2014			
1	L	50 in 1 BOTTLE, PLASTIC; 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	12/15/2014	

Labeler - WinCo Foods, LLC (056098817)

Revised: 7/2024 WinCo Foods, LLC