EXTRA STRENGTH PAIN RELIEVER PM- acetaminophen and diphenhydramine hydrochloride tablet WALGREENS CO.

EXTRA STRENGTH PAIN RELIEVER PM

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 500mg	Pain reliever
Diphenhydramine HCl 25mg	Nighttime Sleep aid

Uses

for the 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 with this product 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 you are 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 other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- in children under 12 years of age
- with any other products containing diphenhydramine, even one used on skin
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have

liver disease

- breathing problems such as emphysema or chronic bronchitis
- trouble urinating due to an enlargement of the 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 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 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

Taking more than the directed dose (overdose) may cause liver damage. 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 of age and over:	 take 2 caplets at bedtime or as directed by a doctor do not take more than 2 caplets in a 24 hour period
children under 12 years of age:	 do not use this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose)

Other information

- each caplet contains: magnesium 0.05 mg
- store between 20°-25°C (68°-77°F)
- see end panel for lot number and expiration

Inactive ingredients

FD&C blue # 1, FD&C blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol-400, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-888-287-1915

Distributed by:

Walgreen Co.
200 Wilmot Rd., Deerfield, IL 60015

PRINCIPAL DISPLAY PANEL

EXTRA STRENGTH
PAIN RELIEVER PM
Acetaminophen 500 mg
Diphenhydramine HCl 25 mg





EXTRA STRENGTH PAIN RELIEVER PM

acetaminophen and diphenhydramine hydrochloride tablet

Product Information					
HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9085			
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		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
STARCH, CORN (UNII: O8232NY3SJ)			
POVIDONE K30 (UNII: U725QWY32X)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	18mm	
Flavor		Imprint Code	S525	
Contains				

F	Packaging					
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0363-9085- 15	1 in 1 CARTON	04/13/2023			
1		15 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	04/13/2023	

Labeler - WALGREENS CO. (008965063)

Revised: 12/2023 WALGREENS CO.