PAIN RELIEVER PM- acetaminophen, diphenhydramine hcl tablet, coated Family Dollar (FAMILY WELLNESS)

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 products 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 a serious underlying medical illness.
- pain gets worse or last more than 10 days
- fever gets worse or last 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.

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)
- avoid high humidity and excessive heat

Inactive ingredients

croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatanized starch, purified water, silicon dioxide,

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENTS IN EXTRA STRENGTH TYLENOL® PM†

EXTRA STRENGTH

PAIN RELIEVER PM

Acetaminophen 500 mg Pain Reliever

Diphenhydramine HCL 25 mg Nighttime Sleep Aid

Non-Habit Forming

For ages 12 years and over

CAPLETS

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY
MIDWOOD BRANDS LLC
500 VOLVO PKWY,
CHESAPEAKE, VA 23320

Package Label



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McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

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FAMILY WELLNESS Extra Strength Pain Reliever PM

PAIN RELIEVER PM

acetaminophen, diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-562
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: 08232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics			
Color	blue	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	P525
Contains			

ackaging			
Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:55319- 562-10	1 in 1 BOX	07/01/2023	
	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
NDC:55319- 562-50	1 in 1 BOX	07/01/2023	
	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
NDC:55319- 562-24	1 in 1 BOX	07/01/2023	
	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
	NDC:55319- 562-10 NDC:55319- 562-50 NDC:55319-	NDC:55319- 562-10 1 in 1 BOX 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product NDC:55319- 562-50 1 in 1 BOX 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product NDC:55319- 562-24 1 in 1 BOX 24 in 1 BOTTLE, PLASTIC; Type 0: Not a	Item CodePackage DescriptionMarketing Start DateNDC:55319-562-101 in 1 BOX07/01/2023100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product07/01/2023NDC:55319-562-501 in 1 BOX07/01/2023NDC:55319-562-241 in 1 BOX07/01/20231 in 1 BOX07/01/2023

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	07/01/2023		

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 3/2024 Family Dollar (FAMILY WELLNESS)