PAIN RELIEVER PM- acetaminophen, diphenhydramine hydrochloride tablet Magno-Humphries, Inc.

Pain Reliever PM

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

This product contains acetaminophen. Severe liver damage may occur if you take **Liver** warning:

acetaminophen may cause severe skin reactions. Symptoms may include: **Allergy alert:**

If a skin reaction occurs, stop use and seek medical help right away.

- 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
- skin reddening
- blisters
- rash

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.

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. **Overdose warning:**

Directions

- do not take more than directed (see overdose warning)
- take 2 caplets at bedtime; do not take more than 2 caplets of this product in 24 hours **adults and children 12 years and over:**
- do not use children under 12 years:

Other information

store between 20° to 25°C (68° to 77° F)

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate, povidone, pregelatinized starch, stearic acid, titanium dioxide.

Questions?

call toll-free 1-800-935-6737

Package Labeling:





DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

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

Drug Facts (continued)

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 (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)

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate, povidone, pregelatinized starch, stearic acid, titanium dioxide.

Questions? call toll-free 1-800-935-6737

*This product is not manufactured or distributed by the owner of the registered trademark Extra Strength Tylenol® PM

Visit our website: www.magno-humphries.com Distributed by: Magno-Humphries Labs Tigard, OR 97223 U.S.A. (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

PEEL FOR DIRECTIONS

G7802-100-01-1

PAIN RELIEVER PM

acetaminophen, diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54257-278
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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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics					
Color	blue	Score	no score		
Shape	CAPSULE	Size	18mm		
Flavor		Imprint Code	G651		
Contains					

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:54257-278- 02	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/24/2020		
Marketing Information					
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

01/24/2020

Labeler - Magno-Humphries, Inc. (063251433)

OTC Monograph Drug M013

Revised: 10/2023 Magno-Humphries, Inc.