TYLENOL PM- acetaminophen, diphenhydramine hydrochloride tablet, film coated
Savings Distributors LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Tylenol PM

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 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 ■ take 2 caplets at bedtime

12 years and over ■ 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)
■ do not use if pouch is torn or damaged

Inactive ingredients

carnauba wax, crospovidone, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Package Labeling

TYLENOL PM

acetaminophen, diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73097-013(NDC:50580-608)
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 - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (Light Blue)	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	TY;PM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73097-013-02	1 in 1 CARTON	07/22/2019	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:73097-013-40	20 in 1 CARTON	07/22/2019	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:73097-013-50	25 in 1 CARTON	07/22/2019	
3		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/22/2019	

Labeler - Savings Distributors LLC (010527359)

Establishment

Name	Address	ID/FEI	Business Operations
Savings Distributors LLC		010527359	repack(73097-013)

Revised: 7/2019 Savings Distributors LLC