

**TYLENOL PM- acetaminophen, guaifenesin, phenylephrine  
hydrochloride tablet, film coated  
JC World Bell Wholesale Co., Inc.**

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**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 reactions 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)**

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adults and children 12 years and over	<ul style="list-style-type: none"><li>• take 2 caplets at bedtime</li><li>• do not take more than 2 caplets of this product in 24 hours</li></ul>
children under 12 years	do not use

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**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:





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. Do not use 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); 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). Distributed by: JOHNSON & JOHNSON CONSUMER INC. McNeil Consumer Healthcare Division Fort Washington, PA 19054 USA Pat. www.kenvuepats.com © J&JCI 2024 [30058261]

## TYLENOL PM

acetaminophen, guaifenesin, phenylephrine hydrochloride tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50269-552(NDC:50580-608)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	TY;PM
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-552-01	20 in 1 BOX	07/11/2016	
1		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 Drug	M013	07/11/2016	

**Labeler** - JC World Bell Wholesale Co., Inc. (805257581)

**Registrant** - JC World Bell Wholesale Co., Inc. (805257581)

### Establishment

Name	Address	ID/FEI	Business Operations
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-552)

Revised: 1/2026

JC World Bell Wholesale Co., Inc.