

**TYLENOL PM EXTRA STRENGTH- acetaminophen, diphenhydramine hydrochloride tablet, film coated**  
**Jones Healthcare Group - Packaging Services, Inc**

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**Tylenol PM Extra Stength**

***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 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.**

### **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	<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

**Other information**

- store between 20-25°C (68-77°F)
- **do not use if carton is opened, or neck wrap or foil inner seal imprinted with "TYLENOL" is broken or missing**

**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 (toll-free) or (collect) **1-877-895-3665215-273-8755**

**Tylenol 50 Pouches Tray**

or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ 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. Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin. Stop use and ask a doctor if ■ pain gets worse or lasts 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: 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 every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor Children under 12 years: ask a doctor

**Other information** ■ store between 20-25C (68-77F) ■ do not use if pouch is torn or damaged. **Inactive ingredients** carnauba wax\*, corn starch\*, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, modified starch\*, polyethylene glycol\*, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide \*contains one or more of these ingredients

**Questions or comments?** call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)  
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To Open: While Folded on Line, Tear At Slit

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

**TYLENOL®**  
FOR ADULTS

Acetaminophen Pain Reliever-Fever Reducer  
**Extra Strength** 2 Caplets  
500 mg each

Active ingredient (in each caplet) ..... Pain reliever/fever reducer  
Acetaminophen 500 mg

**Uses** ■ temporarily relieves minor aches and pains due to:  
■ the common cold ■ headache ■ backache ■ minor pain of arthritis  
■ toothache ■ muscular aches ■ premenstrual and menstrual cramps  
■ temporarily reduces fever

**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  
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Do not use ■ with any other drug containing acetaminophen (prescription)

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## TYLENOL PM EXTRA STRENGTH

acetaminophen, diphenhydramine hydrochloride tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67414-608
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 (15 MPA.S AT 5%)</b> (UNII: 68401960MK)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<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, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue (Light 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:67414-608-06	50 in 1 TRAY	01/25/2018	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67414-608-00	2500 in 1 BOX	01/25/2018	
2		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	01/25/2018	

**Labeler** - Jones Healthcare Group - Packaging Services, Inc (243261024)

**Registrant** - Jones Healthcare Group - Packaging Services, Inc (243261024)

### Establishment

Name	Address	ID/FEI	Business Operations
McNeil Healthcare LLC.		831188763	manufacture(67414-608)

Revised: 11/2023

Jones Healthcare Group - Packaging Services, Inc