TYLENOL PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride solution
Johnson & Johnson Consumer Inc.

TYLENOL PM

Extra Strength

Drug Facts

Active ingredient (in each 30 mL)	***Purpose***
Acetaminophen 1,000 mg	Pain reliever
Diphenhydramine HCl 50 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 (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 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)**
- mL = milliliter
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

adults and children 12 years and over	• take 30 mL in the dosing cup provided at bedtime • do not take more than 30 mL of this product in 24 hours
children under 12 years	do not use

Other information

- each 30 mL contains: **sodium 15 mg**
- store between 20-25°C (68-77°F)
- **do not use if neck band imprinted with "TYLENOL PM" or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing**

Inactive ingredients

anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, sucrose

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-833-01

Extra Strength
TYLENOL ®
PM

NEW

Acetaminophen Diphenhydramine HCl
Pain Reliever, Nighttime Sleep Aid
Non-habit forming

8 fl oz (240 mL)

Bedtime Berry

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TYLENOL® PM

How can we help?
1-877-895-3665

SNAP THIS CODE OR TEXT TYLENOL TO 30241

MSG & DATA RATES MAY APPLY
TEXT HELP FOR HELP.
TEXT STOP FOR STOP.

Acetaminophen (1,000 mg per 30 mL)
Diphenhydramine HCl (50 mg per 30 mL)

8 fl oz (240 mL)

www.tylenol.com

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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30039815

Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

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OPEN TO READ DRUG FACTS (Warnings, Directions...) → PEEL

Do not use if neck band imprinted

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TYLENOL PM EXTRA STRENGTH

acetaminophen and diphenhydramine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-833
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg in 30 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	blue (Dark Blue)	**Score**	
Shape		**Size**	

Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-833-01	240 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	06/25/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/25/2018	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.