

TYLENOL PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride tablet, film coated
Navajo Manufacturing Company Inc.

Tylenol PM Extra Strength

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
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 (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	▪ 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 carton is opened.**

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)

PRINCIPAL DISPLAY PANEL



TYLENOL PM EXTRA STRENGTH

acetaminophen and diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-241(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
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CROSPVIDONE (UNII: 2S7830E561)		
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDWL1A)		

POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)				
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:67751-241-01	1 in 1 CARTON	03/11/2025	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-241-02	2 in 1 CARTON	09/23/2025	
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		03/11/2025	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment			
Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	repack(67751-241) , relabel(67751-241)

Revised: 11/2025

Navajo Manufacturing Company Inc.