PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen diphenhydramine hci tablet, coated
P & L Development, 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.

DRUG FACTS

Active ingredient (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep-aid

Uses

temporarily 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 and 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 a serious underlying medical illness
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lats more than 3 days.

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 (1-800-222-1222) right away. 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 of age and over
  - take 2 caplets at bedtime
  - do not take more than 2 caplets of this product in 24 hours
- children under 12 years of age: do not use

Other information
- store between 15-30ºC (59-86ºF)
- avoid high humidity and excessive heat

Inactive ingredients

carnauba wax*, croscarmellose sodium*, FD&C blue #1 aluminum lake,FD&C blue #2 aluminum lake, hypromellose, magnesium stearate*, microcrystalline cellulose, polyethylene glycol, polysorbate 80*, polyvinyl alcohol*, povidone K 3, pregelatinized starch, purified water, sillcon dioxide*, sodium starch glycolate*,stearic acid*, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

extra strength

Pain Reliever pm

acetaminophen 500 mg Pain Reliever

diphenhydramine HCI 25 mg nighttime sleep-aid

caplets

†Compare to active ingredients in Extra Strength Tylenol® PM

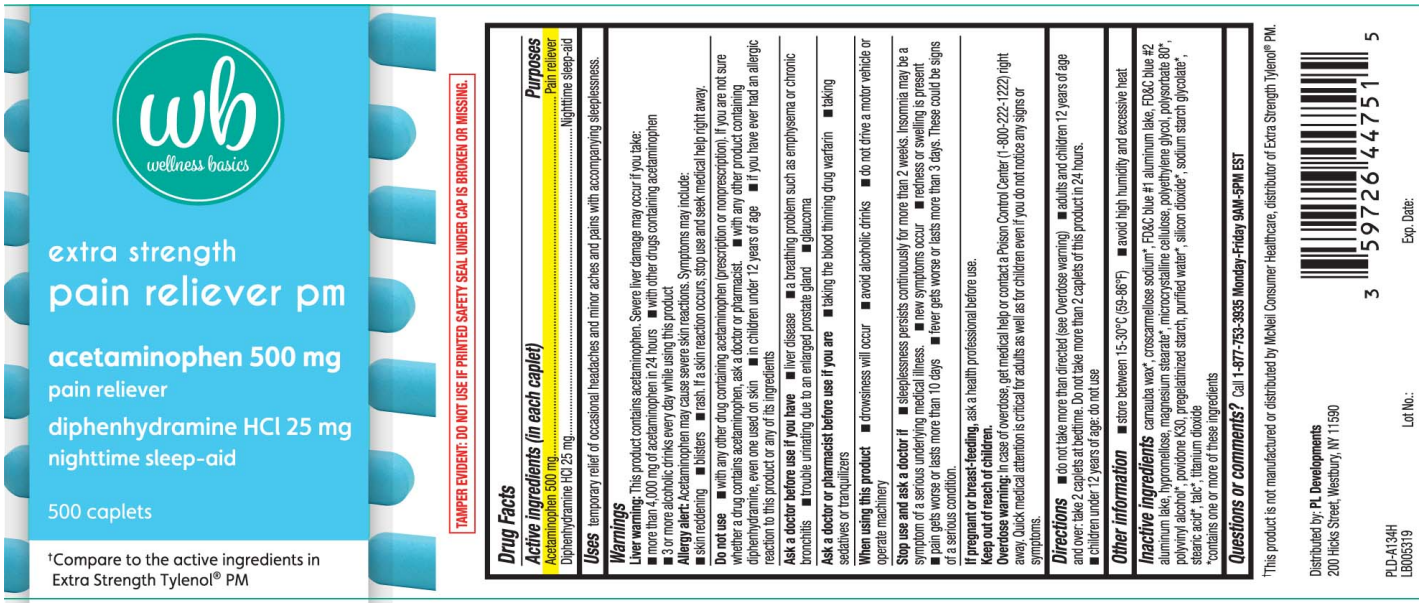
†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Product Label



WELLNESS BASICS Extra Strength Pain Reliever PM

PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen diphenhydramine hci tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59726-032
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	S525;P525;G651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-032-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2017	12/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/31/2017	12/31/2025

Labeler - P & L Development, LLC (800014821)

Revised: 3/2023 P & L Development, LLC