

**PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen diphenhydramine
hcl tablet, coated
P & L Development, LLC**

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
- 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 (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 20-25°C (68-77°F)
- avoid high humidity and excessive heat

Inactive ingredients

croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol,

polyvinyl alcohol, povidone K 30, pregelatinized starch, purified water, silicon dioxide, sodium starch glycolate, talc, titanium dioxide

Questions or comments?

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

Principal Display Panel

Compare to the active ingredients in Extra Strength Tylenol® PM†

extra strength

pain reliever PM

Acetaminophen 500 mg

diphenhydramine HCl 25 mg

pain reliever/nighttime sleep-aid

non habit-forming

for ages 12 years and over

caplets

†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.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

PL Developments

200 Hicks Street, Westbury, NY 11590

Product Label



non habit-forming
for ages 12 years and over

100 caplets

Compare to the active ingredients in
Extra Strength Tylenol® PM†
NDC 59726-868-10

extra strength
pain reliever pm
Acetaminophen 500 mg
diphenhydramine HCl 25 mg
pain reliever/nighttime sleep-aid

actual size

Drug Facts

Active ingredients (in each caplet)

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

Drug Facts (continued)

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 a 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.
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Directions
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Other information
■ store between 20-25°C (68-77°F)
■ avoid high humidity and excessive heat

Drug Facts (continued)

Inactive ingredients croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromelloses, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatinized starch, purified water, silicon dioxide, sodium starch glycolate, talc, titanium dioxide

Questions or comments? Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

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.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590



PLD-8596A
FC007670

Lot No.:
Exp. Date:

READYinCASE Extra Strength Pain Reliever PM

PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen diphenhydramine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-868
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
CROSCARMELOSE 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: 3WJQ0SDW1A)	
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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	P525
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:59726-868-10	1 in 1 BOX	03/26/2021	12/26/2026
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59726-868-50	1 in 1 BOX	03/26/2021	12/26/2026
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59726-868-24	1 in 1 BOX	03/26/2021	12/26/2026
3		24 in 1 BOTTLE, PLASTIC; 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	03/26/2021	12/26/2026

Labeler - P & L Development, LLC (800014821)

Revised: 12/2025

P & L Development, LLC