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 lats 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 20-25ºC (68-77ºF)
- 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, sillcon 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

ready incase®

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

non habit-forming
for ages 12 years and over

100 caplets

actual size

Drug Facts

Active ingredients (in each caplet) — **Purposes**

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.

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Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
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- with other drugs containing acetaminophen
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- skin reddening
- blisters
- rash

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Do not use
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- with any other product containing diphenhydramine, even one used on skin
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- 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
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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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

TRUST QUALITY EXCELLENCE

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FC007670

Lot No.:
Exp. Date:

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
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)	
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

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

Labeler - P & L Development, LLC (800014821)

Revised: 8/2024

P & L Development, LLC