

**PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen, diphenhydramine
hcl tablet, coated
TOP CARE (Topco Associates LLC)**

Drug Facts

Active ingredients (in each geltaab)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purposes

Pain reliever

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.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts 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 and over: take 2 gels at bedtime. Do not take more than 2 gels of this product in 24 hours.
- children under 12 years: do not use

Other information

- store between 20-25°C (68-86°F)
- avoid high humidity and excessive heat

Inactive ingredients

corn starch, croscarmellose sodium, D&C red #27 aluminum lake, edible black ink, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, maltodextrin, microcrystalline

cellulose, polyethylene glycol, povidone, purified water, silicon dioxide, stearic acid, titanium dioxide

Questions or comments?

Call toll free **1-888-423-0139**

Principal Display Panel

COMPARE TO EXTRA STRENGTH TYLENOL® PM ACTIVE INGREDIENTS**

EXTRA STRENGTH NIGHTTIME

Pain Relief PM

ACETAMINOPHEN, DIPHENHYDRAMINE HCl, 500/25mg

PAIN RELIEVER / NIGHTTIME SLEEP-AID

Non-Habit Forming

GELTABS For Ages 12 Years and Over

**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 TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

www.topcarebrand.com

Product Label

Exp. Date:
Lot No.:
FC007633
PLD-130U



NDC 36800-466-50



COMPARE TO EXTRA STRENGTH
TYLENOL® PM ACTIVE INGREDIENTS*

EXTRA STRENGTH NIGHTTIME

Pain Relief PM

ACETAMINOPHEN, DIPHENHYDRAMINE HCl, 500/25mg

PAIN RELIEVER / NIGHTTIME SLEEP-AID

Non-Habit Forming

50 GELTABS

For Ages 12 Years and Over

actual size



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Do not use

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 ■ in children under 12 years of age
 ■ if you have ever had an allergic reaction to this product or any of its ingredients

KEEP OUTER CARTON FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION.

Drug Facts (continued)

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corn starch, croscarmellose sodium, D&C red #27 aluminum lake, edible black ink, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, purified water, silicon dioxide, stearic acid, titanium dioxide

Questions or comments?

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

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 QUESTIONS? 1-888-423-0139 topcare@topco.com
 www.topcarebrand.com

✓ QUALITY GUARANTEED



Scan here for more
information or
call 1-888-423-0139

TOPCARE HEALTH Extra Strength Pain Relief PM

PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-466
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	white, blue	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	BP50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:36800-466-10	1 in 1 BOX	11/05/2021	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:36800-466-50	1 in 1 BOX	11/05/2021	
2		50 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	11/05/2021	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 6/2024

TOP CARE (Topco Associates LLC)