

PAIN RELIEF PM- acetaminophen, diphenhydramine hcl tablet, coated
Topco Associates, LLC

TopCare 44-556

Active ingredients (in each gelcap)

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

Purpose

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

Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis

- difficulty in urination due to enlargement of the prostate gland

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 beverages
- 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
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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**
- adults and children 12 years and over
 - take 2 gelcaps at bedtime
 - do not take more than 2 gelcaps of this product in 24 hours
- children under 12 years: do not use

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

Inactive ingredients

ammonium hydroxide, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, FD&C red #3, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, simethicone, stearic acid, titanium dioxide

Questions or comments?

1-888-423-0139

Principal display panel

+TopCare®
health

NDC 36800-556-09

***COMPARE TO
THE ACTIVE INGREDIENTS IN
EXTRA STRENGTH TYLENOL® PM**

EXTRA STRENGTH NIGHTTIME
Pain Relief PM

ACETAMINOPHEN 500 mg / **DIPHENHYDRAMINE HCl** 25 mg
PAIN RELIEVER • NIGHTTIME SLEEP AID

Non-Habit Forming

20 GELCAPS

actual size

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY
SEAL UNDER CAP IS BROKEN OR MISSING**

*This product is not manufactured or distributed by
Kenvue Inc., owner of the registered trademark Extra
Strength Tylenol® PM.

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SEAL UNDER CAP IS BROKEN OR MISSING

TopCare
health

EXTRA STRENGTH NIGHTTIME

Pain Relief PM

ACETAMINOPHEN 500 mg/DIPHENHYDRAMINE HCl 25 mg
PAIN RELIEVER • NIGHTTIME SLEEP AID

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actual size

NDC 36800-556-09

*COMPARE TO
THE ACTIVE INGREDIENTS IN
EXTRA STRENGTH TYLENOL® PM

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Questions or comments? 1-888-423-0139

Drug Facts (continued)

B-1910-556-09-R
REV0324C55609

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Drug Facts (continued)

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TopCare 44-556

PAIN RELIEF PM

acetaminophen, diphenhydramine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-556
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
AMMONIA (UNII: 5138Q19F1X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (dark) , blue (light)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	L;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-556-09	1 in 1 CARTON	01/03/2020	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:36800-556-10	1 in 1 CARTON	01/03/2020	
2		40 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	01/03/2020	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(36800-556) , pack(36800-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(36800-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(36800-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-556)

Revised: 3/2025

Topco Associates, LLC