

**ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen, diphenhydramine
hcl tablet, coated
CVS PHARMACY**

CVS 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

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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
- a breathing problem such as emphysema or chronic bronchitis

- difficulty in urination due to enlargement of the 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 beverages
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- any new symptoms appear
- redness or swelling is present
- fever gets worse or lasts more than 3 days

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

- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

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?

1-800-426-9391

Principal display panel

CVS™

actual size

Extra Strength

ACETAMINOPHEN PM

Acetaminophen, 500 mg

Diphenhydramine HCl, 25 mg

Pain Reliever, Nighttime Sleep-Aid

Compare to Tylenol® PM

Extra Strength active ingredients*

80 GELCAPS

**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 Tylenol® PM Extra Strength.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS.com®

1-800-SHOP CVS

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ORG032455631



actual size

Extra Strength

ACETAMINOPHEN PM

Acetaminophen, 500 mg
Diphenhydramine HCl, 25 mg
Pain Reliever, Nighttime Sleep-Aid

Compare to Tylenol® PM
Extra Strength active ingredients*

80 GELCAPS

NDC 69842-956-31

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

Drug Facts

Active ingredients (in each gelcap)

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

No print/No varnish
Lot & Exp date

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FPO 80%
UPC# 050428164365

X XXXXXX XXXXXX X

PEEL HERE FOR MORE DRUG FACTS

STOP PEELING

Questions or comments? 1-800-426-9391

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, stearic acid, stearic acid, titanium dioxide

Other information store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F); avoid high humidity; use by expiration date on package

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

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.

If pregnant or breast-feeding, ask a health professional before use.

Stop use and ask a doctor if any new symptoms appear; sleeplessness persists continuously for more than 2 weeks; insomnia may be a symptom of a serious underlying medical illness; redness or swelling is present; pain gets worse or lasts more than 10 days; fever gets worse or lasts more than 3 days

When using this product avoid alcoholic beverages; drowsiness will occur; do not drive a motor vehicle or operate machinery

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin; taking sedatives or tranquilizers

Ask a doctor before use if you have a breathing problem such as emphysema or chronic bronchitis; difficulty in urination due to enlargement of the prostate gland; glaucoma; liver disease

Drug Facts (continued)

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CVS 44-556

ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

| Product Information | | | |
|--------------------------------------------------------------------------------------|----------------|-------------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-956 |
| 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: 3WJQ05DW1A) |
| 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 (light) , blue (Dark) | 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:69842-956-31 | 80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/17/2007 | |
| 2 | NDC:69842-956-09 | 1 in 1 CARTON | 12/17/2007 | 08/31/2023 |
| 2 | | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 3 | NDC:69842-956-13 | 250 in 1 BOTTLE; Type 0: Not a Combination Product | 12/17/2007 | 11/15/2020 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M013 | 12/17/2007 | |

Labeler - CVS PHARMACY (062312574)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------------------------|
| LNK International, Inc. | | 038154464 | manufacture(69842-956) , pack(69842-956) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867837 | manufacture(69842-956) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | manufacture(69842-956) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 868734088 | manufacture(69842-956) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | pack(69842-956) |

Revised: 3/2025

CVS PHARMACY