

**PAIN RELIEF PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated
AmerisourceBergen (Good Neighbor Pharmacy) 46122**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Extra Strength Acetaminophen PM

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep- aid

Uses

temporary relief of occasional headaches and minor aches and pains 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

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 products 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 problems 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 a serious underlying medical illness.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center 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 | <ul style="list-style-type: none"> • take 2 caplets at bedtime • do not take more than 2 caplets of this product in 24 hours |
| children under 12 years | <ul style="list-style-type: none"> • do not use |

Other information

- store at room temperature 15°-30°C (59°-86°F)
- avoid high humidity and excessive heat

Inactive ingredients

croscarmellose sodium*, D&C yellow # 10 aluminium lake*, FD&C blue #1 aluminium lake, FD&C blue #2 aluminium lake*, hypromellose, magnesium silicate*, magnesium stearate*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, pregelatinized starch, silica*, sodium starch glycolate*, stearic acid, titanium dioxide, triacetin*

*contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

Compare to Extra Strength Tylenol®PM active ingredients**

EXTRA STRENGTH

Non- Habit forming

Pain Relief PM

Acetaminophen 500 mg,

Diphenhydramine HCl 25 mg

Pain reliever /Nighttime Sleep-Aid

50 CAPLETS

Tamper Evident: Do not use if imprinted safety seal under cap is broken or missing

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

**NO PRINT
NO VARNISH
NO COATING**

GOOD NEIGHBOR PHARMACY
Extra Strength • Non-habit forming

Pain Relief PM
acetaminophen, 500 mg • diphenhydramine HCl, 25 mg
Pain Reliever/Nighttime Sleep-Aid

50 caplets

Compare to Extra Strength Tylenol® PM active ingredients**

NDC 46122-179-71

**NO PRINT
NO VARNISH
NO COATING**

Drug Facts (continued)

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center 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 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours.
- children under 12 years: do not use

Other information

- store at room temperature 15°-30°C (59°-86°F)
- avoid high humidity and excessive heat

Inactive ingredients

croscarmellose sodium*, D&C yellow #10 aluminum lake*, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake*, hypromellose, magnesium silicate*, magnesium stearate*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, pregelatinized starch, silica*, sodium starch glycolate*, stearic acid*, titanium dioxide, triacetin*

*contains one or more of these ingredients

Drug Facts (continued)

Ask a doctor before use if you have

- liver disease
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- glaucoma

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- taking the blood thinning drug warfarin
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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

- sleepiness persists continuously for more than 2 weeks. Insomnia may be a symptom of a 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.**

Drug Facts (continued)

Questions or comments? Call 1-877-733-3835 Monday-Friday 9AM-5PM EST

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

| PAIN RELIEF PM EXTRA STRENGTH | | | |
|---|----------------|--------------------|----------------|
| acetaminophen, diphenhydramine hcl tablet, coated | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:46 122-179 |

Pain Relief PM Caplets

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: HBR47K3TBD) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| MAGNESIUM SILICATE (UNII: 9B9691B2N9) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) | |
| TRIACETIN (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|----------|---------|--------------|-------------|
| Color | BLUE | Score | no score |
| Shape | CAPSULE | Size | 18mm |
| Flavor | | Imprint Code | S525;CPC752 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:46122-179-71 | 1 in 1 BOX | 04/23/2013 | 12/31/2020 |
| 1 | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part343 | 04/23/2013 | 12/31/2020 |

Labeler - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

Registrant - P & L Development, LLC (800014821)

Revised: 12/2018

AmerisourceBergen (Good Neighbor Pharmacy) 46122