**PAIN RELIEF ACETAMINOPHEN PM- acetaminophen and diphenhydramine hcl tablet, coated**
**Rite Aid Corporation**

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**Rite Aid 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**

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

- 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**
- 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
- pain gets worse or lasts more than 10 days
- 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***
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- 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**

NDC 11822-0556-1

Compare to the active ingredients of
**Extra Strength Tylenol® PM***

EXTRA STRENGTH
PAIN RELIEF
**ACETAMINOPHEN**
**PM**

**ACETAMINOPHEN** 500 mg
DIPHENHYDRAMINE HCl 25 mg

PAIN RELIEVER
NIGHTTIME SLEEP AID
non-habit forming

ACTUAL SIZE

**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 Extra Strength Tylenol® PM. 50844 REV0324G55631

**DISTRIBUTED BY:** RITE AID,
200 NEWBERRY COMMONS, ETTERS, PA 17319 **www.riteaid.com**

**SATISFACTION GUARANTEE:**
If you’re not satisfied, we’ll
happily refund your money.


**Rite Aid 44-556**

# PAIN RELIEF ACETAMINOPHEN PM

acetaminophen and diphenhydramine hcl tablet, coated

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:11822-0556 |
| **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) | |
| **CROSCARMELLOSE 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) | |
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **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:11822-0556-1 | 80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/17/2007 | |
| **2** | NDC:11822-0556-9 | 1 in 1 CARTON | 12/17/2007 | 06/15/2020 |
| **2** | | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **3** | NDC:11822-0556-3 | 1 in 1 CARTON | 12/17/2007 | 05/17/2019 |
| **3** | | 80 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 | 12/17/2007 | |

## Labeler - Rite Aid Corporation (014578892)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 038154464 | manufacture(11822-0556) , pack(11822-0556) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | manufacture(11822-0556) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | manufacture(11822-0556) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 868734088 | manufacture(11822-0556) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 967626305 | pack(11822-0556) |