

**PAIN RELIEF PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl capsule, coated
Kroger Company**

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.

Kroger Co. Pain Relief PM Drug Facts

Active ingredient (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

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.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) 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 Liver warning)

| | |
|---------------------------------------|---|
| adults and children 12 years and over | <ul style="list-style-type: none">• 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 this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage |

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #28, D&C yellow #10, edible ink, FD&C blue #1, FD&C blue #2 aluminum lake, FD&C red #40, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, povidone, pregelatinized starch, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-800-632-6900

Package/Label Principal Display Panel

Rapid Release

COMPARE TO active ingredients of EXTRA STRENGTH TYLENOL® PM

See end panel

EXTRA STRENGTH

Pain Relief PM

Pain Reliever - Nighttime Sleep-Aid

Acetaminophen/Diphenhydramine HCl

Actual Size

Kroger
QUALITY GUARANTEED

Rapid Release

COMPARE TO active ingredients of
EXTRA STRENGTH TYLENOL® PM *See end panel

NDC 30142-829-27

EXTRA STRENGTH
Pain Relief PM

Pain Reliever • Nighttime Sleep-Aid

Acetaminophen/Diphenhydramine HCl

80 GELCAPS

Actual Size

Our Pharmacists Recommend

Store at 20° - 25°C (68° - 77°F).
DO NOT USE IF PRINTED SEAL UNDER
CAP IS BROKEN OR MISSING

Kroger
QUALITY GUARANTEED

Pain Relief PM
Pain Reliever • Nighttime Sleep-Aid

*Tylenol® is a registered trademark of The Tylenol Company, Raritan, NJ 08869. The Tylenol Company is not affiliated with The Kroger Co. or this product.

Made in India
Distributed by The Kroger Co., Cincinnati, Ohio 45202

QUALITY GUARANTEED

If you are not completely satisfied with this product,
return it for a refund or replacement.

Comments or questions? www.Kroger.com

LOT NO.
EXP.
: A2927 45 C3

0 41260 35124 2

Drug Facts

| Active Ingredients (in each gelcap) | Purpose |
|--|---------------------|
| Acetaminophen 500 mg..... | Pain reliever |
| Diphenhydramine HCl 25 mg..... | Nighttime sleep-aid |

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Do not use

- in children under 12 years of age
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- trouble urinating due to an enlarged prostate gland

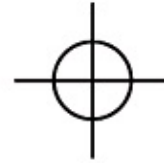
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- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

When using this product, avoid alcoholic drinks and do not drive a motor vehicle or operate machinery.



Drug Facts (continued)

Stop use and ask a doctor if

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Questions or comments? 1-800-632-6900



Rapid Release

COMPARE TO active ingredients of EXTRA STRENGTH TYLENOL® PM *See end panel

NDC 30142-829-27

EXTRA STRENGTH

Pain Relief PM

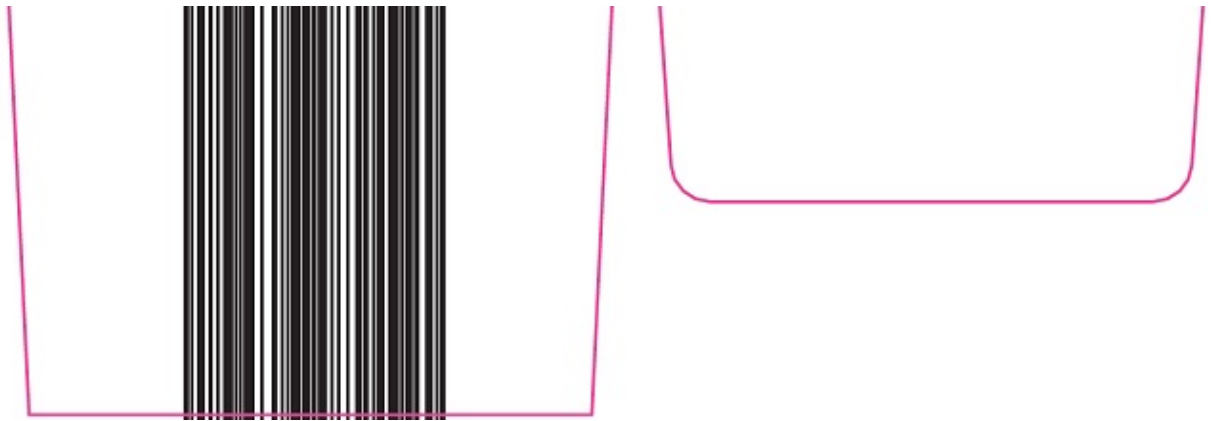
Pain Reliever • Nighttime Sleep-Aid

Acetaminophen/Diphenhydramine HCl

Our Pharmacists Recommend

80 GELCAPS





PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl capsule, coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:30 142-829 |
| 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 |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| D&C RED NO. 28 (UNII: 767IP0Y5NH) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GELATIN (UNII: 2G86QN327L) | |
| HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POVIDONES (UNII: FZ989GH94E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |

Product Characteristics

| | | | |
|-----------------|--|---------------------|----------|
| Color | BLUE (Dark Blue Opaque) , GRAY, BLUE (Light Blue Opaque) | Score | no score |
| Shape | CAPSULE | Size | 22mm |
| Flavor | | Imprint Code | L829 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|---------------------|----------------------|--------------------|
| 1 | NDC:30 142-829-27 | 1 in 1 CARTON | | |
| 1 | | 80 in 1 BOTTLE | | |
| 2 | NDC:30 142-829-60 | 1 in 1 CARTON | | |
| 2 | | 20 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part338 | 08/04/2010 | |

Labeler - Kroger Company (006999528)

Revised: 2/2013

Kroger Company