#### PAIN RELIEF PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated QUALITY CHOICE (Chain Drug Marketing Association)

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### DRUG FACTS

#### Active ingredients (in each geltab)

#### Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

#### Purpose

#### Pain reliever

Nighttime sleep-aid

#### Purposes

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
- 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 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.

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 geltabs at bedtime. Do not take more than 2 geltabs of this product in 24 hours.
- children under 12 years: do not use

## Other information

- store between 20-25°C (68-77°F)
- avoid high humidity and excessive heat

#### Inactive ingredients

corn starch, croscarmellose sodium, D&C red #27 aluminum lake, edible black ink, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, purified water, silicon dioxide, stearic acid, titanium dioxide

#### **Questions or comments?**

Call 1-800-935-2362 Monday-Friday 9AM-5PM EST

#### Principal display panel

\*Compare to the active ingredients in Extra Strength TYLENOL® PM

Extra Strength

PAIN RELIEF PM

Pain Reliever | Nighttime Sleep-Aid

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Non-habit forming

#### GELTABS

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tyleno® PM.

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

## KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

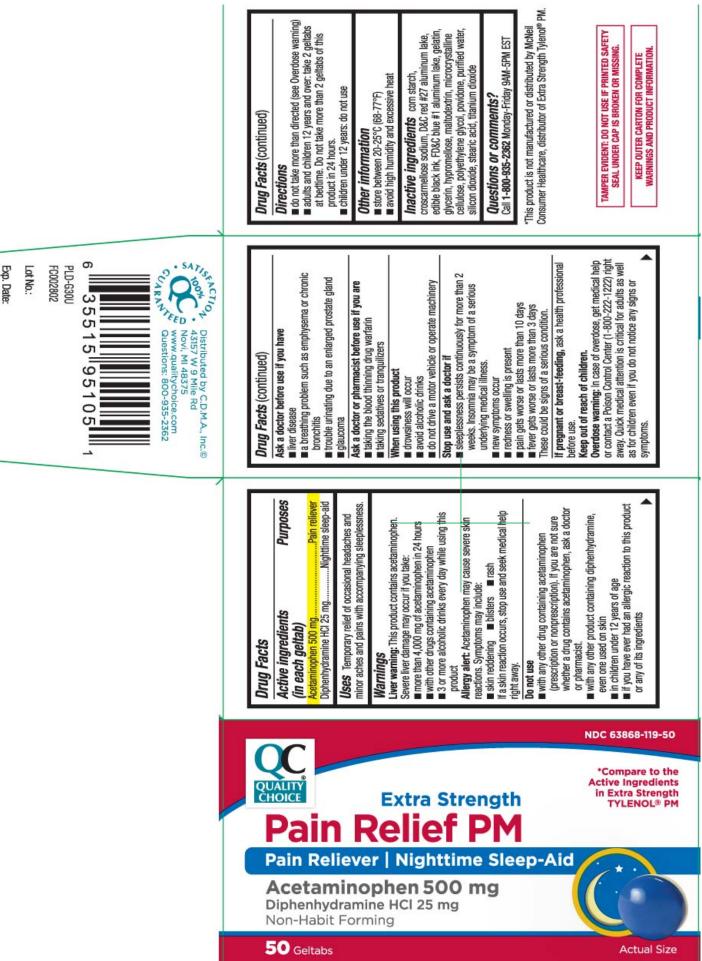
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Novi, MI 48376-0995

www.qualitychoice.com

#### Product Label



QUALITY CHOICE Pain Relief PM

#### PAIN RELIEF PM EXTRA STRENGTH acetaminophen, diphenhydramine hcl tablet, coated **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:63868-119 **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 500 mg DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) DIPHENHYDRAMINE 25 mg (DIPHENHYDRAMINE - UNII:8GTS82S83M) HYDROCHLORIDE **Inactive Ingredients Ingredient Name** Strength STARCH, CORN (UNII: 08232NY3SJ) D&C RED NO. 27 (UNII: 2LRS185U6K) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) GELATIN (UNII: 2G86QN327L) GLYCERIN (UNII: PDC6A3C0OX) HYPROMELLOSES (UNII: 3NXW29V3WO) MALTODEXTRIN (UNII: 7CVR7L4A2D) CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) **POVIDONE** (UNII: FZ989GH94E) WATER (UNII: 059QF0K00R) SILICON DIOXIDE (UNII: ETJ7Z6XBU4) STEARIC ACID (UNII: 4ELV7Z65AP) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CROSCARMELLOSE SODIUM (UNII: M280L1HH48) ALUMINUM OXIDE (UNII: LMI2606933) SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) **Product Characteristics** white, blue Color no score Score OVAL Size 13mm Shape **BP50** Flavor **Imprint Code** Contains Packaging **Marketing End Marketing Start Package Description** # **Item Code** Date Date

119-50	. in 1 BOX	05/31/2015	
	0 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing I	nformation		
Marketing I Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing	Application Number or Monograph Citation	-	-

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 4/2024

QUALITY CHOICE (Chain Drug Marketing Association)