### PAIN RELIEVER PM- 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

#### 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 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 at 20-25°C (68-86°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,

#### Questions or comments?

Call1-800-935-2362 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

\*Compare to the Active Ingredient in Extra Strength TYLENOL® PM

Extra Strength

#### Pain Reliever 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 Tylenol® 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.

Distributed by CDMA, Inc.

Novi MI 48375

#### **Product Label**

Exp. Date

Lot No.:

FC009134 PLD-H30U

S S 15 "95105**"** 

www.qualitychoice.com Questions: 800-935-2362 Novi, MI 48375 Distributed by CDMA, Inc.

SATISTACTION CARANTEED

# *Orug Facts* (continued)

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Purposes

Active ingredients

**Drug Facts** 

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trouble urinating due to an enlarged prostate gland qlaucoma

.Nighttime sleep-aid

Diphenhydramine HCl 25 mg.

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Warnings

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■ with other drugs containing acetaminophen Severe liver damage may occur if you take:

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if pregnant or breast-feeding, ask a health professional

whether a drug contains acetaminophen, ask a doctor

with any other product containing diphenhydramine,

or pharmacist

(prescription or nonprescription). If you are not sure

with any other drug containing acetaminophen

Do not use

right away

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

# **Drug Facts** (continued)

### 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.

## Other information

children under 12 years: do not use

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

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

Questions or comments?

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

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

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

NDC 83324-166-50

\*Compare to the **Active Ingredients** in Extra Strength TYLENOL® PM

any of its ingredients

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if you have ever had an allergic reaction to this product

■ in children under 12 years of age

even one used on skin



**Extra Strength** 

3 or more alcoholic drinks every day while using this

**Allergy alert:** Acetaminophen may cause severe skin

product

Pain Reliever | Nighttime Sleep-Aid

Acetaminophen 500 mg

Diphenhydramine HCI 25 mg Non-Habit Forming



Actual Size

#### **QUALITY CHOICE Extra Strength Pain Relief PM**

#### **PAIN RELIEVER PM**

acetaminophen diphenhydramine hcl tablet, coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-166
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	500 mg	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
<b>D&amp;C RED NO. 27</b> (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: FZ 989GH94E)		
WATER (UNII: 059QF0KO0R)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
ALUMINUM OXIDE (UNII: LMI26O6933)		

Product Characteristics			
Color	white, blue	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	BP50
Contains			

F	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:83324- 166-50	1 in 1 BOX	07/31/2024	
1	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing	Information		
Marketing Marketing Category	<u> </u>	ograph Marketing Start Date	Marketing End Date
Marketing	Application Number or Mon Citation	9 .	_

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

Revised: 5/2024 QUALITY CHOICE (Chain Drug Marketing Association)