

PAIN RELIEF PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride tablet, coated
Chain Drug Marketing Association

QCH - 1095 - 2019-1004

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	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.

Overdose warning

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 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 this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 63868-325-50

QUALITY CHOICE

†Compare to Extra Strength TYLENOL® PM active ingredients

Extra Strength

Pain Relief PM

Pain Reliever, Nighttime Sleep Aid

Acetaminophen, Diphenhydramine HCl

50 Caplets

COATING FREE AREA

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 Diphenhydramine HCl 25 mg. 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 ■ glaucoma
 ■ a breathing problem such as emphysema or chronic bronchitis
 ■ trouble urinating due to an enlarged prostate gland
Ask a doctor or pharmacist before use if you are
 ■ taking the blood thinning drug warfarin
 ■ taking sedatives or tranquilizers
When using this product ■ avoid alcoholic drinks
 ■ drowsiness will occur

QC QUALITY CHOICE NDC 63868-325-50

*Compare to Extra Strength TYLENOL® PM active ingredients

Extra Strength Pain Relief PM
 Pain Reliever, Nighttime Sleep Aid
 Acetaminophen, Diphenhydramine HCl

50 Caplets

QC QUALITY CHOICE NDC 63868-325-50

*Compare to Extra Strength TYLENOL® PM active ingredients

Extra Strength Pain Relief PM
 Pain Reliever, Nighttime Sleep Aid
 Acetaminophen, Diphenhydramine HCl

50 Caplets

Drug Facts (continued)
 ■ retain carton for complete product information
Inactive ingredients colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

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 Novi, MI 48376-0995
 www.qualitychoice.com
 Questions: 248-449-9300

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Drug Facts (continued)
 ■ do not drive a motor vehicle or operate machinery
Stop use and ask a doctor if
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 ■ 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.
Overdose warning: 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.
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 adults and children 12 years and over
 ■ take 2 caplets at bedtime
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 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
Other information
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INK AND COATING FREE FOR LOT AND EXPIRATION STAMPING

0 76566 35515 555 9

QC QUALITY CHOICE

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

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

PAIN RELIEF PM EXTRA STRENGTH
 acetaminophen and diphenhydramine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-325
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)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AAA;1031
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-325-50	1 in 1 CARTON	11/08/2007	11/30/2026
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63868-325-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/08/2007	11/30/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/08/2007	11/30/2026

Revised: 10/2024

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