

**ACETAMINOPHEN DIPHENHYDRAMINE HCL- acetaminophen diphenhydramine
hcl tablet
Granules USA, Inc.**

EXTRA STRENGTH

Pain Relief PM

**Acetaminophen, USP 500 mg/ Diphenhydramine HCl, USP 25 mg
Pain Reliever/ Nighttime Sleep-Aid**

Non-Habit Forming

Active ingredients

(in each caplet)

Acetaminophen, USP 500mg

Diphenhydramine HCl. 25mg

Purposes

Pain reliever

Nighttime sleep-aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

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 have

- 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
 - 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 the reach of children.

Overdose warning

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

adults and children 12 years and over

■ take 2 caplets at bedtime do not use

■ do not take more than 2 caplets of this product in 24 hours

children under 12 years

■ do not use

Other information

■ store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.

■ see end panel for expiration date and lot number

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

Principal Display Panel

size :1+3/4 X 1+3/4 X 3+3/8
 ref # :PP180604B
 material :.016 SBS

COATING FREE AREA

R-00
 537000013
 300000417

Drug Facts (continued)

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
- 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 the reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 (see overdose warning)

Drug Facts (continued)

adults and children 12 years and over	take 2 caplets at bedtime
children under 12 years	do not take more than 2 caplets of this product in 24 hours
	do not use

Other information

- store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.
- see end panel for expiration date and lot number

Inactive ingredients carnauba wax, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hydrocodone, microcrystalline cellulose, polyethylene glycol, polysorbate, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?
 call 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Extra Strength Tylenol® PM Caplets.

Distributed by:
 Granules Consumer Health
 35 Waterview Blvd., 3rd Floor
 Parsippany, NJ 07054

MADE IN INDIA

EXTRA STRENGTH GRANULES CONSUMER HEALTH

Pain Relief PM

Acetaminophen, USP 500 mg/
 Diphenhydramine HCl, USP 25 mg
 Pain Reliever/
 Nighttime Sleep-Aid
 Non-Habit Forming
 20 Caplets*
 (Capsule-Shaped Tablets)

EXTRA STRENGTH GRANULES CONSUMER HEALTH

Pain Relief PM

Acetaminophen, USP 500 mg/
 Diphenhydramine HCl, USP 25 mg
 Pain Reliever/
 Nighttime Sleep-Aid
 Non-Habit Forming
 20 Caplets*
 (Capsule-Shaped Tablets)

*Compare to the active ingredients in Extra Strength Tylenol® PM Caplets

actual size

8 13874 02024 7

Lot Exp.

COATING FREE AREA

Drug Facts

Active ingredients (in each caplet)

Acetaminophen, USP 500 mg... Pain reliever
 Diphenhydramine HCl, 25 mg... Nighttime sleep-aid

Purposes

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 hives rash
 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

COATING FREE AREA

300000417
 537000013
 R-00

Principal Display Panel

size	:1+3/4 X 1+3/4 X 3+3/8
ref #	:PPI80604B
material	:.016 SBS

COATING FREE AREA

R-00
537000023
300000458



Drug Facts (continued)

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
- 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 the reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 (see overdose warning)

COATING FREE AREA

300000458
537000023
R-00



Drug Facts (continued)

adults and children 12 years and over

- take 2 caplets at bedtime
- do not take more than 2 caplets of this product in 24 hours

children under 12 years

- do not use

Other information

- store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.
- see end panel for expiration date and lot number

Inactive ingredients carnauba wax, croscellose, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polyisobutyl methacrylate, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-577-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Extra Strength Tylenol® PM Caplets.

Distributed by:
Granules Consumer Health
35 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

MADE IN INDIA

EXTRA STRENGTH GRANULES CONSUMER HEALTH

Pain Relief PM

Acetaminophen, USP 500 mg/
Diphenhydramine HCl, USP 25 mg

Pain Reliever/
Nighttime Sleep-Aid

Non-Habit Forming

50 Caplets*
(Capsule-Shaped Tablets)

EXTRA STRENGTH GRANULES CONSUMER HEALTH

Pain Relief PM

Acetaminophen, USP 500 mg/
Diphenhydramine HCl, USP 25 mg

Pain Reliever/
Nighttime Sleep-Aid

Non-Habit Forming

50 Caplets*
(Capsule-Shaped Tablets)

actual size

*Compare to the active ingredients in Extra Strength Tylenol® PM Caplets



COATING FREE AREA

8 13874 02027 8

Lot
Exp.



Important Read all product information before using. Keep the carton for important information. CAPLET EQUIVARIANT. DO NOT USE IF IMPROPERLY SEALED. SAFETY SEAL. CHECK CAP TO INSURE ON PACKAGING.

Drug Facts

Active ingredients (in each caplet)

Acetaminophen, USP 500 mg — Pain reliever

Diphenhydramine HCl, 25 mg — Nighttime sleep-aid

Purposes

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:

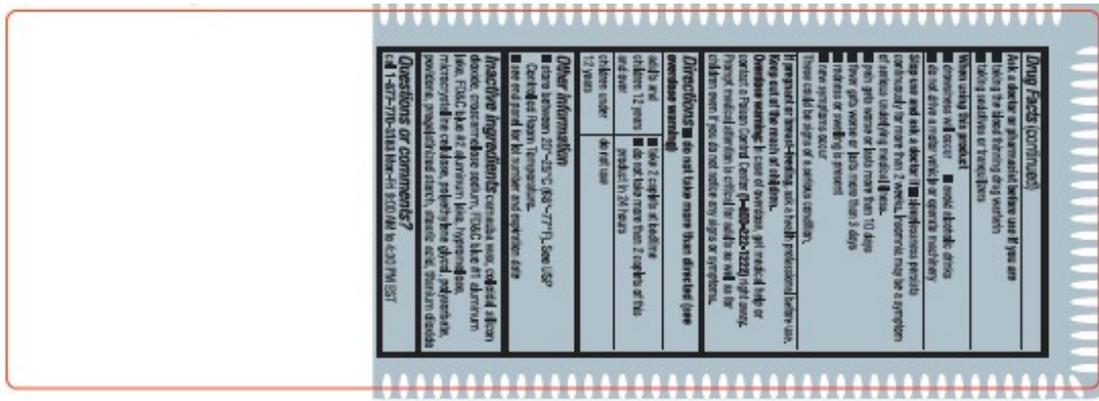
- skin reddening
- hives
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

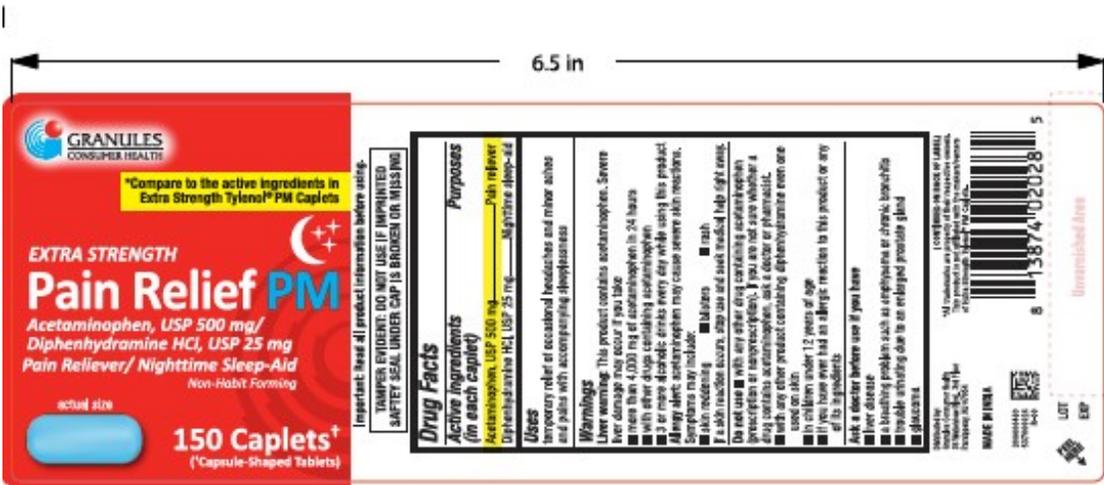
- with any other drug containing acetaminophen (prescription or nonprescription).
- if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

Principal Display Panel



Dion modifications to side 2 incoming artwork:

- 1) Adjusted size of bounding box so text does not extend into it



ACETAMINOPHEN DIPHENHYDRAMINE HCL

acetaminophen diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-014
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL (CAPLET SHAPED TABLET)	Size	17mm
Flavor		Imprint Code	G;651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-014-02	20 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
2	NDC:69848-014-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
3	NDC:69848-014-15	150 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug M013

07/01/2019

Labeler - Granules USA, Inc. (137098864)

Revised: 12/2025

Granules USA, Inc.