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

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.

EXTRA STRENGTH
Pain Relief PM
Acetaminophen, USP 500 mg/ Diphenhydramine HCl, USP 25 mg
Pain Reliever/ Nighttime Sleep-Aid

Non-Habit Forming

Active ingridients

(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 containsacetaminophen. 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 severs skin reactions. Symptoms may include:
■ skin reddening ■ blisters ■ rash
If a skin reaction occurs, stop use and seek medical help right away

DSo 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 brochitis
■ 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 morethan 2 weeks. Insomnia may be a symptom of a serious underlying medical illness
■ pain gets worse or lasts more t han 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 chlidren.

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 andchildren 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 ingridients

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?

item	:CVS APAP RR 50CT
code #	:
size	:1+3/4 X 1+3/4 X 3+3/8
ref #	:PP180604B
view	:PRINT
material	:.016 SBS
date	:06/01

COATING FREE AREA

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Drug Facts (continued)

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- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
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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?
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

GRANULES CONSUMER HEALTH

EXTRA STRENGTH
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

Important: Read all product information before using. Keep the carton for important information.

Drug Facts

Active ingredients (in each caplet)	Purposes
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Diphenhydramine HCl, 25 mg	Nighttime sleep-aid

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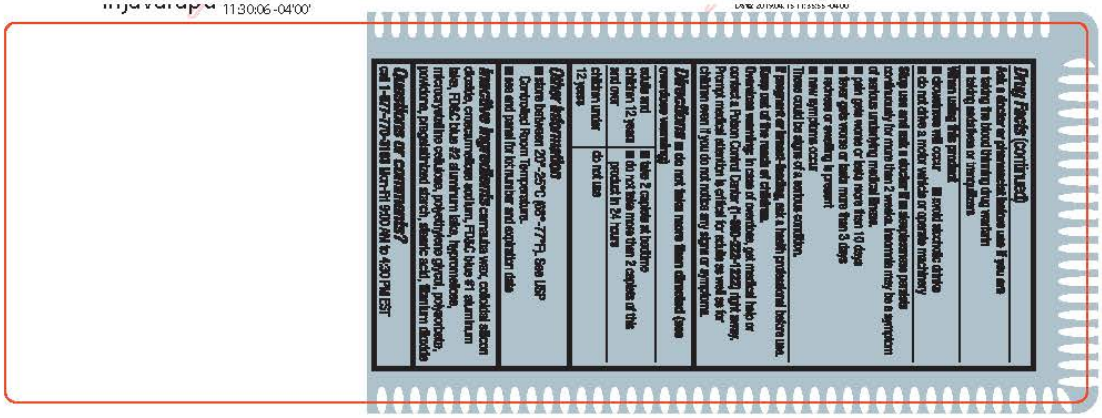

Dion modifications to side 2 incoming artwork:
1) Adjusted size of bounding box so text does not extend into it

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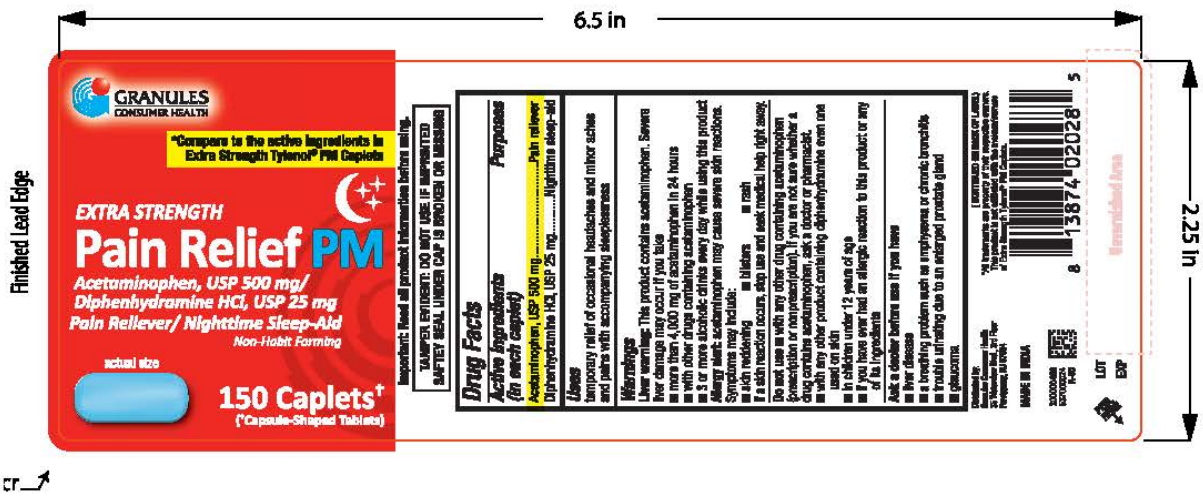

ACETAMINOPHEN DIPHENHYDRAMINE HCL

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: 3WQ0SDW1A)	

POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE 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 not final	part343	07/01/2019	

Labeler - Granules USA, Inc. (137098864)

Revised: 1/2023 Granules USA, Inc.