PAIN RELIEF PM EXTRA STRENGTH- acetaminophen 500 mg and diphenhydramine hcl 25 mg tablet
Allegiant Health

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

Purpose

Pain reliever
Nighttime sleep aid

Uses

temporarily 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 4000 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 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.

- **You may report side effects to 1-888-952-0050**

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children

In case of accidental overdose, contact a doctor or 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 take more than 2 caplets of this product in 24 hours
- **children under 12 years:** do not use

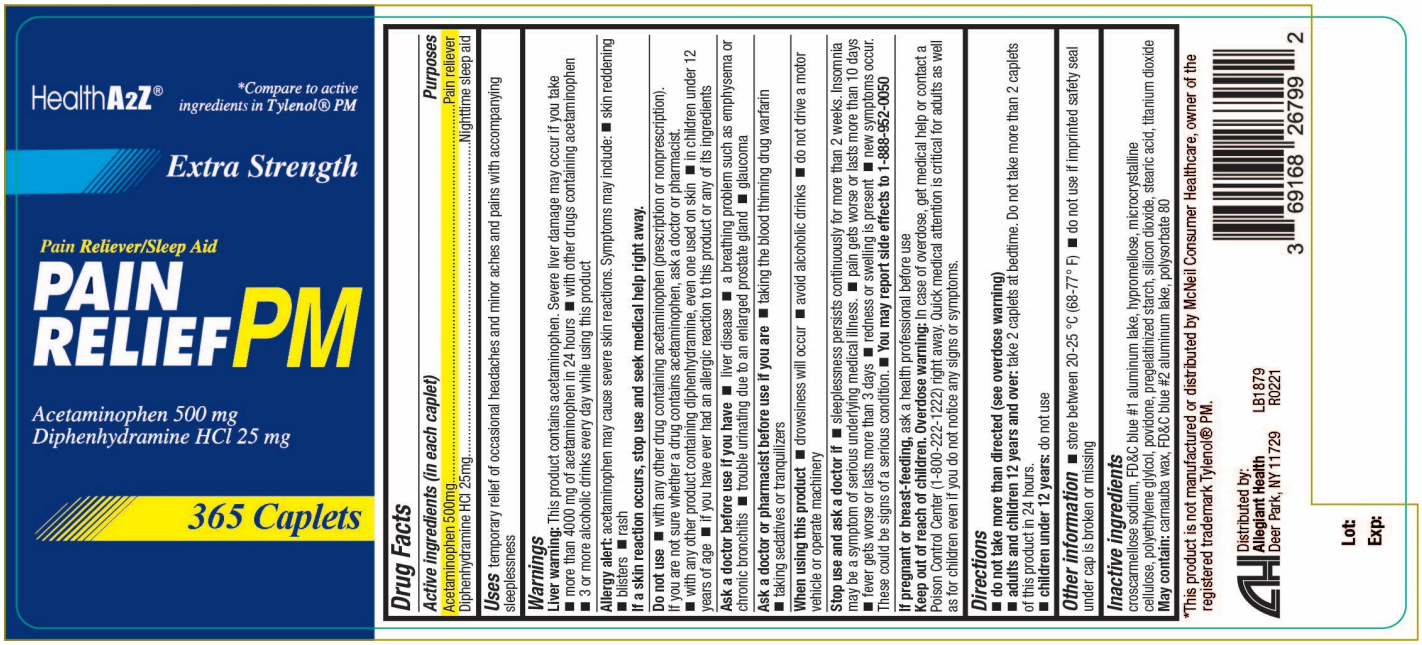
Inactive Ingredients

croscarmellose sodium, FD&C blue #1 aluminum lake, hypromellose, microcrystalline cellulose,

polyethylene glylcol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide

May contain: carnauba wax, FD&C blue #2 aluminum lake, polysorbate 80

Package/Label Principal Display Panel



Pain Relief Label

Pain Relief

PAIN RELIEF PM EXTRA STRENGTH

acetaminophen 500 mg and diphenhydramine hcl 25 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-393
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	G651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-393-02	150 in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2014	
2	NDC:69168-393-24	1 in 1 CARTON	12/23/2014	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69168-393-50	1 in 1 CARTON	12/23/2014	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69168-393-99	365 in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2014	
5	NDC:69168-393-26	1 in 1 CARTON	12/15/2021	
5		20 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

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

OTC Monograph Drug	M013	12/23/2014	

Labeler - Allegiant Health (079501930)

Revised: 12/2018 Allegiant Health