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

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.

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

Purpose

Pain reliever
Nighttime sleep aid

Uses

temporarily relieves 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 sever 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,

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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

Package/Label Principal Display Panel

Health A2Z® Compare to Tylenol® PM active ingredient*

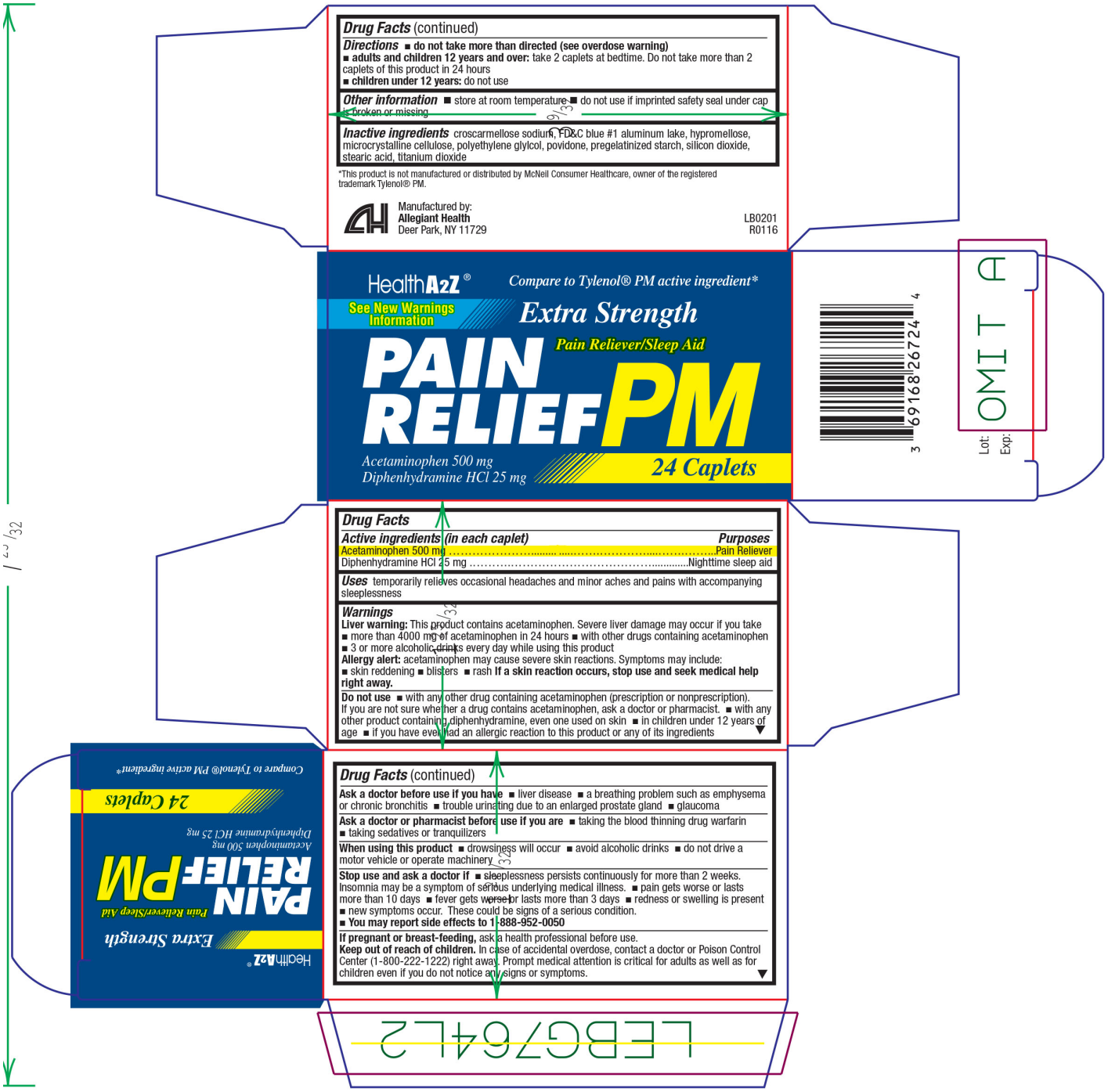
See New Warnings Information

Extra Strength

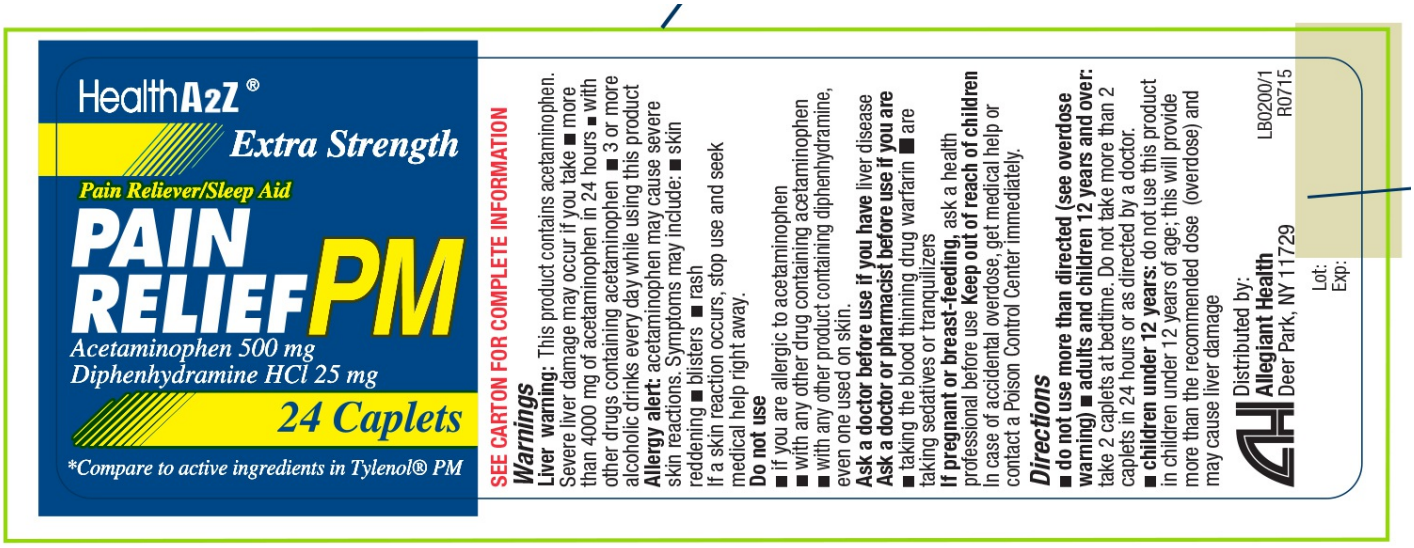
Pain Reliever/Sleep Aid

PAIN RELIEF PM
Acetaminophen 500mg
Diphenhydramine HCl 25mg

Caplets



Pain Relief PM 24 ct. Caplets



Pain Relief PM 24ct. Caplets

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:69168-267
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	16mm

Flavor		**Imprint Code**	AZ267
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-267-02	150 in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2014	
2	NDC:69168-267-24	24 in 1 CARTON; Type 0: Not a Combination Product	12/23/2014	
3	NDC:69168-267-50	50 in 1 CARTON; Type 0: Not a Combination Product	12/23/2014	
4	NDC:69168-267-99	365 in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/23/2014	

Labeler - Allegiant Health (079501930)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	ANALYSIS(69168-267) , LABEL(69168-267) , MANUFACTURE(69168-267) , PACK(69168-267)

Revised: 11/2017 Allegiant Health