PAIN RELIEF PM- acetaminophen and diphenhydramine hydrochloride tablet, coated
Avema Pharma Solutions

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg*

Diphenhydramine HCl 25 mg**

Purpose

*Pain reliever

**Nighttime sleep aid

Uses

Temporary relief of occasional headaches, minor aches, and pains accompanying sleeplessness.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur with this product if you take:

- more than 2 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Do not use

- with other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- in children under 12 years of age
- with other products containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- liver disease
- asthma
- breathing problems such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urinating due to an enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

avoid alcoholic beverages

do not drive a motor vehicle or operate machinery. This product will cause drowsiness.

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 for more than 10 days
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- redness or swelling is present

If pregnant or breast-feeding, ask a health care professional before use. **Keep out of reach of children.**

Directions

- **do not exceed recommended dose**
- **adults and children 12 years of age and over:** take 2 caplets at bedtime. Do not take more than 2 caplets in 24 hours.
- **children under 12 years of age:** do not use this product in children under 12 years of age. This will provide more than the recommended dose (overdose) and may cause liver damage.

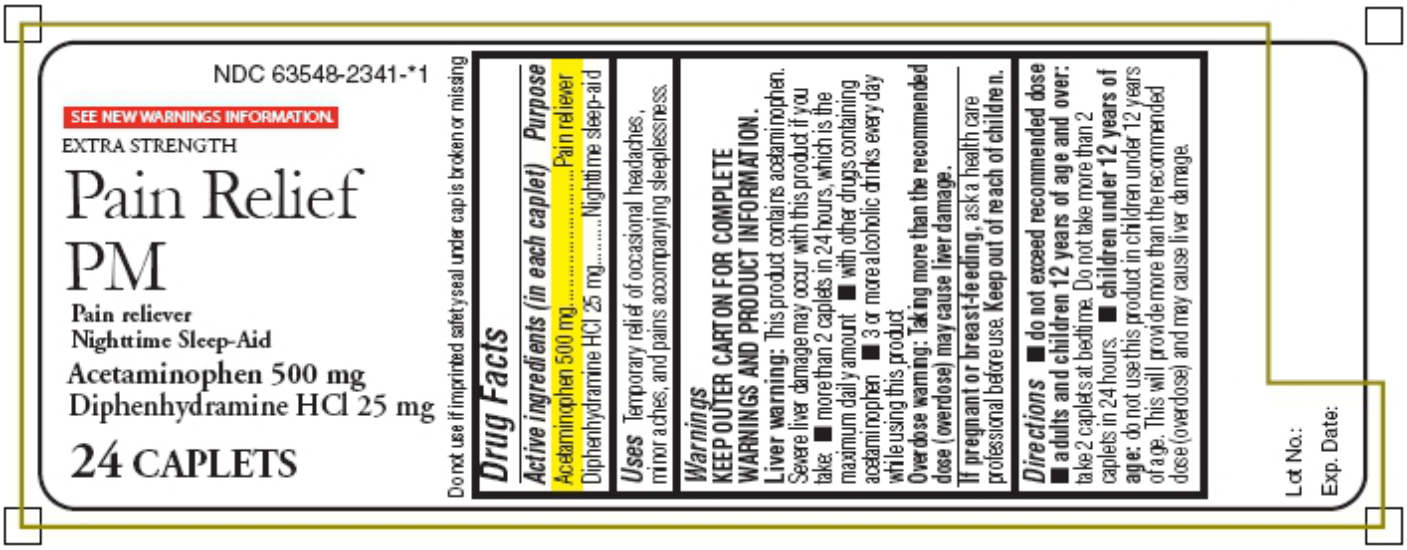
Other information

- store at room temperature 15°-30°C (59°-86°F), avoid high humidity and excessive heat
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

FD&C Blue #1 Aluminum Lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG), polyvinyl alcohol, polyvinylpyrrolidone, sodium carboxymethyl starch, starch, stearic acid, talc, titanium dioxide.

Package/Label Principal Display Panel



NDC 63548-2341-*1

SEE NEW WARNINGS INFORMATION

EXTRA STRENGTH

Pain Relief PM

Pain reliever

Nighttime Sleep-Aid

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

24 CAPLETS

Do not use if imprinted safety seal under cap is broken or missing

PAIN RELIEF PM

acetaminophen and diphenhydramine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63548-2341
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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE	**Score**	no score

Shape	CAPSULE	**Size**	7mm
Flavor		**Imprint Code**	V15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-2341-1	24 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/02/2010	

Labeler - Avema Pharma Solutions (804087749)

Revised: 2/2010 Avema Pharma Solutions