PAIN RELIEF PM - acetaminophen pm tablet
Velocity Pharma

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.

Acetaminophen, Diphenhydramine HCl Tablets

Active Ingredient

(in each tablet)

Acetaminophen 500mg

Diphenhydramine HCl 25mg

Purpose

pain reliever/fever reducer

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 everyday while using this product

Overdose warning: **Taking more than 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 for children even if you do not notice any signs or symptoms.

do not use

- with any other drug containing acetaminophen (prescription or not prescription). 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
- With other products containing diphenhydramine, even one used on skin.

ask a doctor before use if you have

- liver disease
- asthma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- galucoma

ask your doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin

- taking sedative or tranquilizers.

When using this product
- avoid alcoholic drinks
- 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 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.

Keep out of reach of children.

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

Directions
- **do not exceed recommended dose**
- **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 this adult 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 25 °C (77°F) excursions permitted between 15-30°C(59-86°F)
- do not use if imprinted safety seal under cap is broken or missing

this product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol PM

Inactive Ingredients

Colloidal Silicon Dioxide, Croscarmellose Sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, purified water, Sodium metabisulfite, Sodium starch glycolate, stearic acid, Titanium Dioxide, Talc

Questions or Comments

Call toll free 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	Nighttime sleep-aid

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage.

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 adult product in children under 12 years of age. This will provide more than the recommended dose (overdose) and may cause liver damage.

Questions or comments? Call toll free **1-855-314-1850**

Distributed by: Greenbrier International, Inc.
Chesapeake, VA 23320 **811431**
ASSPML

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Lot No.:
Exp Date:

NDC: 76168-011-04 24 COUNT

PAIN RELIEF PM

acetaminophen pm tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-011
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	131
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76168-011-04	24 in 1 BOTTLE		
1		1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/05/2012	

Labeler - Velocity Pharma (962198409)

Revised: 8/2013 Velocity Pharma