

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

NDC: 76168-119-25 50 COUNT



PAIN RELIEF PM

acetaminophen pm tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 168 - 119
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)	
CROSCARMELOSE 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	P525
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-119-25	50 in 1 BOTTLE	05/14/2018	
1		1 in 1 CARTON; Type 0: Not a Combination Product		

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)