PAIN RELIEF PM- acetaminophen, diphenhydramine tablet
Pioneer Life Sciences, LLC

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.

Pain Relief PM

Active Ingredient

Acetaminophen 500 mg

Diphenhydramine 25 mg

Purpose

Pain Reliever/fever reducer

Nighttime sleep-aid

Uses:

temporary relief of occasional headaches and minor aches and pain with accompanying sleeplessness

Warnings:

This product contains acetaminophen. Severe liver damage can 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**

Allergy Alert:

Acetamenophen may cause severe skin reactions,symptoms may include

- **Skin reddening**
- **blisters**
- **rash**

If skin reaction occour stop use and seek medical help right away

- **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 ever had an allergic reaction to this product or any of its ingredients**

Ask Doctor:
- liver disease
- glaucoma
- a breathing problem such as emphysema, or chronic bronchitis
- trouble urinating due to enlarged prostate gland

ASK DOCTOR/PHARMACIST:
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When Using this product

•drowsiness will occur
•avoid alcoholic beverages
•do not drive 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
•new symptoms occur
•redness or swelling is present
•new symptoms occurThese could be signs of a serious condition.

PREGNANCY

If pregnant or breast-feeding,

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Quick 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)
- take 2 caplets bedtime
- do not take more than 2 caplets in 24 hours unless directed by doctor
- children under 12 years do not use

OTHER INFORMATION

- store at 20°-25°C (68°-77°F)
- do not use if foil or inner seal is broken or missing

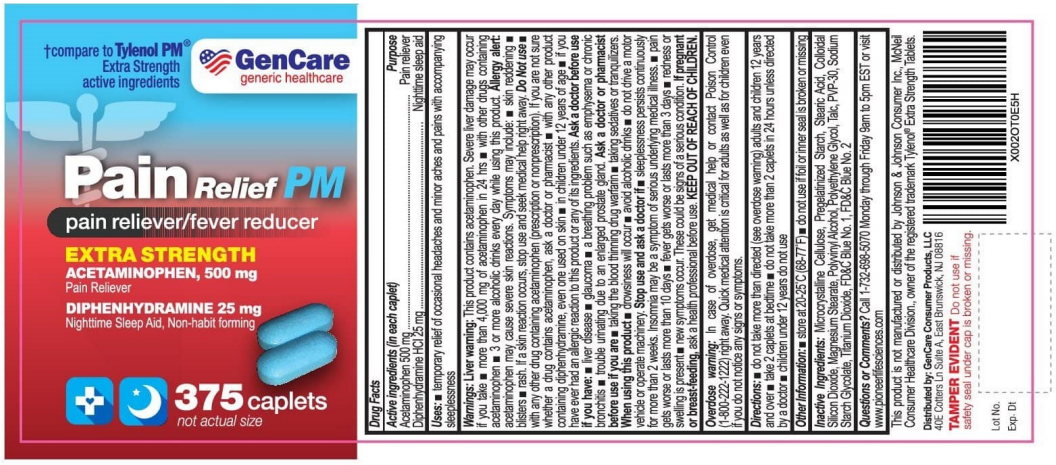
INACTIVE INGREDIENTS

pregelatinized starch, povidone, stearic acid powder, microcrystalline cellulose, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide, talc

QUESTIONS OR COMMENTS?

Call 1-732-698-5070 Monday through Friday 9AM–5PM EST or www.pioneerlifesciences.com

PRINCIPAL DISPLAY PANEL



PAIN RELIEF PM

acetaminophen, diphenhydramine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72090-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	27mm
Flavor		**Imprint Code**	None
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-006-25	375 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/03/2020	

Labeler - Pioneer Life Sciences, LLC (014092742)

Revised: 5/2021 Pioneer Life Sciences, LLC