# PAIN RELIEVER PM- acetaminophen, diphenhydramine hcl tablet, coated Valu Merchandisers Company

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**Best Choice 44-556** 

## Active ingredients (in each gelcap)

Acetaminophen 500 mg Diphenhydramine HCl 25 mg

## **Purpose**

Pain reliever Nighttime sleep-aid

#### Uses

temporary 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 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:** Acetaminophen may cause severe 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

- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to this product or any of its ingredients

## Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

- liver disease
- difficulty in urination due to enlargement of the prostate gland

## Ask a doctor or pharmacist before use if you are

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

## When using this product

- drowsiness will occur
- avoid alcoholic beverages
- 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 a serious underlying medical illness.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

These could be signs of a serious condition.

## If pregnant or breast-feeding,

ask a health professional before use.

## Keep out of reach of children.

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.

### **Directions**

- do not take more than directed
- adults and children 12 years and over
  - take 2 gelcaps at bedtime
  - do not take more than 2 gelcaps of this product in 24 hours
- children under 12 years: do not use

### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

## Inactive ingredients

ammonium hydroxide, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, FD&C red #3, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide

red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, simethicone, stearic acid, titanium dioxide

## Questions or comments?

1-800-426-9391

## Principal Display Panel

Compare to the active ingredients in Extra Strength Tylenol® PM\*

Best Choice®

EXTRA STRENGTH

Pain Reliever PM

ACETAMINOPHEN 500 mg
DIPHENHYDRAMINE HCI 25 mg
PAIN RELIEVER/NIGHTTIME SLEEP AID

**NON-HABIT FORMING** 

**Actual Size** 

### **40 GELCAPS**

## TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol® PM. 50844 REV0322D55610

PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO. 5000 KANSAS AVE, KANSAS CITY, KS 66106



**Best Choice 44-556** 

## PAIN RELIEVER PM

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Product Information					
HUMAN OTC DRUG	Item Code (So	ource)	NDC:6394	11-956	
ORAL					
Active Ingredient/Active Moiety					
Ingredient Name Basis of Strength			Strength		
	HUMAN OTC DRUG ORAL  Moiety	HUMAN OTC DRUG ORAL  Moiety	HUMAN OTC DRUG ORAL  Moiety	HUMAN OTC DRUG Item Code (Source) NDC:6394 ORAL	

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	500 mg
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	blue (dark) , blue (light)	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	L;6	
Contains				

I	Packaging			
4	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941- 956-10	1 in 1 CARTON	04/12/2023	
1	L	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M013	04/12/2023			

## **Labeler -** Valu Merchandisers Company (868703513)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(63941-956) . pack(63941-956)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(63941-956)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(63941-956)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		868734088	manufacture(63941-956)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(63941-956)

Revised: 5/2023 Valu Merchandisers Company