PAIN RELIEF ACETAMINOPHEN PM- acetaminophen and diphenhydramine hcl tablet, coated Rite Aid Corporation

Rite Aid 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

- 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 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

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

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
- use by expiration date on package

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

NDC 11822-0556-1

Compare to the active ingredients of **Extra Strength Tylenol® PM***

EXTRA STRENGTH
PAIN RELIEF
ACETAMINOPHEN
PM

ACETAMINOPHEN 500 mg DIPHENHYDRAMINE HCl 25 mg

PAIN RELIEVER
NIGHTTIME SLEEP AID
non-habit forming

ACTUAL SIZE

80

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

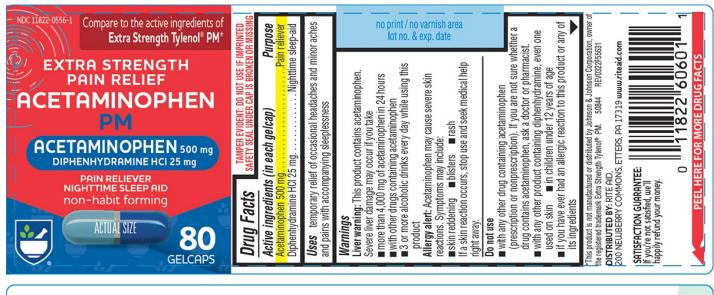
the registered trademark Extra Strength Tylenol® PM. 50844 REV0322F55631

DISTRIBUTED BY: RITE AID,

200 NEWBERRY COMMONS, ETTERS, PA 17319 www.riteaid.com

SATISFACTION GUARANTEE:

If you're not satisfied, we'll happily refund your money.



Directions

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adults and children 12

■ take 2 gelcaps at bedtime

luestions or comments? 1-800-426-9391

yellow, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac

laze, simethicone, stearic acid, titanium dioxide

FD&C red #3, gelatin, hydroxypropyl cellulose,

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1ypromellose, iron oxide black, iron oxide red, iron oxide

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pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days new symptoms occur

Stop use and ask a doctor if ■ sleeplessness persists symptom of a serious underlying medical illness.

continuously for more than 2 weeks. Insomnia may be a ■ redness or swelling is present

do not drive a motor vehicle or operate machinery

taking sedatives or tranquilizers avoid alcoholic beverages

drowsiness will occur When using this product taking the blood thinning drug warfarin

Ask a doctor or pharmacist before use if you are difficulty in urination due to enlargement of the prostate

gland

glaucoma

bronchitis

Ask a doctor before use if you have a breathing problem such as emphysema or chronic liver disease

Drug Facts (continued)

Rite Aid 44-556

medical help or contact a Poison Control Center right away Prompt medical attention is critical for adults as well as for

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acetaminophen and diphenhydramine hcl tablet, coated

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0556
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg		
DIPHENHYDRAMINE HYDROCHLORIDE (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: 3WJQ0SDWIA)
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 (light) , blue (Dark)	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	L;6	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11822- 0556-1	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2007		
2	NDC:11822- 0556-9	1 in 1 CARTON	12/17/2007	06/15/2020	
2		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
3	NDC:11822- 0556-3	1 in 1 CARTON	12/17/2007	05/17/2019	
3		80 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	12/17/2007			

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(11822-0556), pack(11822-0556)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(11822-0556)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(11822-0556)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(11822-0556)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(11822-0556)

Revised: 5/2023 Rite Aid Corporation