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

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.

Rite Aid 44-235

Active ingredients (in each caplet)

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

- if you have ever had an allergic reaction to this product or any of its ingredients
- 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.

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- liver disease
- glaucoma
- 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
- avoid alcoholic beverages
- drowsiness will occur
- 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 accidental 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 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours.
- children under 12 years: do not use

Other information
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C blue #1 aluminum lake, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

RITE
AID
PHARMACY®

*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

actual size

100 CAPLETS

non-habit forming

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 ORG041723515

DISTRIBUTED BY:
RITE AID
30 HUNTER LANE
CAMP HILL, PA 17011

IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.

SATISFACTION
GUARANTEED

Rite Aid 44-235

PAIN RELIEF ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen and diphenhydramine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-2350
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 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	44;235
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-2350-4	1 in 1 CARTON	05/15/1994	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-2350-2	1 in 1 CARTON	05/15/1994	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:11822-2350-5	1 in 1 CARTON	05/15/1994	
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:11822-2350-7	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/1994	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/15/1994	

Labeler - Rite Aid Corporation (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11822-2350)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(11822-2350) , PACK(11822-2350)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(11822-2350)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(11822-2350)

Revised: 5/2020 Rite Aid Corporation