PM PAIN RELIEVER- acetaminophen and diphenhydramine citrate tablet
Rite Aid

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 44-373

Active ingredients (in each tablet)

Acetaminophen 500 mg
Diphenhydramine citrate 38 mg

Purpose

Pain reliever
Nighttime sleep-aid

Uses

for the 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

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 containin diphenhydramine, even one used on skin
- in children under 12 years of age

Ask a doctor before use if you have
- a breathing problem such as emphysema or chronic bronchitis
- liver disease
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product
- drowsiness may occur
- avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- sleeplessness lasts continuously for more than 2 weeks. Insomnia may be a symptom of a 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
- painful area is red or swollen

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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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)**
- adults and children 12 years and over: take 2 tablets at bedtime. Do not take more than 2 tablets 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 controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, shellac, silica gel, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

RITE AID®
PHARMACY

*Compare to the active ingredients in Excedrin® PM

PM pain reliever
acetaminophen 500 mg
diphenhydramine citrate 38 mg
pain reliever • nighttime sleep aid

aspirin free
non-habit forming

100 COATED TABLETS

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Excedrin® PM.

50844 ORG031037312

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

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

Rite Aid 44-373

PM PAIN RELIEVER

acetaminophen and diphenhydramine citrate tablet

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:11822-0373
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE CITRATE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM	
CROSPOVIDONE	
FD&C BLUE NO. 1	
FD&C BLUE NO. 2	
HYPROMELLOSES	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
POLYSORBATE 80	
STEARIC ACID	
TITANIUM DIOXIDE	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	44;373
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0373-2	1 in 1 CARTON		
1		100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	06/07/2004	

Labeler - Rite Aid (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11822-0373)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(11822-0373)