ACETAMINOPHEN, DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen, diphenhydramine hydrochloride tablet, film coated
LEADER/ Cardinal Health 110, Inc.

0752-Cardinal

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purposes

Pain reliever

Nighttime sleep-aid

Uses

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

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

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged 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

- avoid alcoholic beverages
- do not drive a motor vehicle or operate machinery
- drowsiness will occur

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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 of age 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 in a dry place at 15°-30°C (59°-86°F).
- see end flap for expiration date and lot number.

croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, mineral oil, polyvinylpyrrolidone, pregelatinized starch, silica, sodium starch glycolate, stearic acid, talc, titanium dioxide, triacetin

Questions or comments?

1-800-231-4670

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Tylenol® PM Extra Strength.

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

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

100% Money Back Guarantee

Return to place of purchase if not satisfied

LEADER ™

NDC 70000-0411-3

Extra Strength Acetaminophen PM

Acetaminophen, 500 mg

Diphenhydramine HCl, 25 mg

Pain Reliever/Nighttime Sleep-Aid

COMPARE TO TYLENOL ® PM EXTRA STRENGTH active ingredients*

100 CAPLETS

ACETAMINOPHEN, DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen, diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0411
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

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	CPC752
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0411-2	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/29/2018	
2	NDC:70000-0411-1	1 in 1 CARTON	12/10/2018	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70000-0411-3	1 in 1 CARTON	12/10/2018	
3		100 in 1 BOTTLE; 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	11/29/2018	

Labeler - LEADER/ Cardinal Health 110, Inc. (063997360)

Revised: 2/2026 LEADER/ Cardinal Health 110, Inc.