PAIN RELIEF PM- acetaminophen, aspirin, diphenhydramine citrate tablet, film coated

Amerisource Bergen

Good Neighbor Pharmacy 44-674

Active ingredients (in each caplet)

Acetaminophen 250 mg Aspirin 250 mg (NSAID)* Diphenhydramine citrate 38 mg *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever Pain reliever Nighttime sleep-aid

Uses

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

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- shock
- facial swelling
- asthma (wheezing)

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash
- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

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

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- take more or for a longer time than directed
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- 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

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have glaucoma
- you have asthma
- you have difficulty in urination due to enlargement of the prostate gland
- you are taking a diuretic
- you have a breathing problem such as emphysema or chronic bronchitis
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for:
 - diabetes
 - gout
 - arthritis
- any other drug, or are under a doctor's care for any serious condition
- sedatives or tranquilizers
- any product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

When using this product

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

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- pain gets worse or lasts for more than 10 days
- painful area is red or swollen
- new symptoms occur
- ringing in the ears or a loss of hearing occurs
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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, with a full glass of water
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- children under 12 years: do not use

Other information

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

Inactive ingredients

corn starch, crospovidone, FD&C blue #1 aluminum lake, hypromellose, maltodextrin, medium chain triglycerides, microcrystalline cellulose, polydextrose, povidone, sodium lauryl sulfate, sodium starch glycolate, sodium sulfate, stearic acid, talc, titanium dioxide, yellow iron oxide, zinc stearate

Questions or comments?

1-800-426-9391

Principal display panel

GOOD NEIGHBOR PHARMACY®

Compare to Excedrin[®] PM Headache active ingredients[†]

NDC 46122-456-71

Pain Relief PM acetaminophen aspirin (NSAID) & diphenhydramine citrate

Pain Reliever / Nighttime Sleep Aid

Caffeine free

50 Caplets ι • Non-habit forming

Actual Size

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

[†]This product is not manufactured or distributed by GSK Consumer Healthcare SARL, owner of the registered trademark Excedrin[®] PM Headache.

50844 REV1121A67415

Distributed By AmerisourceBergen 1 West First Avenue Conshohocken, PA 19428 Questions or Concerns? www.mygnp.com

GOOD NEIGHBOR PHARMACY BRAND PRODUCTS SATISFACTION GUARANTEED



PAIN RELIEF PM

acetaminophen, aspirin, diphenhydramine citrate tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-456
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
DIPHENHYDRAMINE CITRATE (UNII: 40D433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	674	
Contains				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:46122-456-71	1 in 1 CARTON	08/31/2016			
1	50 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	08/31/2016		

Labeler - Amerisource Bergen (007914906)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(46122-456)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(46122-456)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(46122-456)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(46122-456)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(46122-456)

Revised: 1/2024 Amerisource Bergen