

PM HEADACHE- acetaminophen, aspirin, diphenhydramine citrate tablet, film coated

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED

CVS 44-674 PM Headache

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
- facial swelling
- shock
- 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 more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- 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 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

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

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for diabetes, gout, or arthritis
- 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

- 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
- 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.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear

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 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, croscopovidone, 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

**Nighttime
Headache Relief**

♥CVS™

NDC 51316-674-12

PM HEADACHE

Acetaminophen, 250 mg | Aspirin (**NSAID**), 250 mg
Diphenhydramine Citrate, 38 mg
Pain Reliever, Nighttime Sleep-Aid

Compare to
Excedrin® PM Headache
active ingredients†

100 CAPLETS

Caffeine Free
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
Haleon CH SARL, owner of the registered trademark
Excedrin® PM Headache.
50844 ORG122467412

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Nighttime Headache Relief



PM HEADACHE

100 CAPLETS



NDC 51316-674-12

PM HEADACHE

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Diphenhydramine Citrate, 38 mg
Pain Reliever, Nighttime Sleep-Aid

100 CAPLETS

Caffeine Free
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Compare to
Excedrin® PM Headache
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actual size

BG879L3
Z FOLD

Drug Facts (continued)

■ pain gets worse or lasts more than 10 days
■ fever gets worse or lasts more than 3 days
■ redness or swelling is present ■ any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin 20 weeks or later in pregnancy unless 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 overdose, get medical attention or contact a Poison Control Center right away. Prompt medical help 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

Drug Facts (continued)

■ you have asthma ■ you have glaucoma ■ you have a breathing problem such as emphysema or chronic bronchitis ■ you are taking a diuretic ■ a prescription drug for diabetes, gout, or arthritis ■ sedatives or tranquilizers ■ avoid alcoholic beverages ■ do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if: ■ you experience any of the following signs of stomach bleeding: ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ ringing in the ears or a loss of hearing occurs ■ sleepiness persists continuously for more than 2 weeks. ■ if a skin reaction occurs, stop use and seek medical help right away.

Warnings ■ 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 with hives, itching, or facial swelling ■ shock ■ asthma (wheezing) ■ symptoms may include: ■ rash ■ skin redness ■ blisters ■ If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ rash ■ skin redness ■ blisters ■ If a skin reaction occurs, stop use and seek medical help right away.

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08612246742

Drug Facts (continued)

Other information ■ Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ see red flag for expiration date and lot number

Inactive ingredients corn starch, croscollon, 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? 1-800-426-4391

*This product is not manufactured or distributed by Haleon CH S.A.R.L., owner of the registered trademark Excedrin® PM Headache.
50844 086122467412

Drug Facts

Active ingredients (in each caplet) Acetaminophen 250 mg (Pain reliever) Aspirin 250 mg (NSAID) Diphenhydramine citrate 38 mg (Nighttime sleep-aid)

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

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Lot & Exp

CVS 44-674

PM HEADACHE

acetaminophen, aspirin, diphenhydramine citrate tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-674
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	250 mg
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients		Strength
STARCH, CORN (UNII: O8232NY3SJ)		
CROSPVIDONE, 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: FZ989GH94E)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
SODIUM SULFATE (UNII: OYPR65R21J)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
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
	NDC 51316			

1	NDC:51316-674-12	1 in 1 CARTON	09/11/2025	
1		100 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		09/11/2025	

Labeler -
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(51316-674)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(51316-674)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(51316-674)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(51316-674)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(51316-674)